THE ROLE OF SCIENCE ADVISORY BOARDS IN U.S. FEDERAL HEALTH POLICY

by

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ABSTRACT

In the context of scarce financial resources for government programs in both the United States and internationally, efforts to develop health policies that are informed by evidence may increase in the coming years. In the United States, policymakers repeatedly attempt to integrate research and evidence into the policy process by establishing federal advisory committees (FACs) under the purview of the Federal Advisory Committee Act (FACA) of 1972. Although FACA committees have existed for 40 years, are used frequently by the executive branch, and have accounted for $3.4 billion in government spending between 2002 and 2011, they remain "little-known [and] little-studied" (McApline and LeDonne, 1993).

Two case studies were conducted for this dissertation using a multiple-case study design and a grounded theory approach to data analysis. The overall aim was to describe how FACs play a role in the policy process. The two cases were the science advisory board to the President's Emergency Plan for AIDS Relief and the National Climate Assessment and Development Advisory Committee, established by the US Department of State and the Department of Commerce, respectively. Semi-structured interviews were conducted with purposively-selected FAC members and staff from government agencies and non-governmental organizations (NGOs). Interview transcripts were coded using Atlas/ti following the grounded theory method outlined by Charmaz. Documents from FAC proceedings were also analyzed. Data collection was concluded when theoretical saturation was achieved.

Findings suggest that FACA committees are heterogeneous in their primary objectives, operating structures, decision-making processes, and methods of engaging with NGOs. In addition, ambiguity in the FACA language and the politically sensitive nature of selecting members complicates efforts to establish a FAC. However, in spite of the differences across FACA

committees and the difficulties encountered by government agencies when establishing them, findings indicate that FACs can be effective as mechanisms for agencies to obtain specific and broad guidance from independent experts on scientific matters of concern to the agency. The extent to which recommendations from FACs are adopted by the establishing agency is influenced by the perspectives of the executive and legislative branches on the value of evidence-based policy, as well as the perspective of the agency administrator.

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"No one who achieves success does so without the help of others. The wise and confident acknowledge this help with gratitude."

— Alfred North Whitehead

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CHAPTER 1: INTRODUCTION

The importance of research[1] and its findings to public policy generally, and to health policy more specifically, has been verified repeatedly over time. Although a formal movement calling for health policy to be more evidence-based did not arise until the mid-1990s, the literature suggests that the United States government relied on health research and its findings as early as the 1930s to draft legislation for a national health insurance program. More recently, and in the context of health reform, the emphasis placed on ensuring that health policy decisions are based on evidence has increased substantially. Indeed, President Obama's intention to use evidence to inform decisions about the allocation of resources for social programs has been unprecedented (Haskins, 2011).

An examination of the literature on theories of the policy process, the role of research and its findings in this process and of evidence-based policy highlights disagreement over fundamental assumptions underlying each of these three areas. The traditional model of the policy process assumes that policymaking is linear, with policymakers engaged at each stage as rational actors. The push for policy to be more evidence-based or even evidence-informed relies heavily on these assumptions. Some critics suggest these assumptions are flawed and argue that any call for policy to be evidence-based ignores the reality of the policy process, including that it is irrational and political. This debate is discussed in-depth in Chapter 2.

While there is clearly a disconnect between the literatures on theories of the policy process and the literature on evidence-based policy, policymakers repeatedly attempt to integrate research

[1] For the purpose of this Introduction, the terms "research", "science", and "scientific advisors" are used with fidelity to the literature. More specifically, seminal texts including that by Nutley et al. and Buse et al. refer to research in the policy process. Texts by Jasanoff and Smith refer to science and scientific advisors in policy. The distinctions among research, evidence, and knowledge are discussed in more depth in the next section, but to be precise, research is the process that produces evidence. Evidence, in turn, refers to the empirical findings from research and is one source of knowledge. Broadly, this dissertation is concerned with research, evidence, and knowledge within the domain of science, and as it relates to public health policy.

and evidence into the health policy process by convening committees of experts external to the government to advise on matters related to science and public policy. The U.S. government's reference to external experts for advice and recommendations on policy matters has occurred since the earliest days of this country's existence. Indeed, there is broad agreement in the literature that President Washington established the first advisory committee in 1794 when he sent a delegation of government officials to negotiate a resolution with a group of farmers who were protesting a new tax on distilled spirits that was designed to fund debt incurred during the Revolutionary War. Before making a decision, President Washington and numerous Presidents and government agencies since, have legitimized policy action by investigating a problem, seeking the advice of citizens, and acting on the basis of the information received (McAlpine & LeDonne, 1993). While not restricted to policy issues related to health or even scientific matters more broadly, the pattern of referring to external advisors for guidance and recommendations on policy matters provides an important foundation for how research, evidence, and knowledge can inform policy.

Over time, and as politicians "became less likely to have any detailed grasp of scientific matters or even to aspire to such knowledge" (Smith, 1992, p.16), the federal government's use of and reliance upon advisory committees grew substantially. By the 1950s and 1960s, the government's opinion of the value of research and its findings in the policy process was quite high. "The conviction was that research could and should be of direct use to government in determining and achieving its social policy objectives" (Nutley, 2007, p.10). By 1971, there were approximately 3,000 advisory bodies in existence (Ginsberg, 2009). However, the government's and the American public's enthusiasm for research quickly turned to "lowered expectations for American social policy and for research to improve it" (Fox, 1990, p.492). Congress and the public questioned the effectiveness, transparency, and objectivity of the government's frequent use of advisory bodies.

Broadly, there was concern that the thousands of advisory committees in existence were costly and wasteful. In an attempt to address the discontent about the government's use of advisory committees, Congress passed the Federal Advisory Committee Act (FACA) in October 1972. FACA still serves as the major piece of legislation that regulates federal advisory committees (FACs) of all types [2] (FACA, 1972).

While FACs can be established to provide advice and guidance on any matter of public policy, health seems to be a major focus of FACs, if not the focus of the majority of FACs. Between fiscal year (FY) 2001 and FY2011, the Department of Health and Human Services (HHS) spent $1.72 billion on its SABs, which is roughly half of the total government spending on such committees during the past decade (Lipowicz, 2011). If advisory committee spending from other agencies which address health issues is included, FACs for health easily consume the majority of all government spending on advisory committees.

I. Rationale

Although federal advisory committees as defined by FACA have been in place for 40 years, are used frequently by the executive branch of government, and accounted for over $3.4 billion in government spending between FY 2002 and FY 2011, they remain "little-known [and] little-studied" (Domhoff, 2005). As described in more depth in Chapter 2, the literature about public policy and health policy development and implementation is surprisingly silent on advisory committees. Even the literature specifically assessing the role of research in the policy process – including the literature on evidence-based health policy – neglects FACs as a possible mechanism by which research can be integrated into and have an influence on the policymaking process. An exception to this pattern is

[2] Typically, federal advisory committees are referred to as FACs. For the purpose of this dissertation and for the sake of clarity, the acronym FAC will be used when referring generally to federal advisory committees.

texts addressing the role of science and scientific advisors in public policy. However, while this literature situates FACs in a historical perspective, it does not attempt to harmonize its findings with the literature on the theory of policymaking nor of policy analysis. As a result, not only is little information available regarding the theoretical position of FACs in the health policy process but there is little empirical evidence regarding the extent to which FACs contribute to health policy decision-making and the factors which affect the use of FAC recommendations.

II. Aims

These gaps suggest that there is room in the existing scholarship for additional research on the role of FACs in the health policy process in the United States. FACs for health are uniquely positioned to have a potentially substantial impact on decisions about policies which could affect the health of millions of people.

The overarching objective of this study is to describe the role FACs for health play in the policy process. The specific aims of this study are to:

1. Describe how FACs play a role in the health policy process and how they help to ensure health policy is evidence-based;
2. Identify how internal processes and external contextual factors contribute to whether the recommendations of a FAC will be adopted; and
3. Describe strategies various stakeholders, including advocacy groups, FAC members, and government agency staff have used to facilitate the uptake of recommendations put forward by FACs and propose new, effective strategies.

This study uses a case study approach to examine these aims relative to two federal advisory committees; the science advisory board (SAB) for the President's Emergency Plan for AIDS Relief (PEPFAR) established by the Office of the Global AIDS Coordinator (OGAC) in the US Department of State and the National Climate Assessment Development and Advisory Committee (NCADAC) established by the National Oceanic and Atmospheric Association (NOAA), under the

Department of Commerce (DOC).[3] The rationale for selecting these two committees is explained in depth in Chapter 4.

III. Overview

Chapter 2 reviews the literature related to the health policy process and the role of research and evidence within that process, the evidence-based policy movement, and the legislative and legal history of the Federal Advisory Committee Act. Chapter 3 presents and describes the conceptual framework that guided this research. Chapter 4 describes the methods used for data collection and analysis. Chapter 5 presents the case study for the PEPFAR science advisory board and Chapter 6 presents the case study for the NCADAC. Chapter 7 provides an analysis of the cross-case findings. A discussion of the policy implications from this research and recommendations for future research are presented in Chapter 8.

[3] OGAC refers to the advisory committee to PEPFAR as a science advisory board. Thus, when referring to the PEPFAR advisory committee, the acronym SAB will be used. NOAA refers to the NCADAC as a FAC. Thus, when referring to the NCADAC, the acronym FAC will be used.

CHAPTER 2: LITERATURE REVIEW

As indicated in Chapter 1, the question of how federal advisory committees play a role in the health policy process and facilitate evidence-based or evidence-informed policy, and what and how contextual factors influence whether committee recommendations are taken up by policymakers remains largely unexplored in the literature. As a potentially significant bridge between the research and policy communities and as a frequently-used interpreter of data, research findings, and evidence for policymakers, it is somewhat surprising that the neither the scholarship on the role of research in health policy nor the scholarship on evidence-based policy addresses federal advisory committees.

The existing literature most relevant to the aims described in Chapter 1 addresses the context of health policy and the role of research in health policy, including theories of the policy process, models describing the research-policy relationship, and evidence-based policy. These areas are discussed below. In addition, the evolution of the legislation (i.e., FACA) governing when and how federal advisory committees are developed and implemented and the subsequent case law which clarified this legislation is addressed below, as is the existing scholarship on federal advisory committees. Overall, it is clear that there is room for additional scholarship on FACA committees and their role in the policy process.

Some scholars in the grounded theory field argue that any existing literature should be ignored so that the researcher can remain neutral and avoid any risk of prior knowledge introducing bias into how the findings are interpreted (Andrade, 2009, p.46). However, others argue that from a practical perspective, a literature review is important to conduct to ensure that the proposed study is truly unique, to provide context for and motivate the area of inquiry, and that the research question(s) are actually worthy of study (Hallberg, 2010). The literature review conducted for the

purposes of the study described herein did inform the development of the initial conceptual framework as well as the interview protocol. However, in keeping with the grounded theory method, it was the data collected during this study that formed the basis from which conclusions were drawn.

I. The Context of Health Policy

Public policy can be defined as "what governments choose to do or not to do" (Buse, Mays, & Walt, 2005). Health policy can be considered a sub-set of public policy, at least with respect to action or inaction by government in the health sector. As such, frameworks which describe the factors that affect and influence public policy are broadly applicable to health policy as well.

Understanding the policy context is important to this study because FACs do not operate in a vacuum and in fact, may serve as critical entities in the policy process: how and when FACs are constructed as well the constraints they face may be influenced by the contexts that influence policy. Kraft and Furlong propose one framework for the "contexts" of public policy which refer to "systemic factors…which may have an effect on…policy" (Buse et al., 2005, p.11). Five contexts are described, those being the social, economic, political, governing, and cultural contexts.

It is important to understand these contexts for their relationship to the policy process independent of research and evidence: each of these contexts contributes to a policy environment that "determines which problems rise to prominence, which policy alternatives receive serious consideration, and which actions are viewed as…feasible" (Kraft & Furlong, 2010, p.10). However, in the context of this study, it is also important to understand these policy contexts for their influence on research and in turn, on evidence, because research and evidence can be seen as the 'currency' of FACs for health. Thus, factors which affect this currency (i.e., factors which affect research and evidence) indirectly affect FACs.

The social context, which consists of "dynamic…social conditions" (Kraft & Furlong, 2010,

p.10) could affect what social issues are considered important. In turn, and with respect to health, the social context could influence what issues are considered priorities for research funding and/or the issues considered worthy of being addressed by a FAC. The economic context, or the state of the economy, could affect the volume of funding available for research and the funding available for the basic operating expenses of a FAC. The political context may trump all other contexts by elevating or squelching certain social priorities and their corresponding research funding. In addition, politics could affect whether a FAC is established merely to allow a policymaker to sidestep a difficult issue and whether its recommendations are taken seriously by policymakers. The governing context, which refers to the structure of the U.S. government, could affect the level at which research is conducted (i.e., federal, state, or local), the practical application of research findings, as well as determine which government entity at the federal level is responsible for establishing and implementing the FAC. The cultural context, which refers to political culture, could affect how social issues and their associated research priorities are framed.

Buse et al. in their health policy-specific text Making Health Policy use a framework similar to that of Kraft and Furlong to describe the context of health policy, which is based on the categories defined by Leichter in 1979 (Buse et al., 2005; Leichter, 1979). Although the Buse et al. framework overlaps with the Kraft and Furlong framework directly in only one category (cultural context), the "situational factors" described by Buse et al. broadly encompass Kraft and Furlong's social, economic, political, and cultural contexts. Similarly, the "structural factors" described by Buse et al. are most closely related to the governing context in Kraft and Furlong's framework. Buse et al. include one additional category, namely international or exogenous factors, which is useful for considering health issues of global import.

The influence that each of the contexts in the Kraft and Furlong framework may have on

research, evidence, and advisory committees in the public policy arena broadly also could occur for research, evidence, and advisory committees in health more specifically, given the similarities between the Kraft and Furlong and Buse et al. frameworks. Moreover, research and evidence may play a more important role in health policy relative to policy for other social sectors because of the unique nature of the primary outcomes in health, namely morbidity and mortality. These outcomes are ultimately biological processes. Policies which seek to mitigate illness and death may draw from a range of disciplines, but such policies must be based on knowledge about the mechanisms and channels by which morbidity and mortality occur. Ultimately, this knowledge is derived from research. Because of this unique relationship between research and health policy, the contextual factors affecting the policy environment may play an especially important role in facilitating or inhibiting the use of research and evidence by policymakers as well as in the implementation and outcomes of FACs for health.

II. The Role of Research in Health Policy

Before discussing the literature on the relationship between research and policy, it is critical to define what the literature means by research, evidence, and knowledge. Research has been described as a process that leads to new knowledge (Buse et al., 2005; Nutley, 2007). Research findings must be interpreted; they "cannot speak for themselves" (Nutley, 2007, p.24). The literature is in broad agreement that between research and knowledge, there is evidence. Nutley argues that "research is often seen as one form of evidence, and evidence as one source of knowledge" (Nutley, 2007, p.23) but recognizes that some take a narrower view and define evidence as just the empirical findings of research (Nutley, 2007, p.23). Buse et al. go a step further and define evidence as "any form of knowledge, including, but not limited to research, of sufficient quality to be used to inform decisions" (Nutley, 2007, p.158). Thus, there is a hierarchical relationship among research, evidence,

and knowledge, where knowledge can be defined as the "interpretation of research" (Nutley, 2007, p.23).

However, describing the relationship among the three terms in this way risks oversimplification since "definitions of any research, evidence and knowledge invariably invoke implied accounts of at least one other" (Nutley, 2007, p.25). Moreover, how the terms are used may vary based on the subjective judgments of those using the terms and the surrounding political context. Nutley argues that "there are no easy or value-free ways in which research can be defined separately from the context of its use" (Nutley, 2007, p.25). This investigator would argue that knowledge is more focused on interpretation of research findings than research itself. In line with Nutley's proposition, research findings and any related data used to generate those findings would be one type of evidence.

For the purposes of this study, research is defined as above and refers to the process of generating new knowledge. Evidence is used to refer to a combination of the definitions above, including the empirical findings from research as well as a source of knowledge of sufficient quality to inform decisions. Knowledge is used as above, to refer to the interpretation of research. Exceptions to these definitions arise in the remainder of this literature review where the terms originally used by authors are also used here in an effort to accurately reflect the characteristics of the articles and texts as well as their authors' intentions.

A. Theories of the Policy Process: Where does Research Fit?

Traditional models of policymaking describe the policy process as a sequence of stages which, at a minimum, include four components: agenda setting, formulation, implementation, and evaluation. This step-wise model has also been described as a cycle, to clarify that the stages of the policy process overlap or can be skipped entirely. A fundamental assumption of these traditional

models is that policymaking is a linear process and by extension, that policymakers make rational decisions at each stage. The implications of these assumptions for the use of evidence in policy decision-making are that there would be a direct relationship between evidence and policy decisions at each stage and moreover, that "research precedes the policy solution to a pre-defined problem" (Buse et al., 2005, p.160).

The traditional model of policymaking has been critiqued widely for its failure to adequately reflect "the messy complexity that typically characterizes policy making as it really occurs"(Nutley, 2007), and has been called a "policy myth" (Colebatch, 2005, p.93). At the root of these critiques, there lies frustration with the models' assumption that policymakers themselves can act in a rational manner. All humans – not just policymakers – have limited or "bounded rationality" because "we are simply unable…to deal with complex problems in ways that meet the demands of objective rationality" (Nutley, 2007, p.94).

This concept of humans' limited ability to behave in simply rational ways was first described by Herbert Simon in 1957 (Simon, 1957). Simon argued that the bounds of rationality are further constrained for policymakers who "typically lack both access to the extensive information needed to carry out such comprehensive analyses, and the time to do so" (Nutley, 2007, p.94). As a result, policymakers will focus on outcomes that can be achieved in the short-term rather than on long-term social problems. Simon called this "satisficing" (Simon, 1957). The concept of bounded rationality is important and relevant to this study because if policymakers are in fact constrained in their ability to be rational and also 'satisfice', they may not only have reason to turn frequently to FACs but also to adopt and implement only those recommendations which can be easily enacted in the short term and are likely to yield high-impact results.

From Simon's 'satisfice' concept evolved Lindblom's model of the policy process as

'incremental' (Lindblom, 1968). In Lindblom's model, small-scale, incremental policy change is not only all that is politically feasible, but it also has distinct advantages, such as reducing the number of policy alternatives that need to be considered as well as the complexity of the policy process. According to Lindblom, research plays a key role in the incremental model as a bargaining chip that the numerous actors in the policy process can use to persuade others to cooperate. As a result, research can interact with the policy process at multiple points and through multiple actors. Research is still used in a rational manner but primarily for political or tactical means.

Stronger critiques of the rational policy model are manifest in the garbage can and multiple streams models, developed by Cohen et al. and Kingdon, respectively (Cohen, March, & Olsen, 1972; Kingdon, 1984). The garbage can model portrays the policy process as being fundamentally irrational, where policy problems and their solutions are dumped into a metaphorical garbage can. This process is inherently chaotic and unpredictable, and may not allow for decisions to be made pro-actively, since problems and solutions emerge from the garbage can when new opportunities arise (Nutley, 2007). Kingdon's multiple streams model serves as a slightly more organized extension of the garbage can model but is just as unpredictable. Concerned primarily with agenda setting, Kingdon posits that issues will rise to the policy agenda when and only when the following three conditions are met: (i) problems come to the attention of policymakers; (ii) feasible policy solutions to these problems are generated; (iii) and the political environment is favorable. Both the garbage can and multiple streams model "suggest that research…may enter policy through diverse and indirect routes and from a variety of different sources" (Nutley, 2007, p.97).

Although the traditional model of policymaking may have shortcomings, these may be outweighed by the model's principal value. The policy process model offers "an ideal from which every reality will curve away" (Bridgman & Davis, 2003, p.100). Furthermore, "the rational, linear

model of the relation between research and policy still tends to inform the day-to-day working assumptions of many researchers and policymakers"(Buse et al., 2005, p.160). In addition, research can still play a role at each stage of the process. At the agenda setting stage, research can "help clarify the nature of issues of concern, and to push such issues onto the policy agenda"(Nutley, 2007, p.93). During the implementation phase, research can help define policy alternatives and can help address implementation problems, through process evaluations, for example. During the evaluation stage, research can make a "substantial contribution,"(Nutley, 2007, p.93) since evaluation involves research by definition (Buse et al., 2005, p.160).

Thus, given the recognition by the literature that the policy process model serves as a basis from which other models are derived, the recognition and use it receives in applied policy settings, and the clear opportunities for how research can engage with each phase of the process, the cycle model of policymaking is used for the purposes of this study.

B. Models of the Research-Policy Relationship

The discussion in the above section addresses the literature describing various models of policymaking. These models do not aim to specifically describe the research-policy interface. Those that do are "few and far between in the literature" (Nutley, 2007, p.92). Nevertheless, six additional models warrant discussion for their contribution to the understanding of the specific relationship between research and policy.

The *two communities* model, developed by Caplan, is based on the premise that policymakers rarely use research (Caplan, 1979a). The absence of research in policymaking results from the idea that "researchers and policymakers live in separate worlds, with different and often conflicting values, different rewards systems, and different languages" (Caplan, 1979a, p. 459). Communication and interaction between researchers and policymakers become the primary solutions to bridging the

gap between research and policy and to enhancing the use of evidence. However, just bringing researchers and policymakers together will not suffice to resolve the gap between the two communities: interaction must be effective and involves "value and ideological dimensions as well as technical ones" (Caplan, 1979a, p.461).

Similar to the two communities model, the *general utilization theory model*, developed by Wingens, focuses on researchers and policymakers as two distinct groups. It suggests that the divide between researchers and policymakers is rooted in functional, not cultural, differences. According to Wingens, research use occurs when there is interaction between the systems in which policymakers and researchers exist. This interaction happens when a change in social context occurs that in turn prompts a change in policy issues. However, for research to be used, it must be "adapted, recreated, and transformed" (Nutley, 2007, p.100).

Communication and interaction form the basis of the third model of research-policy interface. The *linkage and exchange model*, developed by Lomas, conceptualizes research and policy as processes, not products, which suggest that there are numerous opportunities for there to be mutual influence between research and policy (Lomas, 2000). These opportunities arise through the interaction of three spheres: information, which includes research and evidence; the institutional structure of decision-making; and the values that frame a decision. Importantly, researchers and policymakers are not the only groups linked by exchanges in this arena: research funders and knowledge purveyors are also key groups. Thus, "the main focus of the model is…on the interfaces between these four groups" (Nutley, 2007, p.101). One way this interface occurs is when policymakers ask researchers for advice on pressing policy problems and researchers aim to provide solutions. According to the linkage and exchange model, when this interface is strong, research use will happen.

Weiss proposes that the *enlightenment model* views the concepts and perspectives generated by a body of research as gradually diffusing through a multitude of pathways – from journal articles to media outlets to conversations with colleagues – to shape how policymakers view certain issues (Weiss, 1979). Rather than referencing the findings of a specific study as the motivation for changing the course of a particular policy, the enlightenment model suggests that general ideas rooted in research almost unconsciously enter the policy sphere. In an important departure from the problem-solving model, the enlightenment model does not assume that research findings have to support policymakers' values to be useful: any research is capable of filtering into the policy arena. And herein lies two of the deficiencies with this model: the sieve of indirect channels through which research is sifted does not screen out poor-quality research and it is an inefficient process which can result in outdated research informing policy decision making.

Not unlike the enlightenment model, the *knowledge-driven model* assumes that knowledge will be used by policymakers simply because it exists. In a linear fashion, this model suggests that basic research provides an opportunity for applied research to assess whether the initial findings are relevant for practical application. If this is found to occur, technologies are then developed and implemented. Weiss argues that this model is more relevant for basic research and if scientific findings "affect government decisions…it is not likely to be through the sequence of events posited in this model" (Weiss, 1979, p.427).

In contrast, the *problem solving model*, also put forward by Weiss (Weiss, 1979), suggests that research findings help solve policy problems. Empirical evidence is applied directly to a specific policy issue, which is then resolved because the gap in knowledge is filled. Weiss argues that this evidence can either be found by searching the existing literature, or policymakers can commission research specifically to guide policy choices. Although Weiss argues that "most studies appear to

come and go without leaving any discernable mark on the direction or substance of policy" (Weiss, 1979, p.428), the commissioning of research component of this model fits well with the grant-making pattern popular in public health, whereby the government or other funders release requests for proposals on specific health or health policy issues.

Of the models discussed above, the linkage and exchange model is the most relevant for this study given its specific acknowledgement that an interface between policymakers and researchers is needed for research use to occur, and that this interface can be created when policymakers request the advice of researchers. Although Lomas does not suggest it, a FAC would be a natural example of an interface through which researchers can provide advice at the request of policymakers.

C. Evidence-Based Policy: Rationality versus Reality

Without much apparent attention to the theoretical underpinnings of the research-policy relationship, policymakers launched a call for health policy to ground itself more fully in evidence in the mid-1990s, following a call for evidence-based medicine (EBM). EBM would use evidence (i.e., empirical findings from research) in a more direct manner during clinical practice decision-making. Systematic reviews from randomized controlled trials were viewed as a particularly valuable and important source of evidence for clinicians.

By the mid-1990s, the evidence-based medicine movement had expanded into a call for evidence-based policy (EBP), or evidence-based policymaking (EBPM). Its proponents argued that "research [should be given] greater weight than other considerations in shaping policy decisions" (Buse et al., 2005, p.159). Others had less ambitious goals and defined EBP as "the integration of experience, judgment and expertise with the best available external evidence from systematic research" (Buse et al., 2005, p.159). Regardless of how ambitious the request to use evidence in health policymaking, the rationale behind the EBP movement can be summarized as follows:

> That politics is driven more by values than facts is not open to dispute. But at a time when [government officials] are arguing that medicine should be evidence based, is it not reasonable to suggest that this should also apply to health policy? If doctors are expected to base their decisions on the findings of research surely politicians should do the same. Although individual patients may be at less risk from uninformed policymaking than from medicine that ignores available evidence, the dangers for the community as a whole are substantially higher. The impact of policies that are poorly designed and untested may be disastrous...As such the case for evidence based policymaking is difficult to refute (Ham, Hunter, & Robinson, 1995, p.71).

As a formal movement with an associated label, EBP seems to have originated in the United Kingdom (UK) during the Blair government, which came into power not long after a Research and Development Strategy was implemented for the National Health Service (NHS) and had the slogan of "'what counts is what works'" as an emblem of its emphasis on policy capability (Buse et al., 2005; Denis & Lomas, 2003; Ham et al., 1995; Head, 2009). The United States and Canada quickly followed the UK's lead. In the United States, Evidence-based Practice Centers were created and funded under the Agency for Health Care Policy and Research (AHRQ), and in Canada, the Prime Minister's Forum on Health recommended creating a multi-year fund with $50 million in annual funding for evidence-based decision-making (Canada, 2004; Denis & Lomas, 2003).

However, the literature suggests that health policy in the United States valued research and was based on evidence – at least in part – long before EBP became an official movement (Fox, 1990; Innes, 2002). As long ago as the 1930s, legislation proposing national health insurance was based on plans from a group of researchers. In 1966, the National Center for Health Services Research and Development was established by the Assistant Secretary for Health to fund studies on health policy. In the 1980s, "research had considerable importance to people who made health policy"(Fox, 1990, p.484) with the Medicare Prospective Payment System being "the most prominent application of research to policy in the decade" (Fox, 1990, p.484). Culminating in the

creation of AHRQ, which conducted much of the research on medical intervention outcomes using funds appropriated by Congress, the health policy environment in the United States was very much evidence-based, even prior to the official EBP movement.

Literature published early in the EBP movement focuses on maximizing the opportunity for research to influence policy by providing advice to researchers and policymakers alike on how to enhance the potential for research findings (i.e., evidence) to be integrated into health policymaking. Barriers to research affecting policy, such as politics, scientific uncertainty, timing, and communication, compound problems resulting from the assumption held by many that the policy process is rational. Walt argues that by recognizing these barriers and the realities of the policymaking process, and by "making the study of the research-policy nexus a fundamental part of…teaching in schools of public health…it is possible to…overcome the barriers to research influencing policy" (Walt, 1994, p.233). Davis and Howden-Chapman conclude that research "is more influential if topical, timely, well-funded, and carried out by a collaborative team that includes academics" (Davis & Howden-Chapman, 1996, p.865). Davies, Nutley, and Smith offer seven goals to "foster an enhanced role for evidence" (Davies, Nutley, & Smith, 1999, p.361) in health policy, and advise that researchers and policymakers should agree on "what constitutes legitimate evidence" (Davies et al., 1999, p.361), as well as considering the cost-effectiveness of interventions, among other priorities.

The spirit of the recommendations from this early literature is largely supported by studies which assess policymaker preferences for the use of research and evidence. A survey of state-based health policymakers in the United States about their "formal and informal methods of acquiring information about health policy issues" (Sorian & Baugh, 2002, p.265) indicates that policymakers have a strong preference for concise information about timely issues. Interviews with federal-level

policymakers provide similar findings (Colby, Quinn, Williams, Bilheimer, & Goodell, 2008). A systematic review of studies in which health policymakers were interviewed about enabling factors and barriers to their use of research found that in addition to being timely and concise, researchers should have "personal and close two-way communication with decision-makers" (Innvaer, Vist, Trommald, & Oxman, 2002, p.243) and strive to ensure that the research and evidence they present to policymakers includes effectiveness data.

As the EBP movement matured, two themes emerged in the literature, both of which are relevant to this study. Proponents of EBP, especially Dobrow et al.(Dobrow, Goel, & Upshur, 2004) and Gold (Gold, 2009), developed frameworks to capture how contextual factors affect the use of evidence as well as the pathways by which evidence is integrated into policy. Critics of EBP argued that at best, EBP is based on a flawed premise, and at worst, policymakers are unable to attain the goals of EBP.

Dobrow et al. developed a framework for evidence-based decision-making, with an emphasis on how context shapes what is considered evidence and how evidence is utilized (Dobrow et al., 2004). Two contexts are relevant: the external context "accounts for the environment in which a decision is *applied* and includes disease-specific, extra-jurisdictional and political factors" which are "fixed, uncontrollable and cannot be manipulated by decision-makers" (Dobrow et al., 2004, p.210) (emphasis in original). This context is important because it can make a substantial contribution to the evidence base. The internal context "accounts for the environment in which a decision is *made*" (emphasis in original) and is important because it may alter "the range of purposes, participants, and processes employed" (Dobrow et al., 2004, p.215). The framework developed by Dobrow et al. includes three stages of evidence utilization – the introduction, interpretation, and application of evidence. The authors argue that EBP needs to consider the context in which decisions are made

just as much as the evidence on which those decisions are based.

In her article outlining pathways by which health services research influences health policy, Gold applies social science theory to illuminate the "black box" which often mediates the relationship between research and its use by policymakers(Gold, 2009). Gold outlines 10 pathways by which research may be applied by policymakers, which fall into three categories. The first category is a traditional pathway, wherein "meritorious research findings will find an appropriate audience without much emphasis on the mediating process" (Gold, 2009, p.1123). This category echoes the key features of the knowledge-driven and problem solving models. The second category focuses on the role of intermediaries or processes which "can support better connections between the policy needs of users and findings from researchers" (Gold, 2009, p.1126). This category is reminiscent of the linkage and exchange model. Finally, the third category involves users enhancing the value of research. This framework provides a useful contribution for its recognition that although policymaking is influenced by politics, there are still ways to enhance research use (Blendon & Steelfisher, 2009).

Critics of EBP range from those who warn researchers to "proceed with care" before "uncritically accepting the notion of evidence-based policy" (Black, 2001, p.275) but remain cautiously optimistic about the potential for EBP to be useful, to those who contend that "health policy decision makers are generally unable to attain the basic goals of evidence-based decision making…and evidence-based policy making because humans make decisions with their naturally limited, faulty, and biased decision-making processes" (McCaughey & Bruning, 2011, p.1). Others seem concerned about the negative exposure and risk EBP forces upon sound science, encouraging "institutions and individuals [to] grow more vigilant against…tactics…that put evidence-based policy making at risk" (Rosenstock & Lee, 2002, p.14).

At the heart of the critiques of EBP is an assertion that the entire phenomenon is based on a set of flawed assumptions, namely that the policy process is linear and that policymakers are rational. Greenhalgh and Russell state that expressions related to EBP, such as knowledge translation, are "fundamentally inaccurate" because such terms are based on a world view that "fails to address key elements of the policymaking process" (Greenhalgh & Russell, 2009, p.304). Clarence argues that governments have many ways of using research, all of which are inherently political. She asserts that the goal of integrating evidence into policy is really a goal related to "depoliticizing the policy process" (Clarence, 2002, p.2). However, Clarence argues that because evidence needs to be interpreted, and because interpretation is a subjective process, "the very evidence [policymakers] choose to make use of is in itself an activity inherently lacking in neutrality" (Clarence, 2002, p.3). Marston and Watts are also concerned about the potential politicization of evidence, arguing that there is a risk for EBP to "become a means for policy elites [to] increase their strategic control over what constitutes knowledge about social problems" (Marston & Watts, 2003, p.159). However, their core concern is that in the process of trying to encourage policy to be based on evidence, there will be an over-simplification of what counts as evidence and what evidence is appropriate to apply in different circumstances. As a result, Marston and Watts call for "policy-makers and researchers [to] remain 'context sensitive' about the sorts of research methodologies and the types of evidence best suited to different circumstances" (Marston & Watts, 2003, p.160).

III. Federal Advisory Committees and Public Health Policy

Although the literature may be conflicted about the role for research in the policy process and the theoretical and practical ability for policy to be evidence-based, policymakers in the United States consistently and systematically create opportunities for research to be integrated into policy and for policy to be based on evidence by establishing FACs. As described in Chapter 1 and in more

detail below, FACs are long-standing appendages to policymaking at the federal level in the United States. FACs for health appear to be one of the most commonly used types of FACs, if not the most commonly used.

Advisory committees have been used by the executive branch of the United States government since the earliest days of the country's history. As noted in Chapter 1, the first recorded use of an advisory committee was by President George Washington in 1794 during the Whiskey Rebellion (General Services Administration, 2011). Although the Whiskey Rebellion was ultimately suppressed by force, President Washington's decision to appoint an external advisory committee prior to action stands out for its symbolism. "In a grave challenge to the authority of the national government, the president felt it necessary to legitimize his actions by first investigating the problem, searching for practical advice from disinterested citizens, and acting on the basis of facts presented to him" (McAlpine & LeDonne, 1993, p.209). While the circumstances under which this first federal advisory committee was called may no longer be relevant, the rationale behind using the committee remains applicable in contemporary times.

IV. The Federal Advisory Committee Act: A Legislative History

Since 1842, Congress has legislated control over various types of advisory bodies created to provide policy recommendations to the federal government, primarily by limiting funding and committee member pay (Ginsberg, 2009). In more recent history, legislation addressing advisory committees was drafted because government officials and the general public were concerned that committees were overstepping their authority: the number of committees steadily increased over time and there was virtually no government oversight or supervision over committees' work. Reacting to the creation of ad hoc advisory committees created by private sector industries to provide unsolicited policy advice to the government, the Department of Justice (DOJ) issued a

statement in 1944 indicating that industry committees could be formed to advise the government only at the request of the relevant government department (U.S. Congress, 1955). A decade later, more specific guidelines were issued by the DOJ in an opinion which indicated, among other issues, that committees "must be purely advisory, with government officials determining the actions to be taken on the committee's recommendations" (Ginsberg, 2009, p.4). A bill was introduced in 1957 which proposed to make the DOJ's guidelines law. While it passed in the House, it never left the Senate Government Operations Committee (Ginsberg, 2009).

In the 1950s and 1960s, there were several attempts to regulate advisory committees but it was not until the early 1970s that there was enough political will in Congress to pass legislation. Hearings held in the late 1960s and early 1970s suggested that Congress believed that advisory committees were "a useful means of furnishing expert advice, ideas and recommendations as to policy alternatives" (Ginsberg, 2009, p.5). However, Congress was also concerned that advisory bodies were not accessible to the public, were a waste of government resources, and needed more oversight. "There are numerous such advisory bodies that are duplicative, ineffective and costly, and many which have outlived their usefulness" (Ginsberg, 2009, p. 5). By 1971, there were between 2,600 and 3,200 advisory bodies in existence (Ginsberg, 2009). In his introductory remarks about a bill that proposed more regulation over the creation and operation of advisory bodies, Senator William V. Roth (R-DE) stated that "Congress has neglected to provide adequate controls to supervise [the] growth and activity [of advisory committees and their participation]" (Ginsberg, 2009, p.6). In addition, some citizens were upset that committees conducted their business "behind closed doors" and claimed that they did not reflect the public will.

Motivated by an interest in ending the 'locker room' discussions that were frequently the manner by which administrative decisions were made and in the context of "general ferment about

government secrecy"(Domhoff, 2005), Senator Lee Metcalf (D-MT) introduced legislation in 1972 that proposed to formally regulate how advisory committees to the executive branch would operate, with special emphasis on chartering, transparency, and reporting. Senator Metcalf's legislation was passed as the Federal Advisory Committee Act and signed into law by President Nixon on October 6, 1972 (Domhoff, 2005).

A. What does it mean to be a Federal Advisory Committee under FACA?

FACA outlines several guiding principles for federal advisory committees which clearly reflect "a desire to cabin the power of advisory committees and place certain constraints on the government's ability to seek private sector advice" (Bull, 2011, p. 3). First, new committees should be established only if considered "essential" although no guidance is provided about how "essential" should be defined. Second, committees should be terminated once they are no longer "carrying out the purposes for which they were established" (FACA, 1972). Third, "the establishment, operation, administration, and duration of advisory committees" (FACA, 1972) should be governed by standards and uniform procedures. Fourth, the scope, cost, and membership of advisory committees should be conveyed to Congress and the public. Fifth, "the function of advisory committees should be advisory only, and that all matters under their consideration should be determined, in accordance with law, by the official, agency, or officer involved" (FACA, 1972). These principles addressed many of the concerns Congress and the public had about FACs in the decades leading up to the FACA legislation, especially regarding their governance and oversight.

FACA also includes specific criteria that determine whether a committee must comply with FACA. More specifically, FACA defines an advisory committee as:

> Any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof…, which is—(A)

> established by statute or reorganization plan, or (B) established or utilized by the President, or (C) established or utilized by one or more agencies, in the interest of obtaining advice or recommendations for the President or one or more agencies or officers in the Federal Government, except that such term excludes any committee which is composed wholly of full-time or permanent part-time officers or employees of the Federal Government, and any committee that is created by the National Academy of Sciences or the National Academy of Public Administration.(FACA, 1972)

Thus, the defining features of an advisory committee that is subject to FACA are that it is established for the purpose of providing advice and recommendations to the government and its members are predominantly not federal employees. Importantly, these criteria indicate that not all advisory bodies established by the executive branch are subject to FACA regulations.

Committees can be established under four different types of authority: statutory (i.e., nondiscretionary establishment authority specifically mandated by law), authorized by law, agency-established (either pursuant to a law or by the decision of the agency administrator), or by Presidential authority (either by executive order or some other direction from the President).

In the case of agency-established committees, which are the focus of this study, senior officials at the sponsoring agency approve the committee membership and a charter is prepared that outlines the committee's mission and specific duties. Originally, the Office of Management and Budget (OMB) was tasked with promulgating regulations to ensure that agencies comply with FACA and committees do not outlive their charters. President Carter transferred these responsibilities to GSA by Executive Order in 1977. Currently, the GSA Administrator is required to assess on an annual basis whether FACs are "executing their missions and adhering to statutes, or whether they are in need of revision or abolition" (Ginsburg, 2009, p.10). Based on this assessment, the Administrator makes a recommendation to the President, Congress, or the agency head regarding

the action to be taken for each advisory committee. Currently, FAC charters must be approved by the Committee Management Secretariat of the General Services Administration (GSA) which is responsible for:

- Conducting annual reviews of advisory committee accomplishments;
- Responding to inquiries from agencies on establishing new committees or the renewal of existing groups;
- Preparing an annual report covering a summary of committee activities; and
- Maintaining a FACA database from which advisory committee information may be obtained via the Internet. (GSA, 2014)

Typically, the charter expires after a two-year period, but can be renewed if approved by the GSA.

During the charter drafting and renewal process, the GSA considers whether the committee has balanced membership (GSA, 2011). FACA law requires "…the membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee" but does not stipulate *how* balanced membership should be achieved. Agencies are thus required to submit a Balanced Membership Plan which details how the agency will "consider a cross-section of those directly affected, interested, and qualified, as appropriate to the nature and functions of the advisory committee" during the member selection process and that committees that require technical experts "should include persons with demonstrated professional or personal qualifications and experience relevant to the functions and tasks to be performed." (41 CFR § 102-3.60(b)(3)).

From an administrative perspective at the agency level, any agency which establishes a FACA committee must appoint a Committee Management Officer (CMO) and a Designated Federal Officer (DFO). Overall, the responsibilities of the DFO are to ensure that the committee chairs and

members comply with FACA regulations. The committee can begin operation only after a required public notification period in the Federal Register (FR) and the filing of the charter with Congress. The FR notice may include a request for nominations for committee members.

There are seven different types of functions that FACA committees can serve. GSA assigns one function to each committee. The seven functions are:

- **National Policy Issue Advisory Board**, which are assigned to committees devoted to advising agencies on the implementation of National Policy Issues.
- **Non Scientific Program Advisory Board**, which are assigned to committees devoted to advising agencies on the implementation of Non Scientific Programs.
- **Scientific Technical Program Advisory Board**, which are assigned to committees devoted to advising agencies on the implementation of Scientific Technical Programs.
- **Grant Review Committee**, which are assigned to committees concerned with making recommendations for grants and awards.
- **Regulatory Negotiations Committee**, which are assigned to committees concerned with making Regulatory Negotiations.
- **Other Committee**, which are committees which either cross categories or do not fit the categories listed above, or a
- **Special Emphasis Panel**. A Special Emphasis Panel generally has a purpose similar to a Grant Review Committee and is not just an advisory committee dealing with a single topic of great concern. This term has limited usage and most Special Emphasis Panels are located in NIH.(GSA, 2014)

The three types of functions most relevant to this study are National Policy Issue Advisory Boards, Scientific Technical Program Advisory Boards, and Other Committees. The process for deciding which committee functions to include in this study is described in depth in Chapter 4.

GSA issued its first set of FACA regulations in 1987 and an updated set in 2001, which still hold to this day. While these regulations helped to clarify what is required of agencies to comply with FACA, there is no standard for how FACA should be interpreted; each agency is permitted to interpret the law how it sees fit. These interpretations – even if made in good faith – do not protect an agency or its committees from claims that FACA has been violated. As described in later chapters,

the variance in how FACA is interpreted by agencies has important implications for how committees are established, implemented, and administered**.**

B. Clarifying FACA's Coverage Post-1972

As it was originally drafted, an advisory committee under FACA could be interpreted as any exchange between a government employee and at least two people not employed by the government. Federal agencies have found this broad language to be vague and problematic because depending on how strictly the language is interpreted, FACA could apply to nearly any exchange between the government and private citizens. Since FACA was passed in 1972, Congress has enacted legislation to clarify FACA's coverage and implementing regulations and executive orders have been issued with the same purpose. In addition, federal courts have ruled to narrow the scope of the law as originally drafted.

1. Post-FACA Legislation, Implementing Regulations, and Executive Orders

Since FACA was passed, there have been several attempts to clarify FACA's coverage and integrate measures to improve the transparency and accountability of FACA committees. In 1977, the Government in the Sunshine Act was incorporated into FACA which requires that FACA committee meetings be open and that the public can participate. If a meeting is to be closed, the DFO must submit a written request to the agency head at least 30 days in advance of the scheduled meeting justifying the rationale for closing the meeting by citing relevant portions of the Sunshine Act that note exceptions to the open meeting requirement (i.e., for matters of national security). This request is also reviewed by agency counsel. Advance notice of the meeting must be posted in the *FR*. Similarly, FACA requires that "the records, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents that were made available to or prepared for or by each advisory

committee shall be available for public inspection and copying" unless the documents qualify for one of the exceptions under the Freedom of Information Act (FOIA).

GSA issued its first set of FACA regulations in 1987 and an updated set in 2001, which still hold to this day. While these regulations helped to clarify what is required of agencies to comply with FACA, there is no standard for how FACA should be interpreted; each agency is permitted to interpret the law how it sees fit. These interpretations – even if made in good faith – do not protect an agency or its committees from claims that FACA has been violated. As described in later chapters, the variance in how FACA is interpreted by agencies has important implications for how committees are established, implemented, and administered.

Although FOIA was passed in 1966, there have been more recent clarifications of how FOIA pertains to FACA. In practice, the FOIA exemption most relevant to FACA committees for "pre-decisional materials" (also known as exemption 5) was determined by the General Services Administration's Office of Legal Counsel in 1988 to be "not generally applicable" (GSA, 1988) because "exemption 5 protects only inter-agency and intra-agency documents and because an advisory committee is not an agency" (GSA, 1988).

During the 1990s there were two bills introduced which clarified what entities are subject to FACA. The Unfunded Mandates Reform Act, passed in 1995, excludes from FACA meetings between federal officials and officials from state, local, and/or tribal governments as long as a two-part test is met: the individuals involved have to act in their official capacity and meetings are solely for the purpose of exchanging information or advice about federal programs designed to share government responsibilities. In 1997, a set of amendments was passed that excluded meetings held by National Academy of Sciences and National Academy of Public Administration from FACA regulation, although the legislation did add new regulations that applied to committee meetings held

by these two agencies.

More recently, there have been two attempts to revise FACA, primarily through measures to introduce greater transparency in FACA proceedings. The first bill, introduced by Congressman William Lacy Clay on March 5, 2009, passed by 250-124 on July 26, 2010 in the House, but the Senate took no further action on the bill. On March 17, 2011, Congressman Elijah Cummings introduced a bill that replicated many of the provisions of Congressman Clay's bill and is now pending in the House.

2. CASE LAW CLARIFYING FACA'S COVERAGE

The federal courts have clarified FACA's coverage in a number of decisions, primarily by providing more precise interpretations of the definitional language in the original legislation. Four of the cases most relevant to this study are discussed here.

As indicated above, FACA defines "advisory committee" to include "any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other sub-group thereof". How a "group" is defined in the original legislation is ambiguous but was clarified in Nader v. Baroody, 396 F. Supp. 1231 (D.D.C. 1975) (Nader v. Baroody, 1975). "To meet the 'group' requirement, a federal advisory committee must be more than a mere assemblage of two or more persons that provides information to the government: the group must include some formal organization and be charged with a specific task" (Bull, 2011, p. 14). In Ass'n of Am. Physicians & Surgeons v. Clinton, 997 F.2d 898, 909, 910 (D.C. Cir. 1993), the D.C. Circuit Court further delineated what a group means under FACA: "a group is a FACA advisory committee when it is asked to render advice or recommendations, *as a group*, and not as a collection of individuals".

Similarly, the FACA definitional language stating that advisory committees are established by the government "in the interest of obtaining advice or recommendations" has resulted in uncertainty.

In two separate cases, Sofamor Danek Group, Inc. v. Gaus, 61 F.3d 929 (D.C. Cir. 1995) and Judicial Watch, Inc. v. Clinton, 76 F.3d 1232 (D.C. Cir. 1996), the D.C. Circuit Court ruled that a committee would not meet the FACA threshold if it was created primarily for the benefit of the private sector and provided factual or other non-policy related information.

C. Scholarship on FACs

Federal advisory committees have been in place for nearly 40 years, are frequently used by the executive branch, and have accounted for over $3.4 billion in government spending since FY02. However, they remain "little-known [and] little-studied"(Domhoff, 2005). As discussed above, advisory committees do not feature prominently in the literature on public policy or health policy development and implementation. Even the literature specifically assessing the role of research in the policy process neglects advisory committees in its discussion of the models of the research-policy relationship.

Existing scholarship on FACs can be grouped into three broad categories: descriptive pieces published by trade organizations or government agencies focused on illuminating the fundamental characteristics of FACs; articles centered primarily in the political science sphere which assess the role of industry influence or "capture" of FACs; and empirical articles and perspectives written for peer-reviewed journals analyzing and commenting on the selection of Food and Drug Administration (FDA) FAC members, their conflicts of interest, and voting patterns.

In the descriptive arena, Wilson and Harsha provide a useful typology of FACs in their December 2008 newsletter to members of the Association for Computing Machinery (Wilson & Harsha, 2008). Blue ribbon commissions are "typically created to provide some focused policy direction" (Wilson & Harsha, 2008, p.25). Standing committees provide "high-level strategic direction" (Wilson & Harsha, 2008, p.25). The authors suggest that the now-disbanded President's

Information Technology Advisory Committee, which was designed to provide expert advice on "maintaining America's preeminence in advanced information technologies" is an example of a standing committee (Wilson & Harsha, 2008, p.25). Specific guidance on narrowly-defined technical problems is provided by "highly specialized committees" (Wilson & Harsha, 2008, p.25). Without examples of FACs which would fall into the first and third of these three categories it is difficult to ascertain how the scopes and charters of FACs might vary across this typology. Though focused on commissions used by presidents, Zegert also defines three categories of advisory bodies: agenda commissions targeting the public and aiming to garner support for presidential initiatives; information commissions intended to provide new information to policymakers; and political constellation commissions which seek to "foster consensus, compromise, and cooperation in a policy domain" (Zegert, 2004, p.372).

Wilson and Harsha also indicate that there are numerous motivating factors that explain why FACs might be created, including breaking political deadlock, answering technical questions, providing strategic guidance, and obtaining perspectives from a range of stakeholders before making a policy decision, as President Washington did during the Whiskey Rebellion. In his examination of the impetus for FAC creation, Campbell takes a more cynical perspective and explains that committees allow politicians to evade blame for issues that are too charged and Congress to trim its workload (Zegert, 2004).

To date, literature on federal advisory committees housed within the political science domain has focused on FAC membership and especially on the extent to which special interests and corporations are represented on advisory boards. As discussed above, a key feature of FACA is its emphasis on balanced membership. Data from the 1970s suggest that FACA was effective in this regard; while corporations represented a substantial proportion of advisory committee members in

the 1970s, that membership declined during the decade (Priest, Sylves, & Scudder, 1984). However, the concern about the "capture" of FACs by special interests, including corporations, and the related closing of FAC meetings to the public, has not dissipated. An analysis of committee-level data for 1974-2000 suggests that special interests captured FACs in some agencies, with the United States Department of Agriculture (USDA) and the DOC being the agencies with the highest proportion of special interest group representation (Karty, 2002). Others suggest that Congress may play a substantial role in creating un-balanced FACs by stipulating specific membership requirements, and that in doing so, Congress exerts control not only of the legislative process but also over regulation (Balla & Wright, 2001).

A sub-set of the literature on corporate influence on FACs takes an empirical approach and focuses on member selection and conflicts of interest in advisory committees to the FDA. The FDA is unique regarding its creation of FACs to advise on health issues because of its close relationship with the pharmaceutical industry. An analysis of all advisory committee meetings of the Center for Drug Evaluation and Research (CDER) held between 2001 and 2004 found that although conflicts of interest were frequently disclosed and were often of considerable monetary value, recusal of committee members rarely occurred (Lurie, Almeida, Stine, Stine, & Wolfe, 2006).

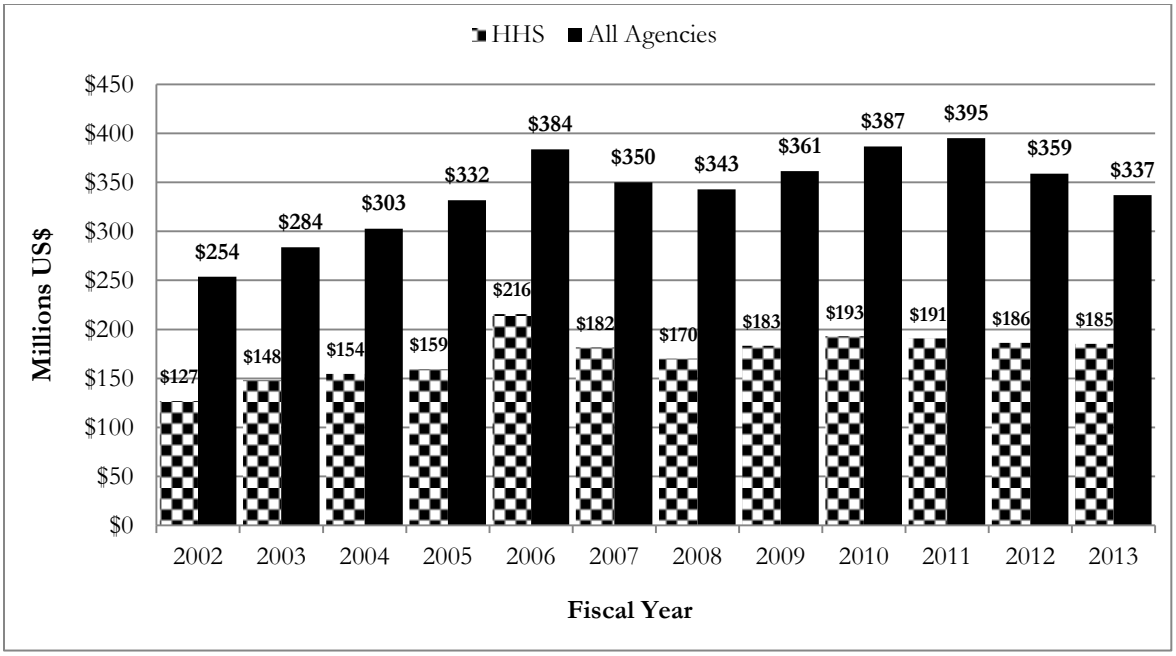
D. FACs for Health: An Overview

In FY2014, there were a total of 1,004 active, chartered FACs that advised the executive branch across a wide range of issues ranging from bio-defense to aviation to rivers, with varying goals and membership (GSA, 2011). A search of the GSA database for active, chartered, FACs under the purview of the HHS and the Environmental Protection Agency (EPA) in FY2014 returns 270 advisory committees total, with 248 from HHS and 22 from EPA. It seems reasonable to hypothesize that there could be an additional 200 advisory committees for health issues across the

rest of the executive branch which would make health the primary issue addressed by FACs.

HHS spends more on its SABs than any other agency. In FY2013 alone, HHS spent $185 million on its advisory boards (Figure 2.1). Between FY2002 and FY2013, HHS spent $2.1 billion. Total government spending on FACs across all agencies was $337 million in FY2013 and $4.1 billion between FY2002 and FY2013 (Lipowicz, 2011). If spending from other agencies which address health issues is included, FACs for health easily consume the majority of all government spending on advisory committees.

Figure 2.1. Spending on FACA committees, HHS vs. All Agencies, FY02-FY13



Given the proportion of all FACs which are devoted to health issues and especially because of the possibility that the majority of FACs may in fact be implemented to provide recommendations on health issues or issues with implications for health, additional research is needed on the role FACs play in the health policy process, the factors which affect whether the recommendations from FACs are utilized by health policymakers, and the strategies stakeholders

can use to facilitate the uptake of FAC recommendations. As bodies designed to ensure that decisions made by the executive branch are informed by expert judgment and evidence, FACs can be important actors in the public policymaking process. In health, where evidence-based policy is frequently considered paramount, FACs may be especially critical to the development of sound public health policy.

CHAPTER 3: CONCEPTUAL FRAMEWORK

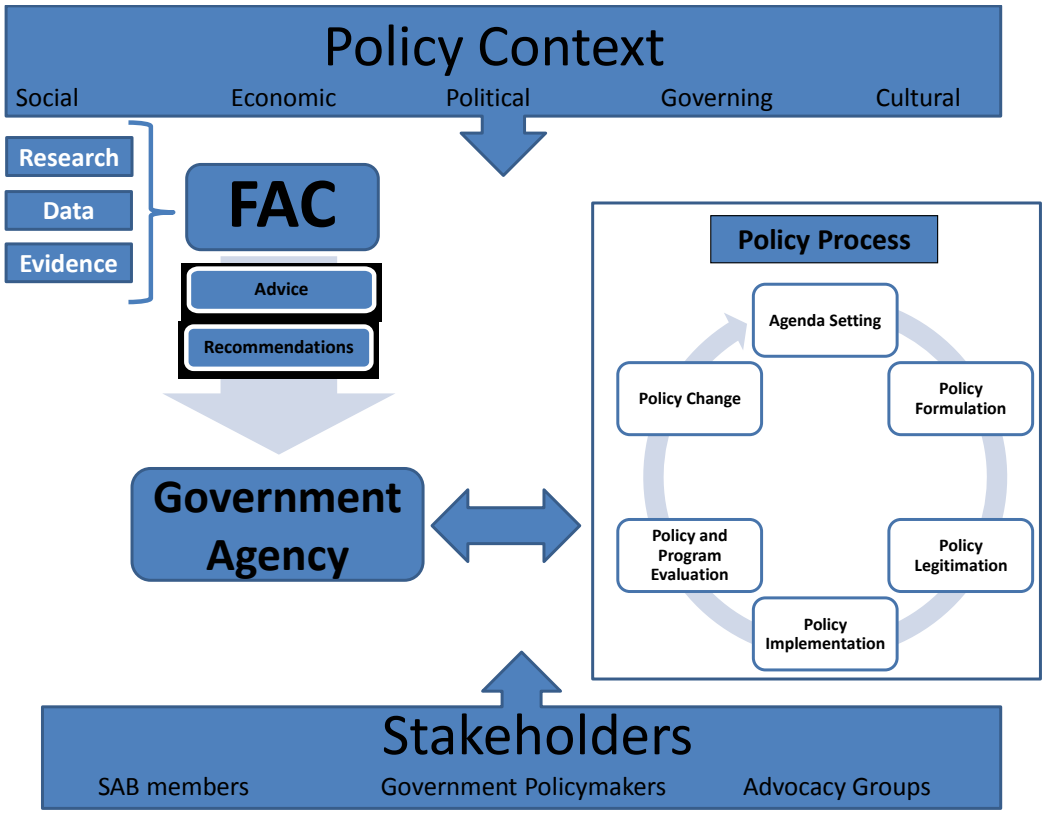
The initial conceptual framework (Appendix A) for this study was developed based on the literature review described in the previous chapter. The initial framework also informed the aims of this study, the categories of questions outlined in the interview protocol, as well as the questions themselves. The initial conceptual framework was refined based on findings of this study and the final conceptual framework (Figure 3.1) now provides a visual aid to summarize key elements of the literature. Thus, the framework presented here links the literature relevant to this study, which is largely theoretical, with the empirical findings. The following text describes the framework's components.

I. Policy Context

The context in which public policy is situated consists of several components. As described in Chapter 2, Kraft and Furlong identify five different "contexts" that shape the public policy process (Kraft & Furlong, 2010). These factors are explicitly identified in the conceptual model for clarity's sake but are represented by the overarching 'policy context'. The influence that the policy context has on the generation of research, data, and evidence, as well as on FACs and the policy process is designated by the box and arrow pointing down into the middle of the framework.

The social context is perhaps the most broad and dynamic, and includes factors such as demographic changes, how communities relate to one another, and immigration patterns. According to Kraft and Furlong, "social changes…alter how the public and policymakers view and act on problems" (Kraft & Furlong, 2010, p.10). The economic context is more straightforward and refers to the state of the economy which can have "a major impact on the policies governments adopt and implement" (Kraft & Furlong, 2010, p.11).

Figure 3.1. Conceptual Framework



The third category, political context, refers to politics related to the major parties, ideological discrepancies between groups of the public, and the ability of advocacy groups and other NGOs to pressure policymakers on various issues. The political context "affects public policy choices at every step" (Kraft & Furlong, 2010, p.12). The governing context is closely related to the political context and refers to the structure of the government, including separation of powers. In the United States, the governing context would also refer to power-sharing between the states and the federal government which has implications for how government agencies share authority over policy implementation.

Finally, the cultural context refers to "political culture", or the "widely held values, beliefs,

and attitudes, such as trust and confidence in government and the political process, or the lack thereof" (Kraft & Furlong, 2010, p.14). In a country as diverse as the United States, political culture can vary widely from one setting to the next resulting in conflicts which manifest "into constraints on policymaking" (Kraft & Furlong, 2010, p.12).

Although not specific to health policy, the contextual factors identified by Kraft and Furlong align with the categories of contextual factors defined by health policy-specific texts. The categories used by Buse et al. are generally broader than those identified by Kraft and Furlong. Situational factors are those conditions which are "more or less transient, impermanent, or idiosyncratic" and help to focus attention on a policy issue (Buse et al., 2005, p.11). In contrast, structural factors are "relatively unchanging elements of…society" such as the political system, the type of economy, and the employment base. Buse et al. note that the demography of a society and its technological base are structural factors that might specifically affect health policy.

One area where the Buse et al. categories align perfectly with Kraft and Furlong at least in title is in the cultural category, although Kraft and Furlong refer primarily to political culture rather than culture more broadly. Buse et al. indicate that the culture category includes religious factors, ethnic and linguistic patterns, as well as the extent to which a society is hierarchical. A marked departure of the Buse et al. framework from Kraft and Furlong is in the inclusion of international or exogenous factors as a unique category. This grouping addresses the multinational co-operation that can occur in health to address issues such as the eradication of diseases. What the Buse et al. framework gains by being more inclusive than that of Kraft and Furlong, it loses in specificity: it is not readily apparent, for example, how the situational and structural categories differ and what types of factors would be included under each. Thus, for the purpose of this study, the conceptual framework utilizes the Kraft and Furlong construction of policy context.

The policy context can directly affect the process and recommendations of a FAC as well as the phase of the policy process in which the FAC is involved. Perhaps most importantly, the policy context can affect whether an FAC is established. For example, a governing context which values transparency, objectivity, and evidence in public policy which is supported by a social context that values addressing public health issues would likely be conducive to establishing a FAC. If the economic context is sound the FAC may be more likely to receive adequate funding for basic operational costs. The interaction between the social context and the strength of the economy could influence whether the agency receives new and/or additional funding to implement the FAC's recommendations. The cultural context could affect the level of faith or trust held by the public, the government agency which established the FAC, and the media in the process and recommendations of a FAC. The extent to which the governing, social, economic, and cultural contexts are conducive to establishing FAC's and adopting their recommendations may be determined by the political context. Genuine commitment by policymakers to the FAC as a mechanism that facilitates the integration of evidence into the policy process can enhance the legitimacy of the FAC.

There are also several factors which are more proximate to the operational process and recommendations of a FAC, including: (i) legislation, which can determine the human and financial resources available to support the operation and administration of the FAC, as well as the general categories of FAC membership; and (ii) the institutional power and dynamics of the government agency to which the FAC reports. These factors are considered to be a part of the policy context and are thus not specifically represented in the conceptual model.

The organizational culture of the government agency that established the FAC may be especially influential (Flitcroft, Gillespie, Salkeld, Carter, & Trevena, 2011). The agency's access to and attitude toward research could affect whether it is interested in engaging a SAB to provide

guidance and furthermore, whether the agency is amenable to integrating the FAC's recommendations into policy. The agency's general ideology and power within the executive branch's governing structure could affect its perception of whether there is a need and/or benefit to approaching external advisors as well as the balance of board's members. In addition, agency power and ideology could affect the attention received by the FAC from members of the general public, advocacy groups, media, other scientists and researchers, and if relevant (i.e., depending on the issue addressed by the FAC), from international donors and foreign country governments.

II. The Role of FACs in the Policy Process

This study is concerned with FACA committees established by agencies that address matters that affect the public's health and/or public health policy. Thus, a key function of any FAC dealing with public health issues is to review, interpret, and evaluate the quality of data and external validity of research findings and evidence related to the issue(s) the board is addressing.

As described above, FACA committees exist to provide advice and recommendations to government agencies. By definition, agency-established advisory boards do not interact directly with the policy process but rather, engage with the various phases of the process indirectly, through the establishing agency. Thus, the establishing agency serves as a gatekeeper for the advice and recommendations put forward by the FAC.

The phase of the policy process to which the advice and recommendations put forward by a FAC are most relevant likely depends on the issue(s) the FAC is established to address, which in turn is determined largely by the establishing agency but also may be influenced by the policy context. Empirical evidence suggests that the "relationship between research and policy making [can change] across the different stages of policy development" (Nutley, 2007, p.43). For example,

analysis of the use of research in developing policies on drug use in UK prisons shows that research initially helped to place the issue on the policy agenda but then was used to help the prison system legitimize its policy. However, it is important to recognize that the case of UK policy on drug use in prisons addresses research, not advisory committees. As described in subsequent chapters, findings from this research indicate that SAB recommendations can address all phases of the policy process.

III. Stakeholders

Additionally, the advice and recommendations provided by the FAC may depend on various stakeholders including FAC members themselves, government policymakers, and staff of NGOs which track the issues addressed by the FAC. These three groups of individuals are involved in and help to drive both the policy process as well as FAC operations. As discussed in more depth in Chapter 4, one of the aims of this study examines how various stakeholders play a role in the how and why FACs are established, influence the advice and recommendations put forward for consideration by the establishing agency and whether those recommendations are adopted, and engage with the FAC while it is active. This engagement is represented by the box and arrow pointing up into the middle of the framework.

CHAPTER 4 : METHODS

This chapter describes the design of this study as well as the methods used to identify, collect, and analyze interview data obtained from study participants for both the PEPFAR and NCADAC case studies. The overall objective of this study was to describe the role of FACs for health in the policy process. This study employed a qualitative approach, which was considered appropriate because the study's objective was exploratory not explanatory in nature, the aims and associated research questions invited a complex understanding of the phenomena they were designed to address, and it was critical to understand the context and settings in which the units of analysis (FACs) and the individuals and institutions associated with them operated (Creswell, 2007). Additionally, because the role of FACs in health policy is an area supported by little theoretical scholarship or empirical evidence as discussed in Chapter 2, it was most appropriate to employ an inductive approach to data analysis to "move from the particular to the general [and] develop new theories or hypotheses from many observations" (Sbaraini, Carter, Evans, & Blinkhorn, 2011, p.3). Consistent with the grounded theory method, which is described in detail in Section 3 of this chapter, any theories of how advisory committees are used by the US government will be "'grounded' in the data themselves" (Charmaz, 2006a, p.2).

After outlining the study's aims and research questions in Section I, Sections II-V provide an overview of case study design and the grounded theory method as well as the ethical review process for this research. Sections VI-VIII describe the procedures followed to select the two cases included in this study, the sampling strategy used to recruit interview respondents, and the process for data analysis.

I. Research Questions

This study analyzed specific FACs using a multiple case study design (described in the next section) to understand how they facilitate the use of evidence by policymakers.

AIM 1: Describe how FACs play a role in the health policy process and how they help to ensure health policy is evidence-based.

- *Research Question 1a:* What are the mechanisms and processes by which FACs function, including how they are structured, implemented, convened, and operate?
- *Research Question 1b:* To what extent does the theoretical disconnect between the literature on the health policy process and the literature on evidence-based policy have empirical support?
- *Research Question 1c:* How do FACs facilitate and impede the utilization of research and evidence by policymakers?

Building on the findings from Aim 1, the study assessed the contextual factors associated with the uptake of FAC recommendations as well as associated challenges.

AIM 2: Identify and explain how internal processes and external contextual factors contribute to whether the recommendations of a FAC will be adopted.

- *Research Question 2a:* What factors are associated with the uptake of FAC recommendations?
- *Research Question 2b:* What challenges are associated with adopting FAC recommendations?

Finally, and synthesizing the findings of Aims 1 and 2, Aim 3 examined how different FAC stakeholders have already attempted to encourage the integration of FAC recommendations into policymaking and proposed new strategies.

AIM 3: Describe strategies various stakeholders, including NGOs, FAC members, and government agency staff have used to facilitate the uptake of recommendations put forward by FACs and propose new, effective strategies.

- *Research Question 3a:* How have FAC stakeholders, including advocacy groups, FAC members, and policymakers, attempted to incorporate FAC recommendations into the policy development process?
- *Research Question 3b:* What are effective strategies that FAC stakeholders could use to facilitate the uptake of FAC recommendations by policymakers?

To address the aims and research questions outlined above, in-depth, semi-structured interviews were conducted with FAC members, government agency staff managing the two FACs included in this study, and NGO staff members tracking the issues of the FACs included in this study. In addition, documents produced by the FACs and their respective government agencies were analyzed. The approach is described in more detail in the rest of this chapter.

II. Study Design

The case study has been referred to as a research method, an approach, a research strategy, and a type of study design (Andrade, 2009; Charmaz, 2006a; Eisenhardt & Graebner, 2007; Yin, 2009). In his seminal text *Case Study Research*, Yin refers to case studies as one method among several that social science researchers can choose to employ, depending on the research questions, the ability of the investigator to exert control over the events occurring in the study, and whether the research addresses contemporary or historical events (Yin, 2009, p.8). Yin also describes four different case study designs: holistic single-case, embedded single-case, holistic multiple-case, and embedded multiple-case (Yin, 2009, p.46).

Strict fidelity to Yin's approach would imply concurrence with the paradigm of the case study as both a type of study design as well as a research method which is accompanied by guidelines for data collection, procedures for data analysis, and criteria for evaluating the rigor of the research. Further, Yin's text is positivist in its approach: while he excuses the need for study propositions, which are similar to hypotheses, in exploratory research such as this, he argues that it is

"essential"(Yin, 2009, p.35) to construct a preliminary theory in the design phase of a study before data collection begins. This step, he asserts, is the "one point of difference between case studies and related methods such as 'grounded theory'" (Yin, 2009, p.35).

For the purpose of this research, it was most appropriate to apply Yin's approach for its study design elements and the grounded theory method as the methodology guiding data analysis. This section draws from Yin's text to explain the rationale for selecting the case study design for this research and the contribution of the approach to defining the unit of analysis and the boundary of each case study.

A case study is defined in two parts. The scope of a case study involves "an empirical inquiry that investigates a contemporary phenomenon in depth and within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident" (Yin, 2009, p.18). The concept of the "real-life context" in which the case is embedded is particularly important for this research because each FAC is likely to be heavily influenced by various contexts, as described in Chapter 3. It would be challenging to have an in-depth and comprehensive understanding of the research findings without considering these contexts (Baxter & Jack, 2008). The second part of the case study definition concerns the data collection and data analysis strategies. A distinctive feature of the case study inquiry is that there will be "many more variables of interest than data points…[from] multiple sources of evidence, with data needing to converge in a triangulating fashion, and…benefits from the prior development of theoretical propositions to guide data collection and analysis" (Yin, 2009, p.18).

Broadly, case studies were appropriate for this research because "case studies are the preferred method when (a) 'how' or 'why' questions are being posed, (b) the investigator has little control over events, and (c) the focus is on contemporary phenomenon within a real-life context"

(Yin, 2009, p.2). Since the overall objective of this study was to understand how FACs are involved in the policy process, which was a phenomenon over which this investigator had little control and existed within the institutional context of the establishing agency and the federal government more broadly, case studies were the most suitable approach. The case study was also appropriate for this study because it allowed the unit of analysis to be "some event or entity other than a single individual" (Yin, 2009, p.29), namely a FAC.

Case study research does not have a typical study design (Yin, 2009, p.25). However, there are components of a research design for the case study approach that are accepted as being fundamental, including defining the research questions; defining study propositions; and determining the boundaries of a case. Ultimately, the research questions define what phenomenon will be studied. As described above, the research questions broadly addressed the role FACs play in the policy process. Although Yin states that the research questions direct the researcher to the case study method and help to capture what he/she is interested in studying, they do not point to what should be studied. Thus, following the critical step of determining research questions, the researcher must define study propositions which put forward an assertion about why the phenomenon under study occurs. As described above, exploratory studies should have a purpose but do not need to have propositions. In addition, because this study used the grounded theory method of analysis, it would be contradictory to define study propositions.

Determining the boundaries of a case "will ensure that [the] study is reasonable in scope" (Baxter & Jack, 2008, p.546). One type of boundary that was critical for this study is the definition of a FAC. For the purposes of this study, all included FACs are subject to FACA. While the federal government uses many different types of advisory bodies, even for health matters, not all of these are subject to FACA. For example, the United States Preventive Services Task Force (USPSTF) is an

important advisory body to AHRQ, and more broadly to HHS, but USPSTF is not subject to FACA[4]. A more detailed description of the criteria used to determine which FACs were considered eligible for inclusion is provided in Section VI.

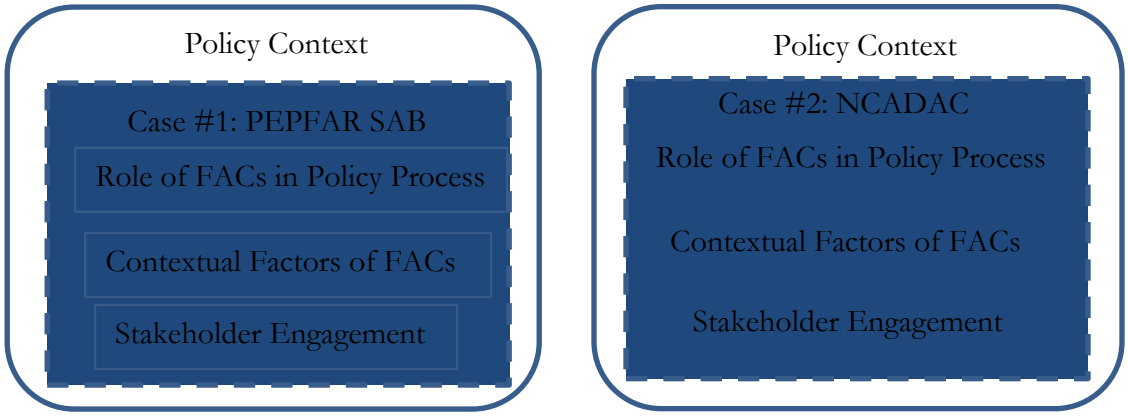
Another boundary that was important for this study was time. Fortunately, the topic for this study was identified within two months after the effective date of authority for each advisory committee (November 1, 2010 and December 5, 2010 for NCADAC and PEPFAR, respectively). While Institutional Review Board (IRB) approval was not obtained until June 2012, the concurrency of activity in both cases with the study period allowed the investigator to collect data and attend committee meetings as an observer in real time. Further, it reduced recall bias among respondents because they were providing information about events in real time or that had occurred recently. Although the current version of the charters for the PEPFAR SAB and the NCADAC are not due to terminate until March and June of 2015, respectively, activity for both committees came to a halt in the late spring of 2014. A new Ambassador for the PEPFAR program was sworn in in April 2014 and the NCADAC released the National Climate Assessment (NCA) in May 2014. Thus, the beginning of the time boundary for each case can be defined as the effective date of authority for each committee and the end of the time boundary for the PEPFAR case is April 2014, when

[4] The Congressional Mandate which established the USPSTF exempted the Task Force from FACA, although it is unclear exactly why. However, the reason may be found in subtleties in the FACA language, which states that "all matters under [advisory committees'] consideration should be determined, in accordance with law, by the official, agency, or officer involved." According to Section 1.10.1 of the USPSTF Procedure Manual, "topics can be nominated by organizations, individuals, EPCs [evidence-based practice centers], and Task Force members." Thus, AHRQ does not determine what topics the USPSTF addresses. Further, throughout the process of review and comment on USPSTF reports and recommendations "the Task Force maintains its independence by making these decisions without outside influence by professional societies or governmental entities." Thus, in contrast to FACA committees, the USPSTF maintains control of which topics it addresses as well as the recommendations it makes. The final recommendations are published in peer-reviewed journals, but are not "delivered" to AHRQ and then left for AHRQ to decide what (if anything) to do with the guidance.

Ambassador Debbie Birx took office at OGAC, and May 2014 for the NCADAC case, when the NCA 2014 was released. Theoretical saturation was reached and data collection for this study was concluded in September 2014. A wide time boundary for each case was important to capture the contextual factors influencing the establishment of a FAC as well as its impact, especially with respect to the effect of the FAC recommendations.

More specifically, this research employs a multiple-case study design, wherein individual FACs are the units of analysis (Figure 4.1).

Figure 4.1. Diagram of Study Design



This was preferable to a single-case design because "a multiple…case study will allow the researcher to analyze within each setting and across settings…and understand the similarities and differences between the cases" (Baxter & Jack, 2008, p.550). In addition, a multiple-case design had the benefit of being "considered more compelling and the overall study is therefore regarded as being more robust" (Yin, 2009, p.53). Finally, without multiple cases, there may not have been sufficient data available to answer the research questions.

III. The Grounded Theory Method

The grounded theory method was first proposed in the late 1960s by Barney Glaser and

Anselm Strauss in their book *The Discovery of Grounded Theory* (B. Glaser & Strauss, 1967). At a time when the core principles of quantitative research—"systematic observation, replicable experiments, operational definitions of concepts, logically deduced hypotheses, and confirmed evidence" (Charmaz, 2006a, p.4) which were underpinned by a positivist epistemology—provided grounds for undermining the scientific value of qualitative research, Glaser and Strauss offered a method to systematically conduct qualitative research which was viewed as credible in its own right, in addition to serving as "a precursor for developing quantitative instruments" (Charmaz, 2006a, p.6). According to Glaser and Strauss, at its core, grounded theory involved "*developing* theories from research grounded in data rather than *deducing* testable hypotheses from existing theories" (Charmaz, 2006a, p. 4) (emphasis in original).

While Glaser and Strauss intended for grounded theory to counter the positivistic assumptions permeating qualitative research methods in the mid-20th century, gradually the method became identified as being positivistic in its approach. A detailed description of the evolution of Glaser and Strauss' work from a rejection of positivism to positivistic falls outside the scope of this research. Currently, the constructivist approach to grounded theory proposed by Kathy Charmaz in her book *Constructing Grounded Theory* (Charmaz, 2006a) is favored, rather than the positivist or post-positivist approaches proposed by Glaser and Strauss and Strauss and Corbin (Strauss & Corbin, 1990), respectively. At its core, the constructivist approach to grounded theory aligns with the original, positivist approach: both emphasize the concept that "theories [are] 'grounded' in the data themselves" (Charmaz, 2006a, p.2). According to Charmaz, the departure between the two approaches results from the following:

> In the classic grounded theory works, Glaser and Strauss talk about discovering theory as emerging from data separate from the scientific observer. Unlike their position, I assume that neither data nor theories are discovered. Rather, we are part

> of the world we study and the data we collect. We *construct* our grounded theories through our past and present involvements and interactions with people, perspectives, and research practices (Charmaz, 2006a, p.10).

This research followed Charmaz's approach to data analysis which promotes the development or construction of theories grounded in the data, as opposed to the analysis approaches offered by Yin. Yin's approaches are not well-suited to this research because they emphasize comparing patterns found through empirical results with predicted patterns and should be applied to explanatory, not exploratory, case studies, or involve time-series analyses (Yin, 2009, p.146-156). Thus, integrating Charmaz's constructivist grounded theory approach to data analysis and the positivist approach to study design proposed by Yin provides an optimal way to adapt the case study method to the inductive approach of grounded theory. Under Charmaz's approach, the grounded theory method involves the following core principles (Charmaz, 2006a, p.178):

- The grounded theory research process is fluid, interactive, and open-ended.
- The research problem informs the initial methodological choices for data collection.
- Researchers are part of what they study, not separate from it.
- Grounded theory *analysis* shapes the conceptual content and direction of the study; the emerging analysis may lead to adopting multiple methods of data collection and to pursuing inquiry in several sites.
- Successive levels of abstraction through comparative analysis constitute the core of grounded theory analysis.
- Analytic directions arise from how researchers interact with and interpret their comparisons and emerging analyses rather than from external prescriptions.

According to Charmaz, grounded theories should be situated in specific context(s) because this facilitates detailed cross-theory comparisons. Abstractions are constructed by comparing data. Across studies, such abstractions can develop into formal theories. These theories can then be compared across studies. Thus, in grounded theory just as in case study research, generalizability

from empirical data does not imply that results from the study sample should be representative of a population (Charmaz, 2006a; Yin, 2009). Rather, the focus of generalizability should be on whether the study's results transfer or can be applied to other settings (Malterud, 2001, p.485).

A. Use of Prior Knowledge, Research, and Literature in Grounded Theory

Chapter 2 briefly mentioned the debate in the grounded theory literature regarding whether and how previous knowledge, research, and literature should be included in grounded theory studies. This issue warrants more in-depth discussion here given the role of the researcher in theoretical sampling and the importance of reflexivity in qualitative research. Reflexivity is discussed in more detail in the next sub-section.

The original conceptualization of grounded theory as conceived by Glaser and Strauss argues strongly that the researcher should begin a grounded theory study as a blank slate. According to Glaser, the researcher should "enter the research setting with as few predetermined ideas as possible—especially logically deducted prior hypotheses. The research problem and its delimitation are discovered" (Glaser & Holton, 2004, p.11). The idea that hypotheses have no place in grounded theory research is consistent with Yin's acknowledgement that exploratory research can be free from propositions. However, Glaser takes it a step further, arguing that it is important that "the start [of a good grounded theory analysis] is not blocked by a preconceived problem, a methods chapter or a literature review" (Glaser & Holton, 2004, p. 11). Additionally, "to undertake an extensive review of literature before the emergence of a core category violates the basic premise of GT—that being, the theory emerges from the data not from extant theory" (Glaser & Holton, 2004, p. 12).

Others are more flexible with respect to how prior knowledge and even a review of the literature can be incorporated into grounded theory research (Andrade, 2009; Hallberg, 2006). In general, this more accommodating approach recognizes the value of existing literature to new

research for assisting the investigator with maintaining theoretical sensitivity. This concept "reflects the researcher's ability to use personal and professional experiences as well as methodological knowledge and thereby see data in new ways and think abstractly about data in the process of developing theory" (Hallberg, 2006, p.144). Prior knowledge, research, and literature helps to sensitize the investigator to what problems are in need of exploration and thus helps to focus the study. The theory which emerges from the data is what determines the relevance of the literature. The researcher keeps an "open mind" not an "empty mind" (Andrade, 2009, p.46).

Thus, instead of analyzing data under the framework of existing theories, a literature review can help focus the investigator as she constantly compares incidents to incidents, incidents to concepts, and concepts to concepts (Hallberg, 2010). For the purposes of this research, the literature initially reviewed at the study proposal phase was helpful in developing the preliminary conceptual framework and the original interview guide. As data collection proceeded and new themes emerged, it became clear that the literature review would need to be expanded to address the legal history of FACA, for example, among other areas.

B. Reflexivity

While any findings and new theories emerging from a grounded theory study should be grounded in the empirical data analyzed for the research, ultimately there is some subjectivity in how the findings are interpreted. This results from the fact that in qualitative research studies generally, and in grounded theory studies in particular, "the researcher is the primary 'instrument' of data collection and analysis" (Watt, 2007, p.82). The information received from interview subjects "is *always* influenced by the interviewer and interview situation" (Maxwell, 2005, p.109) (emphasis in original). Further, theoretical sampling and inductive coding depend inherently on the investigator's perspectives and judgments. Thus, it is not possible to eliminate the effect of the researcher.

Maxwell argues that rather than focusing efforts on obviating the effects of the researcher, what is important is to understand "how a *particular* researcher's values and expectations influence the conduct and conclusions of the study" (Maxwell, 2005, p.108) (emphasis in original).

This understanding can be achieved through reflexivity, which is defined as "thoughtful, conscious self-awareness" and "explicit meta-analysis of the research process" (Finlay, 2002, p.532). The ambiguity of what reflexivity means in practical terms is acknowledged as are its numerous approaches (Dowling, 2006; Finlay, 2002; Jootun, McGhee, & Marland, 2009). "When it comes to practice, the process of engaging in reflexivity is perilous, full of muddy ambiguity and multiple trails" (Finlay, 2002, p.212). While reflexivity should be constantly engaged through all of the phases of a study, and was in this research, it is not always feasible or practical for a researcher to provide a detailed account of her reflexive process, particularly in academic settings which value publication in journals that impose word limits on their authors. In addition, there is an opportunity cost to an intensive focus on reflexivity, namely that it could come at the expense of focusing on the study participants (Finlay, 2002). For these reasons, this study limited its discussion of reflexivity to a reflexive statement in this section, as recommended by Finlay (Finlay, 2002, p.543).

Overall, however, reflexivity was integrated throughout the process of conducting this research. Once data collection was initiated, the investigator sent bi-monthly progress updates to her academic advisor. These updates provided an opportunity for the investigator to reflect on the data obtained during the interviews conducted since the prior progress report, not only in terms of the dynamic and rapport between the investigator and the respondents and how those two elements varied across the cases but also provided an opportunity to note when new themes that were not initially anticipated as being relevant emerged from the data. The progress updates usually included at least one quote from an interview that raised a particularly interesting or novel issue. At the

monthly in-person meetings between the investigator and her advisor, ideas and theories emerging from the interview data were discussed at length, particularly in terms of how these ideas and theories related to the study's research questions whether these new themes warranted additional exploration or even a shift in the study's direction, and how the investigator's own professional experience in the policy arena in Washington, DC was affecting her interpretation of the data. In addition, the investigator met annually with her thesis advisory committee during the study period, during which time preliminary findings and decisions about analytical and methodological issues were discussed.

1. Reflexive Statement

The role advisory committees for public health-related issues play in the policy process is a topic that interested me initially because of my work experience in global health financing and evaluation of the effectiveness of the aid provided by donors to low- and middle-income countries for health. Over time, I have observed first-hand how the major issues on the global health policy agenda shift in priority and how funding for those issues can increase or decrease rapidly depending on their prominence on the global agenda. Oftentimes, these shifts in policy priorities are not necessarily aligned with the latest evidence on the effectiveness of a certain intervention or the actual burden of disease (Schieber, Gottret, Fleisher, & Leive, 2007; Shiffman, 2006a, 2006b; Shiffman & Smith, 2007). While I had a clear understanding that evidence was not the only factor that policymakers considered when making decisions about how to allocate resources, I did find it challenging to accept that evidence at times seemed to play such a small role.

More specifically, my interest in studying FACs established by US government agencies stemmed from an announcement in January 2011 that PEPFAR had established a science advisory board. As described in depth in Chapter 5, PEPFAR has not always been known as a program

which valued research. Initially, it was acknowledged that PEPFAR was serving as an emergency response to the dire situation of high HIV morbidity and mortality in low- and middle-income countries, especially those in sub-Saharan Africa, and that research was not a primary concern. However, PEPFAR also has been criticized for allocating resources to priorities that evidence indicated to be ineffective or inappropriate for the setting. Thus, I was curious about the changes to the political and institutional environment at OGAC that provided the right context for establishing the SAB as well as what types of scientific and policy issues the SAB was going to address.

I was familiar with the PEPFAR program prior to starting this research because I had worked for one organization that received PEPFAR funding and for another organization that tracked both the funding PEPFAR received from Congress as well as the effects of changes made to the legislation re-authorizing PEPFAR, which was passed in 2008. I did not, however, know any individuals working for PEPFAR at the time this study was initiated and was not at all familiar with the internal processes involved with deciding how PEPFAR resources were be allocated.

My experience with the PEPFAR program and in the global health policy field more broadly may have affected the interviews I conducted for the PEPFAR case. I felt more relaxed during these interviews than during the interviews conducted for the NCADAC case because I have more knowledge about the global HIV/AIDS epidemic than climate change and because of my familiarity with the broad policy context in which the PEPFAR program operates. My sense was that interview respondents for the PEPFAR case felt comfortable being candid about their perspectives when I told them about my work experience because it helped to build rapport and they may have felt they were talking to "one of their own". While I do not have a background in climate science, I admitted this freely to my respondents, which seemed to encourage them to be especially descriptive in their responses and not to make assumptions that I already knew certain acronyms or other jargon

associated with the climate change field.

More broadly, the dynamic in the interviews with the NCADAC respondents was similar to that of a professor (the respondent) teaching a student (me), whereas the dynamic in the interviews with the PEPFAR respondents was more peer-to-peer. The difference in the interview dynamics between the two case studies did not seem to affect the data or the analysis; surprisingly, the respondents in the NCADAC case were generally less formal and had a more relaxed style than the respondents in the PEPFAR case, so the professor/student and peer-to-peer dynamics were tempered by the demeanor of the individual respondents. However, I did find that to feel adequately prepared for the interviews for the NCADAC case I needed to conduct more background research prior to each interview than for the PEPFAR case as a result of my initial lack of exposure to climate change science.

My interactions with the interview respondents were also likely to have been affected by my status as a young, educated, female who was comfortable and broadly familiar with the dynamics of the Washington, DC policy and advocacy communities. Over the years, I have worked with individuals in the US government, at NGOs/advocacy organizations, and with researchers. Thus, going into this research, I expected that several of the respondents from the advisory committee and the government official categories were likely to be older males. Similarly, I expected respondents from the NGO/advocacy organizations to be closer to my own age. Further, I knew from my research prior to conducting each interview that some of the interview respondents were quite senior in their fields. While it was certainly exciting to be granted an interview with individuals of remarkable professional achievement, because I was accustomed to working with each type of respondent, I was not intimidated during the interviews beyond some initial nervousness related to initiating data collection and becoming comfortable with my interview questions and style. Further,

many of the respondents have doctoral degrees themselves and remembered their own dissertation process and were empathetic and interested in helping me to complete my degree. This common history may have introduced some selection bias into the sample; those respondents who had PhDs may have been more likely to respond to my request for an interview. However, given that nearly all potential respondents from both cases had either PhDs or MDs (or both), I do not think that the similarity in educational backgrounds substantially biased the self-selection of participants.

C. Criteria for Evaluating Grounded Theory Research

As described above, case study and grounded theory research rely on different principles for external validity than quantitative studies; instead of selecting cases or interview subjects with the goal of statistical generalizability, which would facilitate making an inference about a population based on a sample, grounded theory and case study research emphasize generalizing to the level of theory, or analytical generalizability. However, Charmaz and Diaz-Andrade both offer additional criteria beyond just external validity to evaluate the quality of studies such as the one described here.

Diaz-Andrade adapts Yin's criteria for evaluating the quality of case studies to align more directly with the principles of grounded theory research. Diaz-Andrade proposes that construct validity in grounded theory research is best represented by *theoretical saturation*, or theoretical sufficiency. He argues that these concepts "should allow interpretive researchers to build up and work upon constructs which emerge from the problem under investigation" (Andrade, 2009, p.48). Similarly, internal validity is addressed by *theoretical coding*, which permits researchers to build theory linked conceptually to the original data. External validity, as mentioned above, is focused on *theoretical generalizations* rather than testing hypotheses. Finally, Diaz-Andrade argues that reliability in grounded theory research should not focus on the ability of a second researcher to replicate the findings of the first given the role of the researcher's own perspectives in grounded theory research,

but rather should emphasize the *trustworthiness* of the research. In this case, trustworthiness refers to presenting a chain of evidence in the analysis that would allow another researcher to trust the results and find them meaningful (Trauth, 1997, p.242).

Charmaz offers four other criteria for evaluating grounded theory research which do not align well with the four criteria listed above (Charmaz, 2006a, p.182). *Credibility* broadly refers to whether the claims made by the researcher are supported by sufficient data and evidence so that another individual could make an independent assessment of the research and agree with the claims proposed. This research sought to ensure credibility by transcribing interviews verbatim, using in-vivo coding as part of the initial coding process, collecting rich data through semi-structured, in-depth interviews, and interviewing three categories of respondents in an effort to triangulate data on the role of FACs in the policy process. *Originality* is self-explanatory, referring to whether the research makes a novel contribution to the field and has social and theoretical significance. As explained in Chapter 2, this study makes a novel contribution to the literature given the paucity of empirical research or theoretical assessments of FACs in public policy broadly or health policy more specifically. At its core, *resonance* refers to whether the study participants or others in their circumstances agree that the proposed theories make sense. Throughout the data collection process, the investigator engaged in member checking or member validation, which involves providing study participants with the opportunity to judge whether the themes emerging from research resonate with their own experiences (Kuper, Reeves, & Levinson, 2008). During interviews, the investigator occasionally would indicate that a particular theme was beginning to emerge from the data, based on interviews with other respondents, and she would ask the respondent for his or her opinion about the extent to which the emerging theme resonated. Finally, the research has *usefulness* if it can spark additional research, contribute to knowledge, or provide insights that can be used outside of

academic settings. As discussed in more depth in Chapter 8, the findings from this research offer a number of opportunities for future, follow-on research both in applied and academic settings and could ideally inform efforts to establish FACs going forward.

IV. Grounded Theory Steps

The first step in grounded theory research is data collection based on theoretical sampling with the goal of achieving "'analytic generalization"' (Yin, 2009, p.38). Theoretical sampling, according to Charmaz, "involves starting with data, constructing tentative ideas about the data, and then examining these ideas through further empirical inquiry" (Charmaz, 2006a, p.102). The process of constructing ideas about the data and then exploring them through additional data collection is facilitated by collecting and analyzing data concurrently, memo-writing, and the constant comparative method.

Data analysis in grounded theory research involves coding the data in a series of steps which are outlined below. Theories emerge as data are coded, which help to define gaps in the data and direct the investigator to additional data collection needs. Memo-writing allows the investigator to reflect on the appropriateness of the codes used, explore new concepts emerging from the data, and refine future data collection efforts (Charmaz, 2006a). The constant comparative method, as described by Hallberg, means "every part of data, i.e., emerging codes, categories, properties, and dimensions as well as different parts of the data, are constantly compared with all other parts of the data to explore variations, similarities and differences in data" (Hallberg, 2006, p.143).

Grounded theory calls for inductive coding, which was appropriate for this study given its exploratory nature. Deductive coding would have been more appropriate had propositions been applied, and would have involved creating a codebook before analysis began and applying the pre-determined codes to the transcript data. In contrast, the process of inductive coding involves a

'bottom-up' approach whereby patterns and themes emerge from the data as codes are applied in a series of steps (Andrade, 2009; Charmaz, 2006a).

Inductive coding is implemented in two phases: initial coding and focused coding (Charmaz, 2006a). Initial coding involves coding sections of interview transcripts line-by-line or incident-by-incident. This phase of coding should stay close to the data and often uses the words from the respondents themselves, which is referred to as *in vivo* codes. Charmaz acknowledges that this method of coding is a departure from earlier grounded theory approaches, which advocated that the investigator should not have any pre-conceived notions in mind when coding begins (B. Glaser, 1978, 1992). Charmaz agrees that the researcher should remain open through the coding process, but accepts that prior ideas may affect coding (Charmaz, 2006a, p.48). One advantage of initial coding is that it puts a buffer between the investigator's own perspectives and the data. Through the coding process, the investigator is forced to gain distance from the data and study it in such a way that new interpretations of participants' responses emerge (Charmaz, 2006a, p.55).

Following this initial phase, focused codes are developed based on codes which appear frequently in the line-by-line codes. At this stage, codes should be applied to large segments of data and the investigator can begin to compare interpretations across interviews. The last step involves developing category codes based on topics that were particularly salient through the interview process and which relate categories to subcategories (Charmaz, 2006b). The application of codes to data obtained from interviews in this research is described in detail in Section 8 of this chapter.

In summary, Yin's positivist approach to case study design and Charmaz's constructivist approach to grounded theory may seem to have irreconcilable epistemological differences but the two approaches actually can be complementary provided that selective components of each are combined. For this study, Yin's guidance on case study design proved to be critical to defining the

unit of analysis, the time boundaries for each case, and for the screening and ultimately, the selection of viable cases. Charmaz's guidance on data collection and analysis was particularly relevant for this study, given its exploratory nature and the goal of developing new theories about how science advisory boards play a role in health policy.

V. Ethical Review

Approval for this study was obtained from the Johns Hopkins Bloomberg School of Public Health IRB in June 2012. The IRB determined that the study was minimal risk (Appendix B). In spite of this determination, a number of steps were taken to ensure the privacy and confidentiality of the study participants.

An electronic copy of the informed consent document was attached to the initial interview request email sent by the investigator to potential respondents, before they agreed to participate. The informed consent document described in detail the purpose and procedures of the study, the potential risks and benefits, how data would be kept confidential and privacy protected, and the voluntary nature of participation in the study (Appendix C). The contact information for this study's Principal Investigator and the IRB were provided in case the participants had any questions or concerns.

All interviews began with a brief discussion of the study aims and objectives and a review of the informed consent form. Prior to beginning each interview, participants were permitted to ask any questions about the consent form and/or the study itself. In addition, the investigator ensured that participants understood that providing consent for the interview included providing permission for it to be audio recorded. Participants interviewed by Skype printed, signed, and returned the signed consent form via email or fax before the interview. A fully executed copy was then emailed to each participant if the interview was conducted by Skype or left with each participant if the interview

was conducted in person.

An amendment (Appendix D) to the informed consent document was approved by the IRB in July 2014 to include language requested by a government agency, which cleared two of its employees to participate in this research. The language noted that the respondents were participating in this research with authorization and in their official capacity as an employee of the US government.

Identifiers, namely the name, titles, organizational affiliation, and email address(es) of interview participants were stored in password-protected Excel spreadsheets (one spreadsheet for each case study) on the investigator's password-protected laptop. Identifiers were needed to keep track of recruitment efforts and to arrange second interviews as needed. These spreadsheets were stored separately from interview transcripts, which used pseudonyms for participant names. As indicated in the informed consent document, names, organizational affiliations, and titles are not reported in the study findings.

All study materials were stored on the investigator's password-protected computer. Copies of files with participant personal identifiers (i.e., signed consent forms from participants interviewed by Skype, audio recordings, recruitment tracking spreadsheets, lists of potential interviewees provided through snowball sampling, and interview transcripts) were maintained for back-up purposes using a secure online service (SpiderOak.com). Other non-sensitive files were backed up SpiderOak.com and Dropbox.com. The recruitment tracking spreadsheets and other documents listed above, as well as any back-up copies will be destroyed one year after any manuscripts resulting from this dissertation have been published. Audio recordings will be deleted once manuscripts have been approved.

VI. Case Selection

As recommended by Yin, this study implemented a two-stage case study screening process because the number of potential eligible cases was larger than 20-30 FACA, 1972; Yin, 2009, p.92). It was important to develop a case selection process that narrowed the pool of potential cases in an objective and transparent manner. From a feasibility perspective, carefully selecting cases prior to data collection was critical to ensure that each case was viable and adequately represented an instance of what this investigator intended to study.

The first stage of the screening process consisted of collecting "quantitative data about the entire pool [of cases] from some archival source" (Yin, 2009, p.92), namely, the FACA database maintained by the General Services Administration (GSA). The goal of this first stage of screening was to "reduce the number of candidates to 20 or 30 and then to conduct the second screening stage" (Yin, 2009, p.92). During the second stage of screening, the candidate cases were evaluated according to a "defined set of operational criteria whereby candidates will be deemed qualified to serve as cases" (Yin, 2009, p.91).

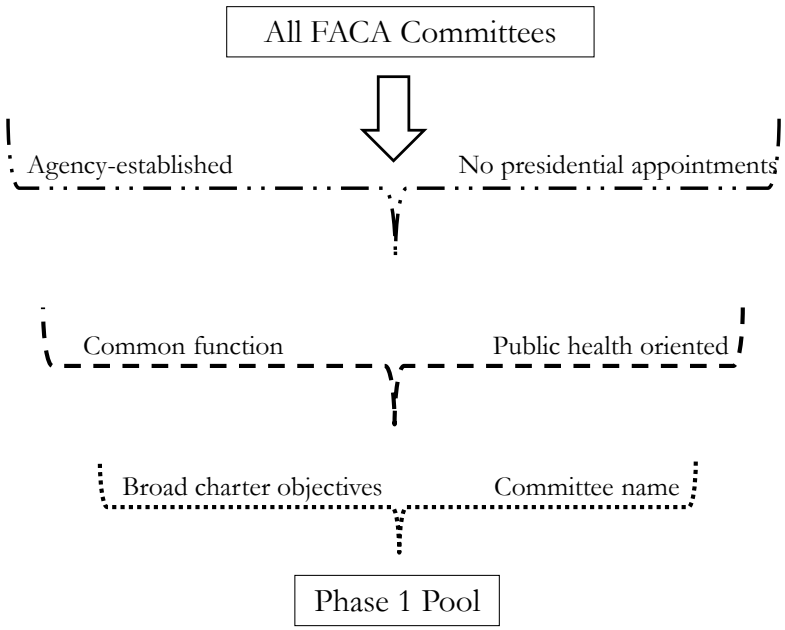
A. Stage 1 Screening Process

According to Yin, the process of selecting cases should follow a replication logic, whereby "each case…[is] carefully selected so that it either (a) predicts similar results (a *literal replication*) or (b) predicts contrasting results but for anticipatable reasons (a *theoretical replication*)" (Yin, 2009, p.54). This logic is similar to what is used in multiple experiments: upon discovering a significant finding from one experiment, the study would be repeated in an effort to replicate the finding. These replications might duplicate exactly the conditions of the first study or they might vary certain conditions to ascertain whether the finding could still be replicated. The first stage of the screening process emphasized literal replication and the second stage of the screening process emphasized

theoretical replication.

The objective of the first stage of the case study screening process was to narrow the pool of FACs according to criteria that would ensure literal replication across characteristics that were believed to influence the policy context of the FAC and how FACs are structured, staffed, and implemented (Figure 4.2). The constructivist approach to grounded theory would likely not employ replication logic in case study selection but rather would use cases more holistically (Andrade, 2009, p. 51). However, given the large number of potential cases (i.e., FACA committees), replication logic was critical to ensure the feasibility of this research.

Figure 4.2. Stage 1 Case Screening Criteria



These criteria are based on the characteristics of the PEPFAR SAB, which provided the initial motivation for this research. While it was important to have some diversity across the cases to adequately address the research questions, it was critical that all the cases had some factors in

common so that the research could better isolate the contextual factors which might have affected the uptake of FAC recommendations. Variation in the cases was introduced in the second stage of the screening process (described below).

The Stage 1 case screening criteria were applied to the pool of all FACA committees, as contained in the GSA FACA database. This database contains information on FACA committees established since 2002 so it is not possible to determine how many committees have been established since FACA was passed in 1972. The database would not permit a single download of all FACA committees at one time. Thus, to obtain the complete universe of all FACA committees, four separate downloads were conducted[5], one for each of the four establishment authorities for FACA committees (agency authority, statutory authority/Congress created, authorized by law, and Presidential). The four separate files created from these downloads were merged using STATA 11. Subsequent steps taken to further narrow the database as described below were also conducted using STATA 11.

The initial merging of the four files of FACs, grouped by establishment authority, yielded 11,049 FACs. However, this total does not accurately represent the number of unique FACA committees because FACs existing over multiple years were included as individual, separate committees, creating a substantial number of duplicate listings. For the purpose of this research, one record per FAC was kept, yielding 1,611 unique FACA committees (Table 4.1).

[5] This download and all data management were conducted on February 26, 2012. As such, the pool of all FACA committees considered eligible for inclusion in this study was developed from the FACA database as it existed on February 26, 2012.

Table 4.1. Application of Phase 1 Case Study Screening Criteria

Phase 1 Screening Criteria	# of SABs
Unique FACA Committees in FACA database	1,611
of which **Agency-established with no Presidential appointments**	883
Common Function	654
National Policy Issue Advisory Board	*72*
Scientific Technical Program Advisory Board	*133*
Other	*449*
of which **Public-health Oriented (23 topics from 5 categories)**	67
of which **Potentially viable case studies**	14

All FACs not established by agency authority or established by agency authority with Presidential appointments were excluded, yielding 883 FACA committees. The next step was to limit the potential pool of cases based on the function of the FAC. As described in Chapter 2, this study focused on FACs which addressed policy issues that were scientific in nature. Some FACs which addressed these issues, such as the PEPFAR SAB, were designated as having an 'Other' function. Within the group of committees established by agency-authority, FACs identified as National Policy Issue Advisory Board, Scientific Technical Program Advisory Board, and Other were included, yielding 654 committees.

While all of these 654 FACs addressed policy issues and/or scientific matters, not all of them addressed issues related to public health. Each FACA committee is 'tagged' in the GSA database with a topic. However, topic tags are not unique – committees can be listed under multiple topics. There were a total of 41 categories, which are sub-grouped into 169 topics, 20 of which relate to public health, broadly defined (see Appendix E for a list of all categories and topics). There were 67 committees tagged in the GSA database with topics that relate broadly to public health.

A review of the names of the 67 FACs which were tagged with public health-related terms showed that not all of them actually addressed public health matters. For example, FACs tagged with the topic 'environment' were included in the Phase 1 case study selection. However, one of the

FACs with this tag was the Advisory Committee for Geosciences, which was not directly relevant to public health. Of the 67 FACs tagged with topics broadly related to public health, 14 were determined to be eligible for additional review in screening Stage 2 (Appendix F).

B. Stage 2 Screening Process

Preliminary research was conducted on each of the 14 FACs identified through the Stage 1 screening process. More specifically, committee charters and websites were reviewed to obtain information about the scope and objectives of each FAC. Several exclusion criteria were identified through this additional review process to ensure the feasibility of the study but also to ensure literal replication (e.g., topics addressed are only tangentially related to public health or are very narrow in scope). (See Appendix G for list of excluded committees with rationale for exclusion.) From the initial results of Stage 1 screening, four advisory committees were selected for inclusion (Table 4.2).

Table 4.2. Final List of Eligible FACs

	Committee	Acronym	Agency
1.	National Climate Assessment and Development Advisory Committee	NCADAC	Department of Commerce (National Oceanic and Atmospheric Association)
2.	President's Emergency Plan for AIDS Relief	PEPFAR	Department of State (Office of the Global AIDS Coordinator)
3.	National Emergency Medical Services Advisory Committee	NEMSAC	Department of Transportation (National Highway Traffic Safety Administration)
4.	National Advisory Committee on Microbiological Criteria for Foods	NACMCF	Department of Agriculture (Food Safety and Inspection Service)

Data collection was initiated in March, 2013. Instead of initiating data collection with all four cases at once, the decision was made in consultation with the investigator's thesis advisory committee to initiate the research with two cases due to the anticipated volume of data to be collected and the importance of maintaining clarity about the patterns and themes emerging in each case over time. In addition, it was acknowledged that should the research from two cases be

sufficient to address the research questions, it would be unethical to continue data collection with two additional case studies. While the IRB deemed this study "minimal risk" there is still some risk posed to participants if confidentiality were breached; exposing additional respondents to this risk after saturation was reached is not necessary or ethical.

The PEPFAR SAB was the impetus for this research study and the model from which the inclusion criteria were constructed, and it was of special interest to the investigator because of her professional background. The PEPFAR SAB case study focuses on the SAB as it stood under Ambassador Eric Goosby. The NCADAC was the second case selected for inclusion out of the final list of eligible committees because like global HIV/AIDS, climate change is a high-profile policy issue within the US and internationally, and has substantial implications for global health.

VII. Interview Data

In-depth, semi-structured interviews served as the primary source of data for this research. This type of interview was considered most appropriate given the likelihood that the investigator would only have once chance to interview each respondent because all of the respondents were either "high-level bureaucrats [or] elite members of a community—people who are accustomed to efficient use of their time" (Bernard, 2006, p.212). To enhance the reliability and comparability of the interview data, an interview guide was developed prior to the start of data collection.

The guide addresses three major topics: how FACs function and their role in health policy; the impact of FACs; and how different groups can facilitate the uptake of recommendations put forth by FACs. Since the interviews were semi-structured, there was flexibility to explore topics brought up by the interview respondents through probing. The full range of probing techniques suggested by Bernard (Bernard, 2006) were used and proved successful to clarify information provided by the respondents in response to questions on the interview guide and elicit new topics

not explicitly addressed in the guide.

As data collection proceeded, the interview guide was edited to more accurately reflect the key themes emerging from the data. While the three major topics included in the guide remained constant throughout the study, some of the initial background questions were excluded because it quickly became clear that they were too basic and it would be inefficient to use interview time addressing them. In addition, biographical sketches for the respondents were available online and read prior to the interview as a part of the preparatory research which essentially answered the original background questions. Other questions were left out when the respondent's expertise was squarely within one of the topics of the guide, and still others were refined to be more specific and clear. Further, questions were added to address new themes raised by respondents in initial interviews. For example, questions were added to address participant perceptions of how the membership of the FAC is balanced in terms of expertise and other criteria, how the size of each FAC affects the proceedings and efficiency of its operations, and how the government agency that established the FAC plays a role in managing the FAC. This gradual and iterative revision to the interview guide aligns with the principles of theoretical sampling in grounded theory (Draucker, Martsolf, Ross, & Rusk, 2007). The final version of the guide is included as Appendix H.

A. Interview Sampling Frame

The first potential interview participants approached for each case were the FAC Chair(s) and the government officials managing each FAC. The key government officials for each FAC consisted of the DFO and others who were responsible for the oversight and management of the FAC or managed research and science within the government agency which established the FAC. In the PEPFAR case study, the SAB Chair was a consultant to OGAC and thus considered a government official. FACA mandates that any government agency sponsoring a FAC must assign a

DFO for each advisory committee. The DFO is responsible for ensuring that the FAC complies with FACA, including maintaining records on FAC proceedings, managing FAC meetings, and ensuring the FAC operates efficiently (Secretariat). Thus, for each case study, the initial sample consisted of a core group of three individuals.

These individuals were purposively sampled for several reasons. First, it was thought that they could provide rich information to address the study's research questions given their familiarity with the history, implementation, proceedings, and recommendations of the FAC as well as the actors involved. Second, it was thought that these individuals would be the most appropriate individuals to recommend additional interview participants via snowball sampling. Finally, these individuals were approached first to maximize the feasibility of the study by showing respect for the leadership role of the Chair and ensuring that each government agency was aware of the research from its initial stages.

Snowball sampling was used to identify additional potential interview participants from all categories of informants. The importance of maximum variation sampling was emphasized to each person interviewed to mitigate the potential for bias in their recommendations.

B. Interview Data Collection Procedures

FAC member lists are publicly available through the FACA database and through Google, as all committees have their own web pages hosted on their respective government agency websites. These lists also identify the Chair of each FAC. Member lists contained in the FACA database were cross-referenced with agency member lists because agency websites often had been updated more recently than the FACA database. If there were discrepancies between the FACA database member lists and the lists obtained through Google searches, the more recent list was used.

A database was created for each case study which listed the names, titles, organizational

affiliation, and email address for each individual in the three categories of interview subjects in Microsoft Excel. Initially, the databases only included information on the FAC members, which was downloaded from the FACA database, and the government officials who were part of the initial core sample. As they were populated through the snowball sampling process, the databases served as a tracking tool to manage participant recruitment. As discussed in Section V of this chapter, to protect the confidentiality of interview participants, these files were maintained separately from any interview transcripts which used pseudonyms in place of respondents' actual names, and the Excel databases did not include these pseudonyms.

Potential interview participants were contacted via email. Email addresses for the individuals included in the initial core sample for each case study were obtained through Google searches. Email addresses for subsequent participants were also obtained via Google searches or from the interviewee who recommended the new participant. If potential interview respondents did not reply to the initial email within two weeks, a follow-up email was sent. An amendment to the research protocol was approved by the IRB in July 2014, to permit the investigator to send one additional (i.e., a third) email to non-respondents and follow up with a phone call. Thus, a total of four contacts from the investigator were permitted. If no reply was received after the fourth contact, that respondent was excluded from the pool of potential interview subjects.

Between March 2013 and August 2014, a total of 50 individuals were contacted for interviews. Of these, 11 failed to respond. Only six individuals declined to participate. Three individuals declined because of workload constraints and three individuals declined because they felt they were not the most appropriate people to interview. In the NCADAC case, there were two individuals who initially agreed to participate in the research and even proposed days and times for the interview to occur, but were ultimately unresponsive to follow-up emails from the investigator

attempting to finalize the interview.

A total of 33 individuals were interviewed, with 17 individuals interviewed for the PEPFAR case and 16 individuals interviewed for the NCADAC case. Table 4.3 summarizes the responses for each case study by category of respondent. Of these 33 total interviews, five completed interviews were from the core group of six initially identified through purposive sampling. One of the individuals from this core group never responded to an interview request. The remaining 27 interviews were suggested via snowball sampling. In the PEPFAR case study, seven SAB members, six government officials, and four staff members from NGOs were interviewed. The total number of interviews conducted for the PEPFAR case study was 17 and the overall response rate was 68 percent. There is a similar distribution for the NCADAC case, with interviews conducted with eight NCADAC members, four government officials, and four NGO staff. The total number of interviews conducted was 16 and the overall response rate for the NCADAC case study was 64 percent.

Table 4.3. Summary of Interview Response by Case Study

	PEPFAR				
Respondent Category	Completed	Declined	No Response	Total Approached	Acceptance Rate
SAB Member	7	1	2	10	70%
Government Official	6	1	3	10	60%
NGO/Advocacy/Civil Society	4	1	0	5	80%
TOTAL INTERVIEWS	**17**	**3**	**5**	**25**	**68%**

	NCADAC				
Respondent Category	Completed	Declined	No Response	Total Approached	Acceptance Rate
SAB Member	8	1	3	12	67%
Government Official	4	1	2	7	57%
NGO/Advocacy/Civil Society	4	1	1	6	67%
TOTAL INTERVIEWS	**16**	**3**	**6**	**25**	**64%**

Table 4.4 provides summary data on the method of interview by case study. In-person interviews were conducted with 19 participants total, nine from the PEPFAR case and 10 from the NCADAC case. This represents 58 percent of the total sample. When in-person interviews were not possible because respondents lived in another state or country, the interview was conducted via Skype (without video). Skype was used to conduct 14 interviews, which represents 42 percent of the total sample. Eight interviews from the PEPFAR case and six from the NCADAC case were conducted via Skype. Using Skype increased the interview completion rate because the software allowed the investigator to conduct interviews that would not have otherwise been feasible.

Table 4.4. Summary of Method of Interview by Case Study

	PEPFAR		NCADAC	
Respondent Category	In-Person	Skype	In-Person	Skype
SAB Member	1	6	3	5
Government Official	5	1	3	1
NGO/Advocacy/Civil Society	3	1	4	0
TOTAL	9	8	10	6
TOTAL INTERVIEWS	**17**		**16**	

Although Skype audio-only interviews do not allow the investigator to observe participants' body language and other visual cues, a review of literature on telephone interviews in qualitative research indicates that "there is little evidence that data loss or distortion occurs, or that interpretation or quality of findings is compromised when interview data are collected by telephone. In fact, telephones may allow respondents to disclose sensitive information more freely, and telephone conversation has been reported to contain several features that render it particularly suitable for research interviews" (Novick, 2008, p.397).

Many participants work in the Washington, DC metropolitan area and efforts were made to

conduct interviews while non-Washington, DC-based respondents were in the area for a business trip. In-person interviews were recorded using an Olympus VN810005 digital voice recorder with the investigator's iPhone 4S or iPhone 5 (after December 2013) used for a back-up recording with the QuickVoice application. Skype interviews were recorded using free Skype recording software called MP3 Skype CallRecorder, Version 3.1.

Interviews lasted between 30 and 98 minutes. The average interview length was 61 minutes. All of the interviews were transcribed by the investigator. Given the lengthy data collection period, the transcription process helped to ensure that the investigator was constantly familiar with the data, self-critiquing her interview technique throughout, and fostered an iterative process whereby the investigator modified the interview guide to reflect the data obtained from the interviews, as previously described. Transcripts were imported into Atlas.ti qualitative data analysis software (7.0.82) for coding and analysis, as described below.

VIII. Data Analysis

As described in Section III and IV, the grounded theory method provides specific guidelines for how and when data analysis should occur, namely that data collection and analysis occur concurrently. This study implemented a modified approach, whereby analysis was initiated as data collection was concluding. This approach was employed for several reasons. Interviews were often scheduled close together, with some occasions of two interviews occurring on the same day, so it was not possible to complete transcription and code the transcribed data before the next interview. However, as noted above, the investigator transcribed all of the interviews herself instead of sending the audio files to a transcribing service. This provided an opportunity for the investigator to be constantly aware of new topics emerging from the data collection process and to modify the line of questioning in subsequent interviews based on these emerging themes. In addition, the investigator

made every effort to transcribe the interviews soon after the interview occurred and prior to the next interview. If this was not possible, the investigator reviewed her notes prior to the next interview. At each interview, the investigator took notes by hand on a legal pad of paper. The purpose of this was primarily to note key issues raised by the respondent about which the investigator wanted to probe or follow-up.

Interview transcripts were coded using the qualitative data analysis software Atlas.ti and followed the grounded theory process outlined by Charmaz and described in Section IV of this chapter (Charmaz, 2006a). Interviews conducted early in the study period were coded with initial codes line-by-line and used in-vivo codes to the extent it was appropriate so that the interview respondents' own language was maintained through the analysis process. As new codes were developed or old codes were refined, transcripts were re-visited to adjust the coding. Comparisons were made between individual interview transcripts within each category of interview respondent within each case study as well as across respondent categories within each case, and also across the two case studies.

The coding process evolved into focused coding because of the number of initial codes generated (nearly 200). Focused codes are more conceptual than initial codes, require the researcher to make decisions about which initial codes should be used to categorize data, and should be applied to large amounts of data (Charmaz, 2006a). The initial codes that were most frequently applied or significant were used while examining the data to subsequently condense it. Categories, which are intended to integrate patterns from several codes, were developed from the focused codes that had the most explanatory significance across the interviews.

Given that the interview guide was developed to address the aims and research questions outlined in Section I of this chapter, there were themes that emerged from the focused codes.

Categories were based on these themes. There were three categories that emerged: FAC operations, factors affecting use of FAC recommendations, and stakeholder engagement. The following tables show the progression of coding from initial codes to focused codes to categories that were used for each case. Each case study includes particularly salient quotes linked to the focused codes.

Initial codes were linked with categories using the Code Family Manager in Atlas.ti. This option essentially provides a way to create "families" (i.e., categories) and then select codes relevant to each category from all of the codes used for each case study. Once the relevant initial codes were grouped by family, the investigator sub-divided them by focused code. As part of this process, the quotes linked to each focused code were reviewed to further refine the initial and focused codes to ensure that the categories accurately reflected the original data provided through the interviews. This process was followed for the coding of transcripts for both the PEPFAR and NCADAC case studies.

Table 4.5. Coding Progression for PEPFAR Case Study

Initial Codes	Focused Codes	Categories
Reaching out to main State to find out how to implement a FACA committee; working with RM and L Bureaus; provide guidance on legal processes; charter renewal and membership goes through M and H bureaus; FACA training only for direct hires; helpful if FACA training was open to contract staff	*Navigating FACA legislation*	**SAB Operations**
Seeking recommendations from other agencies; wanting breadth of expertise and leaders in the field; personal preference for certain individuals; Ambassador's preference for individuals; variety of institutions and perspectives represented; membership should be broad-based; wanting to consult with external, non-USG expertise; adding members with specific expertise; wanting leaders in specific areas of expertise; recommendations based on what PEPFAR needs; no patient or community advocate on the board; more rabble-rousers needed; long-standing relationship with Ambassador; Ambassador hand-picked SAB members; aggressive, assertive people selected	*Selecting SAB members*	
Weak representation from scientists and implementers outside the US; patient community from PEPFAR-funded countries is completely unrepresented; can't not have experts who PEPFAR also funds;	*Bias and balance among SAB members*	

Initial Codes	Focused Codes	Categories
recognize that situation is deeply conflicted		
Establish a new working group if there is a topic of interest that arises; based on needs of SAB; based on needs of Ambassador; working group participants volunteer or are nominated by Ambassador; huge amount of work for PEPFAR when a working group is established; PEPFAR staff integrate comments from SAB members into WG reports; not effective to have 40 people working at once; have to break board into working groups	*Establishing and functioning of SAB Working Groups*	
Assuming Chair and DFO could not be same person; bringing in external advisor to Chair; there is no Chair for SAB, working groups have leaders; meetings facilitated by different people; letting discussion run; a little more direction on some occasions; late in getting agendas together; late in coming onto conference calls; did not hold disciplined discussions; Chair should be someone experienced in advisory boards; did not have discipline to shut off SAB members; Chair should be someone from outside agency; SAB needed a manager	*Effectiveness of SAB Chair*	
Difficulty thinking of what scientific questions PEPFAR should answer; challenging to think of what SAB should address; the SAB defined priorities; reflecting that PEPFAR should have narrowed issues for SAB consideration; shared with SAB members beforehand; internal PEPFAR staff preparing specific questions for SAB; SAB needed someone to outline what a useful agenda would be	*Setting PEPFAR SAB meeting agendas*	
Too little time to let them talk; doesn't make good use of members; debate is robust; members are comfortable expressing opinions; members raise tough issues in the meetings; too burdensome to have meetings twice a year; conference calls are operator-assisted; moving through agendas on time; hard to schedule conference calls because SAB members are involved in too many things at once; beneficial to meet more than once a year; huge struggle first year;	*Managing PEPFAR SAB meetings*	
Having consensus in what is put forward to the Ambassador; evidence supports PEPFAR taking action; looking to SAB for advice about priorities; looking to SAB for advice about how scientific findings should influence PEPFAR program; discussing issues in open forum and noting dissent; ensuring recommendations are feasible; having dialogue between SAB and OGAC; including implementation as a consideration in recommendations; increasing specificity of questions for SAB; relevancy of recommendations; synergy between SAB and OGAC priorities; timeliness of SAB given 052 results; SAB discussions are transparent and well-documented; receiving guidance from establishing agency to refine SAB scope; SAB members knew PEPFAR program well; SAB members understanding what was needed on the ground; providing recommendations that are best practices in terms of policy	*Facilitating the use of evidence*	**Factors Affecting Use of SAB Recommendations**
Wanting to drill down into issues; not staying at right level; need to provide advice to the Ambassador; absence of novel information or	*Impeding the use of evidence*	

Initial Codes	Focused Codes	Categories
neutral SAB; failing to ask hard questions is rubber stamping business as usual; lack of funding limits take-up of SAB recommendations; lack of understanding of how PEPFAR works; SAB recommendations not politically feasible; advice has to be actionable; recommendations are inappropriate in terms of regulatory constraints; not bringing anything new to the table; lack of familiarity with PEPFAR program; ensuring recommendations are within PEPFAR's mandate; irrelevant or low-priority advice; recommendations are not financially feasible; lack of direction or management from host agency		
Obama as a leader in using evidence to inform policy; favorable political context; previous policy context not conducive to using science for policy; SAB provides validation for PEPFAR; ensuring the SAB is independent and not providing too much guidance; timeliness of HPTN 052 results; support of agency leadership; Ambassador has history as convener; Republican Congress under Bush did not follow science	*Contextual factors*	
Surprised about lack of engagement; public comment period is short; want input from NGOs but don't want to be dominated by their voice; influencing SAB by calling members; influencing SAB by working with OGAC staff off-the-record; announcements about meetings aren't widely circulated	*Formal and informal engagement*	**Stakeholder Engagement**
Meetings require two days away from the office; not a big yield by engaging with SAB;	*Time constraints*	
Engagement with NGOs is ongoing; SAB not a huge nexus for NGOs; topics of interest to NGOs not necessarily same as topics of interest to SAB; questioning relevancy of advocacy community in influencing the scientific evidence base; SAB issues aren't hot topics for the American public; contentious issues aren't necessarily scientific issues; people don't think it's politically important; end-users of PEPFAR are in other countries and cannot attend SAB meetings; lack of recognition of what the SAB is; releasing draft materials in advance of the meeting would be helpful;	*Relevance for concerned stakeholders*	

Given that the same aims and research questions were applied to each case study, the coding process used the same focused codes and categories for all interviews. Consistent with the grounded theory method, the initial codes varied for each case study.

Table 4.6. Coding Progression for NCADAC Case Study

Initial Codes	Focused Codes	Categories
Hurry up and meet the law; lack of clarity on how to implement a FACA committee; a lot of time talking to GAO; FACA is severely flawed; different agencies interpret FACA differently; spirit of the law is transparency and access to documents in a timely manner; some agencies are very lax in interpretation and others are very strict; NOAA is so strict it is almost hard to function	*Navigating FACA Legislation*	**FAC Operations**
Experts from a variety of climate science issues and other areas; Federal government did not have expertise to do NCA properly; lengthy process of selecting members; negotiations over nominations for six months; co-production model of drafting the NCA; deliberate attempt to have balance of perspectives; Commerce, NOAA, and OSTP involved in reviewing applications; seeking expertise in climate science as well as demographic diversity, geographic representation; collaborative, collegial people end up on FACs; screen out people who would take NCA in a different direction; choice of members gets buy in from certain groups; White House and NOAA came up with additional names; second tranche of NCADAC members had less climate expertise than first set of nominees; engaging a network of people by	*Selecting NCADAC Members*	
Ex officio members tend to be turf conscious; membership is too incestuous; initial list of members seen as not balanced;	*Bias and Balance among NCADAC Members*	
No one's full time job; helpful to have discussions off the record;	*Establishing and functioning of NCADAC Working Groups*	
Want someone who can handle delicate balance with committee and NOAA Administrator;	*Effectiveness of NCADAC Chair*	
	Setting NCADAC meeting agendas	
Conversation was stiff; hierarchical organization; decision-making at top; consensus is not an easy process; need for consensus delayed report by a few months; hard to oppose something by the time it comes to a vote; sustained assessment report was contentious; quality of internal communication	*Managing NCADAC meetings*	
Perception that NCADAC is independent and less biased than government opinion; transparent process to understand decision making; having federal agencies at the table; public acceptance comes with having right people on committee; blind review of public comments; consensus-based process; people on the ground are part of the NCA; important to know how agency functions; filter	*Facilitating the use of evidence*	**Factors Affecting Use of FAC Recommendations**

Initial Codes	Focused Codes	Categories
controversies in data and publications to form recommendations; transparent process; bring the best science; serving as an ambassador back to communities; alignment with objectives of Administration; providing sufficient guidance to FAC; adequately representing different segments of users of information;		
NCA is not decision support; lack of political use for NCA; agency may disagree with advice; may not have legal authority to implement advice; lack of financial resources to implement recommendations; FAC members do not understand regulatory context of agency; receiving end doesn't know what to do with advice; policy prescriptive instead of policy relevant; recommendations are not logistically feasible;	*Impeding the use of evidence*	
Very complicated thing that involves lots of different people; all kinds of administrative and technical support provided; possible to get across transitions in Administrations if well managed; same core group involved in all NCAs; lawsuit claiming original assessment violated Federal Data Quality Act; process for peer review in IPCC reports; right people being in leadership; alignment with objectives of Administration; recommendations are too difficult to implement institutionally; releasing draft NCA after the election; Congress could not care less about climate change;	*Contextual factors*	
Decision makers and scientists have to be able to put themselves in each other's shoes; it's in the interaction between scientists and managers that people will have their thinking changed; ongoing process needed to bring management experts together with science experts; communications has to be part of the process; build a network of partners; co-production model; public comment period not useful; no one reads Federal Register notices; public comment period is too short; NCAnet helps gain buy in to NCA; NCAnet partners not used effectively; direct contact between NGOs and key NCADAC members and White House officials through personal connections	*Formal and informal engagement*	**Stakeholder Engagement**
Difficult to get people engaged; no time to actively sell NCA; people assume their interests are represented already; no time to attend two-day meetings; no opportunity to interact in real-time with NCADAC; NCAnet partners not provided with enough information to be useful	*Time constraints*	
Interactions between scientists and people makes dissemination broader; interest from USGCRP in	*Relevance for concerned stakeholders*	

Initial Codes	Focused Codes	Categories
engagement is just lip service; inclusivity not what it could have been; attempt to pull in on-the-ground knowledge; most communities aren't personally invested; stakeholders did not understand NCA process; climate change affects many aspects of our lives;		

IX. Strengths and Limitations

The primary strength of this study is that it represents the first empirical assessment of FACs for health at the federal level in the United States. Other studies have considered FACs broadly as well as the role their members play in the public policy process but none have looked specifically and only at FACs for health. Given that U.S. government agencies which include health in their purview consistently and systematically establish federal advisory committees to provide recommendations regarding how research and evidence can be integrated into policy, gaining a better understanding of how FACs operate makes a valuable contribution to the understanding of how research and evidence are integrated into the health policy process.

In addition, including PEPFAR and the NCADAC as case studies allows for a novel and 'real-time' examination of two high-profile advisory boards addressing issues that are front and center in the public policy arena. PEPFAR is the largest program to combat a single disease by any nation. In the context of repeated funding cuts from Congress and calls by policy elites for an "AIDS Free Generation", PEPFAR is faced with tough decisions about how best to finance anti-retroviral treatment in low- and middle-income countries given new science showing that treatment can substantially reduce the risk of sexual transmission of HIV in sero-discordant heterosexual couples. Climate change is now a major policy priority for the Obama Administration, which announced a Climate Action Plan in 2013 to strengthen adaptation and mitigation efforts of the United States.

FACs as a mechanism for the provision and potential integration of research into policy decisions are not well-understood but, in the context of ever-increasing healthcare costs in the United States, ensuring that health policy is based on sound evidence is increasingly important. This may be especially true for policies determining what programs receive government funding and the volume of funding allocated. The renewed interest in evidence-based policy suggests that FACs may be used more frequently in the coming years, although the highly politicized and partisan nature of public policy in the United States may complicate efforts to inform policy with sound evidence and inhibit FACs from operating successfully. This research makes a novel contribution to the understanding of how FACs function in the policy process.

There are several limitations to this study that are important to address. The first limitation relates to the interview data. The interviewees self-selected into the study: not all invited participants responded and some declined. The perspectives of those who did agree to be interviewed may not be representative of others in their interview "group" (i.e., committee members, NGO/advocacy staff, and government officials). A few of the participants who did not respond to multiple requests for an interview or declined were recommended by a large number of other participants, which suggests that there may have been a missed opportunity to obtain additional and rich data. However, saturation was reached and the findings from each case study (see Chapter 5 and 6) are responsive to the study's research questions.

There are also potential limitations related to theoretical or analytical generalizability. Aim 3 seeks to outline a set of strategies or recommendations that stakeholders can use to facilitate the uptake of FAC recommendations into the policy process. Ultimately, these strategies are based on only two case studies. However, this concern is mitigated to some extent because replication logic was used in the Stage 1 screening process: "if two or more cases are shown to support the same

theory, replication may be claimed" (Yin, 2009, p.38). Generalizing to the level of theory "becomes the vehicle for generalizing to new cases" (Yin, 2009, p.54).

Finally, the departure from the grounded theory method in the timing of data analysis relative to data collection is a limitation because it may have compromised theoretical sampling. The investigator raised ideas with respondents during data collection based on her memory of topics raised in previous interviews and her interview notes, which she reviewed in between interviews. Although all interviews were transcribed by the investigator which enabled her to remain close to the data, recall bias may have affected which topics were ultimately raised as the interview questions were modified.

CHAPTER 5: THE PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF SCIENCE ADVISORY BOARD - A CASE STUDY

I. Introduction

This case study provides empirical evidence about how the PEPFAR SAB contributed to decisions about what issues should be considered priorities for HIV prevention, care, and treatment policy as well as formulating and changing OGAC policies in these areas between 2010 and 2013 under the leadership of Ambassador Eric Goosby. The evolution of the PEPFAR program is described, beginning with the initial announcement made by President George W. Bush in June 2002 about a large HIV program, to the most recent legislation authorizing the PEPFAR program. This background information, discussed in Section II, focuses on the stipulations for how PEPFAR funds were to be allocated, especially for the prevention of HIV, to highlight how the role of science and research in PEPFAR has changed substantially since the program's inception. Some of the challenges associated with PEPFAR's prevention funding stipulations are discussed in Section III. Core components of the SAB are discussed in Section IV, including the SAB charter and stipulations contained therein for the membership of the SAB. Sections V and VI address the findings from the document review and in-depth interviews, respectively. Conclusions are offered in Section VII.

II. Background

The origins of the President's Emergency Plan for AIDS Relief (PEPFAR) date back to a speech made by President George W. Bush in the Rose Garden on June 19, 2002 (The White House, 2002) during which he announced a $500 million initiative to address the transmission of HIV from mothers to their children during childbirth or breastfeeding. The specific goal was to treat

one million women on an annual basis with nevirapine, an anti-retroviral drug which had proven to be cost-effective for the prevention of mother-to-child transmission (PMTCT) of HIV, and reduce by 40 percent the number of children infected with HIV over a five year period in 12 African and Caribbean countries (Guay et al., 1999; Lallemant et al., 2004). However, the President had larger goals in mind, stating at the end of the speech that "as we see what works, we will make more funding available" (The White House, 2002). Following the Rose Garden announcement, the President's then Chief of Staff Josh Bolten told Dr. Anthony Fauci, the Director of the National Institute of Allergy and Infectious Diseases (NIAID) that the President wanted his advisors to "think big" (Dietrich, 2007, p. 2).

During the following six months, Dr. Fauci, along with one of his deputies, Dr. Mark Dybul, developed a five-year plan with goals for the prevention, care, and treatment of HIV focused in countries with the highest burden of disease and where the United States government already had a strong presence in global health (Donnelly, 2012).[6] Dr. Dybul and others drafted a concept paper for the plan, which was based heavily on Uganda's experience with treating individuals with HIV because clinical trials there testing the efficacy of different approaches to providing anti-retroviral therapy (ART) had been successful (Donnelly, 2012). The concept paper emphasized treating the HIV epidemic as a global emergency and funds would be used to rapidly build systems and infrastructure to establish basic health system capacity in focus countries so that their governments could then expand efforts to prevent, care, and treat HIV/AIDS. The plan included stipulations that US government agencies, including the Centers for Disease Control and Prevention (CDC) and the United States Agency for International Development (USAID) work together to integrate their

[6] The development of this plan is described in depth by Donnelly in *Health Affairs* 2012 and thus only the highlights are reviewed here.

service delivery efforts under a global AIDS coordinator. Cost projections informed the development of scenarios for prevention, care, and treatment goals. The concept paper included treatment and care targets to be achieved by 2008: provide antiretroviral therapy to two million people and other medical care to 10 million people. The target to prevent seven million new infections was set for 2010. During his State of the Union address on January 28, 2003, President George W. Bush requested Congress appropriate $15 billion, which included $9 billion in new money for the Emergency Plan for AIDS Relief to "'meet a severe and urgent crisis abroad"'(Bush, 2003).

III. PEPFAR Authorizing Legislation: A Brief History

The legislation which initially authorized PEPFAR in 2003 and then re-authorized the program in 2008 is important to this case study because of the requirements stipulated in the legislation for how funding should be allocated, especially for the prevention of HIV. While PEPFAR program implementers, advocates, and researchers acknowledged that PEPFAR was initially designed as an emergency response to the growing HIV pandemic, the funding requirements stipulated by Congress – especially for the prevention of sexual transmission – were widely criticized for not aligning with scientific consensus (Lyerla, Murrill, Ghys, Calleja-Garcia, & DeCock, 2012; IOM, 2013; Santelli, Ott, Lyon, Rogers, & Summers, 2006; Santellia, Speizerb, & Edelsteinc, 2013). The disconnect between funding allocations and the evidence base was amplified by the fact that such large volumes of money were appropriated. This historical element of the PEPFAR program is important because the creation of the SAB marked a substantial departure from prior philosophies about how scientific evidence and research should be used by OGAC to inform PEPFAR programming.

1. THE LEADERSHIP ACT

Congress passed on May 27, 2003 the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (the Leadership Act), which authorized a total of $15 billion to fight HIV/AIDS, tuberculosis (TB), and malaria globally from FY2004-FY2008[7]. Included in this legislation was language authorizing $9 billion of the total $15 billion to address HIV/AIDS prevention, care, and treatment in 15 focus countries[8] for the program President Bush announced in his State of the Union address in January 2003, now known as PEPFAR. The legislation established OGAC at the U.S. Department of State to oversee all U.S. Government (USG) efforts to combat HIV/AIDS globally.

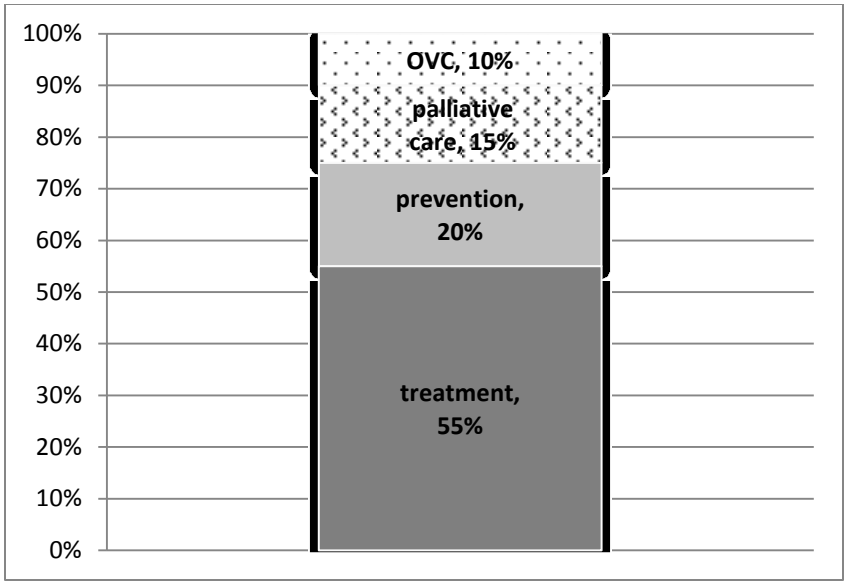
The Leadership Act provided recommendations and requirements for PEPFAR's funding priorities. It was recommended (i.e., the "sense of Congress") that for FY2004-FY2006, 55 percent of funds be allocated for the treatment of individuals with HIV/AIDS, prevention of new infections and palliative care for persons living with HIV receive 20 percent and 15 percent of total funds, respectively, and 10 percent of funds be allocated for orphans and vulnerable children (OVC)[9] (Figure 5.1). Of the prevention funds, Congress recommended that 33 percent be allocated for abstinence-until-marriage programming.

The legislation stipulated requirements for how funds were to be allocated for FY2006-FY2008: at least 55 percent of total funds should be spent on treatment of people living with HIV, of which 75 percent was to purchase antiretroviral drugs and 25 percent was for related medical care; 20 percent of total funds were to be spent on prevention, of which at least 33 percent was to

[7] Actual appropriations by Congress reached nearly $19 billion by FY2008.
[8] Initially, the following 14 countries were designated as PEPFAR focus countries: Botswana, Cote d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda and Zambia. Vietnam was added later by President George W. Bush.
[9] Orphans and vulnerable children are those who have had at least one parent die from HIV/AIDS.

be spent on abstinence-until-marriage programs; and no less than 10 percent of total funds were to be spent on OVC, with at least 50 percent of those funds directed to organizations working at the community level (e.g., non-profits, NGOs, including faith-based organizations).[10] Thus, while there was no difference between the "recommendations" and "requirements" in terms of allocations for overall funding priorities (i.e., prevention, care, and treatment), the specific stipulations of the legislation for FY2006-FY2008 had substantial implications for how PEPFAR allocated funds within categories.

Figure 0.1. Recommendations for PEPFAR Funding Priorities, FY04-FY06



The targets for prevention, care, and treatment outlined in the Leadership Act matched those that were defined in the concept paper drafted by Dr. Dybul and Dr. Fauci: prevent seven million new HIV infections; care for 10 million people infected and affected by HIV/AIDS, including orphans and vulnerable children; and treat two million people with HIV/AIDS.

[10] The sum total of these spending category allocations is only 85 percent. It is unclear from the legislation and related documents on what the remaining 15 percent of funds were to be spent. However, given that the requirements state that the funding proportions should be "no less than", it may be the case that the remaining 15 percent of total funds could be used to supplement the required allocations.

As mentioned above, the recommendations and requirements in the Leadership Act for how prevention funds were to be used has been the subject of considerable debate. The legislation defined prevention activities as those that are:

> designed or intended to impart knowledge with the exclusive purpose of helping individuals avoid behaviors that place them at risk of HIV infection, including integration of such programs into health programs and the inclusion in counseling programs of information on methods of avoiding infection of HIV, including delaying sexual debut, abstinence, fidelity and monogamy, reduction of casual sexual partnering, reducing sexual violence and coercion, including child marriage, widow inheritance, and polygamy, and where appropriate, use of condoms ("United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003," 2003).

More specifically, the legislation touts the "Abstain, Be Faithful, use Condoms" (ABC) model implemented by Uganda nationwide in 1986 as an exemplary approach to prevent the sexual transmission of HIV. The campaign emphasized three behaviors, in order of priority: abstaining from sex until marriage; being faithful to one partner ("zero-grazing"); and using condoms when necessary. The prevalence of HIV declined in Uganda between the 1980s and the early 2000s, but the extent to which the change in the course of the epidemic can be attributed to the ABC campaign or any of its individual components is unclear (Cohen, 2006).

With the Leadership Act as guidance, OGAC defined five areas for HIV prevention programming: (i) abstinence/faithfulness ("AB"); (ii) "other prevention" which included programs for high-risk groups and condom promotion and distribution, among others; (iii) prevention of mother to child transmission; (iv) safe medical injections; and, (v) blood safety. Any abstinence-until-marriage activities fell under "AB" prevention programming. Thus, prevention efforts were categorized into two broad areas: prevention of the sexual transmission of HIV, which would focus on abstinence/be faithful programs, and "other prevention"; and the prevention of non-sexual

transmission, which would occur through programming in the other three areas.

OGAC's guidance to its officials implementing PEPFAR programs in the 15 focus countries indicated that country teams should develop interventions that responded to the epidemiologic profile of the countries' HIV epidemic while taking cultural norms into account (OGAC, 2006). At least 50 percent of prevention funds at the country level were to be allocated to sexual transmission prevention activities with AB activities receiving 66 percent of that funding. Country teams were required to specifically designate AB spending in their annual reports to demonstrate adherence to the spending requirement. Some country teams were allowed to request a waiver from these policies, for example if they had small budgets, so that they could respond appropriately to the countries' prevention needs. The focus of the debate on PEPFAR's prevention expenditures focused on programming related to the prevention of sexual transmission. This debate is described in more depth below.

Apart from the spending directives for prevention, care, and treatment, the Leadership Act also required the Institute of Medicine (IOM) to conduct a study on the performance of the different components of PEPFAR by 2006.

2. THE LANTOS-HYDE ACT

In 2008, Congress passed the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 (P.L. 110-293) (the Lantos-Hyde Act). The legislation authorized appropriations up to $48 billion between FY2009 and FY 2013, of which $5 billion was designated for anti-malaria efforts globally, $4 billion was allocated for anti-tuberculosis efforts globally, and $2 billion was allocated for the Global Fund to Fight AIDS, Tuberculosis, and Malaria. Thus, up to $37 billion was available to PEPFAR. The Lantos-Hyde Act is important primarily for the directives which it continued and relaxed relative to

the Leadership Act.

The most significant departure of the Lantos-Hyde Act from the Leadership Act was the elimination of the requirement that 33 percent of prevention funds be spent on abstinence-only programs although the Act does not specify the proportion of overall PEPFAR funding that should be allocated to prevention. However, while the law stipulated that funding for programs addressing the sexual prevention of HIV should be "balanced", an emphasis on the role of abstinence and faithfulness to one partner in the prevention of sexual transmission of HIV remained in the law. The Lantos-Hyde Act required the Global AIDS Coordinator to develop a strategy for each focus country that allocated 50 percent of prevention funding "for activities promoting abstinence, delay of sexual debut, monogamy, fidelity, and partner reduction". If funding in any one country dropped below the 50 percent threshold, the Global AIDS Coordinator was required to report to Congress to justify the discrepancy.

The abstinence spending requirement was tempered by the inclusion of language allowing spending on additional prevention measures that aligned with the new emphasis on "balanced funding" for the prevention of sexual transmission of HIV. The National Institutes of Health (NIH) and CDC were granted authority to research the development and use of microbicides. In addition, voluntary male circumcision was added as a method that could be supported under PEPFAR to prevent or reduce the risk of transmission of HIV. In terms of behavioral interventions, the Lantos-Hyde Act included language allowing PEPFAR funds to be used to promote the reduction of multiple sexual partners. Finally, with respect to the purchase of commodities, the Act allowed the purchase of male and female condoms (as opposed to just male condoms in the Leadership Act).

The spending directive for treatment was also changed: 50 percent of funds would be allocated for treatment and care of persons living with HIV (as opposed to a total of roughly 70

percent under the Leadership Act). Funding for OVC programs remained the same, at 10 percent of total funds. Due largely to the absence of a directive on the proportion of overall funds to be allocated for prevention, it is not possible to compare funding priorities by overall category between the two Acts.

The targets and goals for prevention, care, and treatment under the Lantos-Hyde Act were increased and new goals were added. The goal for prevention was increased by five million, so that the new target was to prevent 12 million new HIV infections. Similarly, the goal for care was increased by two million, so that the new target was to care for 12 million individuals living with HIV, including five million OVC. The goal for treatment was more complicated. The Lantos-Hyde Act indicated that treatment target should be increased above the original two million people target from the Leadership Act by at least the percentage increase in the amount appropriated for bilateral global HIV/AIDS assistance in any fiscal year as compared to FY2008 and that the treatment goal should be increased above this calculated number in proportion to the decrease in the per patient cost to the United States Government of providing treatment in countries receiving bilateral aid, as compared with fiscal year 2008. Thus, the treatment target would theoretically vary from fiscal year to fiscal year.

New goals were added for several areas, all of which involve providing assistance to partner governments/countries[11] to achieve various targets. Assistance would be provided to help partner countries: reach a PMTCT coverage target of at least 80% of pregnant women; provide care and treatment to children with HIV/AIDS in proportion to their share of the HIV-infected population in country; train at least 140,000 new health workers; and equip teachers with skills needed to

[11] The term 'partner government' means a government with which the United States is working to provide assistance to combat HIV/AIDS, tuberculosis, or malaria on behalf of people living within the jurisdiction of such government.

address HIV.

Similar to the Leadership Act, the Lantos-Hyde Act also required studies from the IOM. In the re-authorizing legislation, the IOM would submit three studies on PEPFAR's performance, impact on health outcomes in the prevention, care, and treatment areas, and collection and use of data, respectively. In addition, the legislation required a report from the Comptroller General on the performance of the various global HIV/AIDS programs funded by USG and a report from PEPFAR on its best practices.

3. THE PEPFAR STEWARDSHIP AND OVERSIGHT ACT OF 2013

Unlike the Leadership Act and the Lantos-Hyde Act, the PEPFAR Stewardship and Oversight Act of 2013, which was signed by President Obama on December 2, 2013, is not a full re-authorization. It largely extends various provisions of the prior law that were set to expire on September 30, 2013 and strengthens PEPFAR's reporting duties to Congress.

The new reporting requirement mandates that OGAC submit an annual report to Congress with information on a variety of areas related to setting and achieving targets and metrics for measuring progress. Particularly relevant elements of the new reporting requirement include progress toward achieving prevention, care, and treatment targets by country and how that progress contributes to a reduction in incidence; HIV treatment rates and retention rates in treatment programs by country; and a description of efforts to achieve greater cost-effectiveness in PEPFAR programs at the country level.

One important divergence from prior legislation is the absence of any funding requirements. Instead of authorizing appropriations for an overall funding level, such as the $15 billion or $48 billion in the Leadership Act and the Lantos-Hyde Act, respectively, the new legislation is silent on this matter, leaving it up to Congress to determine the volume of funding PEPFAR would receive.

The specific allocation for treatment (50 percent of overall funds) and OVC (10 percent of overall funds) remain intact. However, the absence of an overall funding requirement may have been a strategic political maneuver to ensure that the bill would be passed relatively quickly; had Congress been required to vote on a bill with large requests for foreign aid, it may not have ever been passed given the political environment in Congress at the time.

IV. PEPFAR Prevention Programming: Scientific Debate, Human Rights Issues, and Operational Challenges

As mentioned above, there has been considerable debate about the funding allocation requirements stipulated in the Leadership Act and the Lantos-Hyde Act. Under the Leadership Act era of PEPFAR, this debate focused on the program's emphasis and related funding allocations for ABC programming as a means to prevent the sexual transmission of HIV, which was viewed by many behavioral scientists, HIV program implementers, and advocates to be inappropriate for the epidemics in the PEPFAR focus countries or in any country, not based on scientific consensus, and challenging for country teams to comply with.

Objections to the emphasis on abstinence-only programming stemmed from several perspectives. Scientific critiques questioned the efficacy and the accuracy of information included in abstinence-only programs. Several rigorous evaluations of abstinence-only curricula conducted in the United States and elsewhere found that the programs failed to have a positive effect on key outcomes such as increasing condom use, delaying initiation of sexual intercourse, or partner reduction (Chin, 2012; Kirby, 2008; Kirby, 2009; Mavedzenge, 2011; Trenholm, 2008; Underhill, 2007). The CDC conducted a meta-analysis of 23 abstinence-only evaluations and referred to the findings from these evaluations as "inconsistent", but the only evidence of a reduction in the number of sexual partners was based on small, non-experimental studies (Chin, 2012). A review of

federally-funded abstinence education programs conducted by the U.S. House of Representatives in 2004 found that programs contained false information about the effectiveness of contraceptives and the risk of abortion (United States House of Representatives Committee on Government Reform—Minority Staff, 2004).

In addition to the critiques of abstinence-only education from the scientific arena, concerns were raised about the human rights implications of such programming. In particular, there were questions about the potential efficacy of focusing on abstinence in countries where women often have limited control over their sexual relationships. In many PEPFAR focus countries, transactional or commercial sex is used as a mechanism to generate income for school fees, for example. Focusing on abstinence denies women who engage in transactional sex access to comprehensive information about how to prevent the acquisition of HIV as well as other diseases. Further, even the "Be Faithful" element of the programming was potentially problematic given that in many countries, being married was actually a risk factor for women to acquire HIV given the high rates of extra-marital sex among married men. Finally, focusing on the A and B without the C ignored vulnerable groups, or key populations, such as men who have sex with men and people who inject drugs (PWID) (Murphy, 2006).

Aside from the scientific and human rights concerns about PEPFAR's focus on abstinence-only and be faithful programming as strategies for preventing the sexual transmission of HIV, there were operational challenges for the PEPFAR country teams in complying with the spending requirement. A Government Accountability Office (GAO) report issued in 2006 which reviewed PEPFAR's prevention strategy provides key information about how the 15 PEPFAR focus country teams interpreted and implemented OGAC's ABC guidance and abstinence-until marriage spending requirement (OGAC, 2006). Through structured interviews with country-level staff, the report finds

that the majority of country teams found components of OGAC's ABC guidance to be confusing. For example, country teams found the definition of at-risk populations in the guidance to be unclear and were concerned that populations in need of ABC programming would not receive it because they did not meet the guidance definition of at-risk. Further, the guidance was unclear about what activities were permissible under "C" programming and what messages could be delivered about condom use to groups which included youth younger than 15, who were prohibited under the guidance from receiving condom information through school-based programs. As a result, teams were concerned about violating the guidance and felt constrained in what information they could provide about correct and consistent condom use. Interviews conducted by GAO also revealed that country teams found that the abstinence-until-marriage spending requirement complicated their efforts to develop programs which were appropriate for the epidemiology and socio-cultural norms of the country in which they were working (OGAC, 2006).

V. The PEPFAR SAB

The PEPFAR Science Advisory Board was established on November 5, 2010, and was officially in operation one month later, on December 5, 2010. As described above, the SAB was established by the authority of the U.S. Department of State. Ambassador Eric Goosby was the Global AIDS Coordinator at the time the SAB was established. He was sworn in by President Obama on June 23, 2009 and resigned on October 31, 2013. Currently, Dr. Debbie Birx serves as the Global AIDS Coordinator (Department of State, 2014). This case study focuses on the SAB as it stood under Ambassador Goosby's leadership.

A. The PEPFAR SAB Charter

Since it was first implemented, the PEPFAR SAB has had its charter renewed twice. The FACA database contains two charters from December 2010, one of which was signed on December 5, 2010 and the other was signed on December 13, 2010. The next charter contained in the database was signed on December 21, 2012. The primary webpage for the PEPFAR SAB lists the current charter date as March 28, 2013 and a termination date of March 28, 2015. This discrepancy is due to the fact that the charter signed in December 2012 was not filed until March 28, 2013. It is unclear why there was a three-month delay between when the charter was signed and when it was filed.

In accordance with FACA, each charter terminates after two years, unless it is renewed. However, every year, the agency which established the committee must justify to GSA why the committee should continue on an annual basis. The justification provided in December 2011 was the following: "The committee is necessary to keep PEPFAR programs at the forefront of scientific knowledge" (GSA, 2013). A year later, the justification was similar:

> The committee is necessary to keep PEPFAR programs at the forefront of scientific knowledge. The members of the committee have specific expertise which is relevant and crucial to S/GAC[12] in creating and implementing high-quality programs. Advice received by S/GAC from the committee in the past fiscal year has assisted S/GAC in building strengthened programs that have evolved to meet S/GAC's presidentially mandated targets (GSA, 2013).

In 2013, the justification for continuing the SAB was identical to the justification provided in 2012. The current charter is set to expire on March 28, 2015. However, the SAB has not been convened since Ambassador Goosby stepped down.

As outlined in the charter, the objective of the PEPFAR SAB is to advise the Global AIDS Coordinator on scientific, implementation, and policy matters related to the global response to

[12] S/GAC refers to the Office of the U.S. Global AIDS Coordinator.

HIV/AIDS. The charter notes that these issues are relevant to PEPFAR because of how they might influence "the priorities and direction of PEPFAR evaluation and research, the content of national and international strategies and implementation, and the role of PEPFAR in the international discourse regarding appropriate and resourced responses" (Department of State, 2010).

As is consistent with FACA, the PEPFAR SAB serves the Global AIDS Coordinator in a purely advisory capacity. The Ambassador is under no obligation to adopt any of the SAB's recommendations. The charter notes the following five areas on which the Ambassador sought the advice of the SAB:

1. Advise on priority global evaluation and research issues to guide the PEPFAR agenda;
2. Review the quality and relevance of the scientific and technical evidence being used or proposed as the basis for PEPFAR policies;
3. Review research programs and the technical basis of implementation strategies of particular relevance to PEPFAR;
4. Advise on broad scientific matters in technology, social and economic issues relevant to PEPFAR; and
5. Advise on emergency and short-notice scientific issues of immediate concern to PEPFAR.

As described in Chapter 2, FACA committees can have a variety of functions. The PEPFAR SAB has duties which are cross-functional which is what determined its classification as "Other": the SAB advises OGAC on the implementation of scientific programs, which is the defining characteristic of Scientific Technical Program Advisory Boards, as well as on the implementation of policy issues, which is the defining characteristic of National Policy Issue Advisory Boards.

The charter indicates that the board will meet semi-annually in Washington, DC and that conference calls may be held in the interim on a quarterly basis. The board met annually in Washington, DC, and conference calls were held periodically. More frequent conference calls were held among the three working groups that were created under the SAB which are not required by FACA to make their meeting proceedings publicly available. These smaller working groups are

permissible under FACA and under the PEPFAR SAB charter as long as they report to the SAB as a whole and not the Ambassador. However, the charter did not specify which working groups should be created. Rather, the SAB, in collaboration with OGAC officials, determined the need for working groups on three topics: Combination Prevention, Most at Risk Populations, and Data. The efforts of these three groups are described under the section on SAB recommendations.

B. PEPFAR SAB Membership

The PEPFAR SAB under Ambassador Goosby originally had a total of 50 members. All of the members were appointed for one-year terms with an option for renewal for one additional year. The total number of SAB members has remained relatively constant since the SAB was established: at the time Ambassador Goosby stepped down, there were 49 members. Over the lifetime of the board, there was one addition, one board member passed away, and another member's term was not renewed.

As stipulated by the charter, the members served without compensation, although travel expenses were covered by the State Department. The first two charters indicate that the SAB shall consist of 25-30 members, but the most recent charter excludes that language. The charter indicates that "the membership will be representative of the HIV/AIDS community, academia, international experts, partner government representatives, multilateral and bilateral agency representatives, foundations, advocates, and non-governmental organizations"(Department of State, 2010).

With respect to the demographic characteristics of the board members as originally constituted in 2010, 14 board members were employed at institutions based in other countries, half of which were in Sub-Saharan Africa and the other half in Western Europe (Geneva or London). No other regions were represented on the board. The remaining 36 board members were employed at institutions based in the United States. Table 5.1 provides summary data on the organizational

affiliations of the board members.

Table 5.1. Summary of SAB Members' Organizational Affiliation

Organizational Affiliation	Number of SAB Members *of which* (not US based)
University	18 (5)
Research Institution (not affiliated with a university)	14 (6)
US Federal Government Agency	5
UN Organization/Global Health Partnership	4 (3)
Foundation	3
NGO	3
Think Tank	2
Private Sector Company	1
TOTAL	**50**

There were nine women on the board, which represents 18 percent of the total membership. A Balanced Membership Plan was filed with the GSA on December 13, 2011, but it contains no additional information apart from what was already written into the charter, other than to note that the board is composed of individuals "representing a diversity of backgrounds and perspectives" and that "the membership will be fairly balanced in terms of the points of views represented" (Department of State, 2011). Findings related to the balance of the board are discussed below.

While OGAC did indeed strive to have an SAB whose members were balanced in their backgrounds and perspectives, many of the individuals on the SAB work for organizations which receive PEPFAR funding. Although such information was disclosed when each SAB member was vetted by the State Department before his or her appointment, questions about the independence of the board's recommendations linger given the potential bias of members receiving large volumes of PEPFAR funding. Findings related to this issue are discussed in Section VI.A.

VI. Findings from Document Review: Issues and Recommendations Addressed by the PEPFAR SAB

The PEPFAR SAB made a number of recommendations to OGAC during its tenure. According to the PEPFAR SAB page of the FACA online database, the SAB made 25 separate and distinct formal recommendations to Ambassador Goosby, of which approximately 25 percent have been fully implemented and 50 percent have been partially implemented (GSA, 2013). However, this database is not well-maintained: none of the meetings of the SAB are listed in the appropriate fields, none of the reports issued by the SAB are available through the database, and one of the working groups of the SAB is not listed. Unfortunately, there is no official list of recommendations received by OGAC from the SAB to cross-reference with the FACA database, nor is there any publicly available information that tracks which recommendations have been fully or partially implemented, and if partially implemented, what aspects of the recommendation have and have not been adopted, aside from the recommendations related to the use of anti-retroviral treatment as prevention.

A review by this investigator of the minutes of all of the SAB meetings, official reports of recommendations from the SAB, and all of the presentations given at SAB meetings to date does reveal 25 recommendations formally labelled as such. However, there are numerous additional presentations that include what could be interpreted as recommendations, but are not formally presented as such. Rather, they are conveyed as key messages, conclusions from data, or "bottom lines".

Assuming that the 25 recommendations formally labelled as such in the PEPFAR SAB reports, meeting minutes, and presentations are indeed the same 25 recommendations noted in the FACA database, the following sections briefly summarize the four sets of formal recommendations that are easily identifiable, were discussed in depth during SAB meetings, and have been referred to

repeatedly over the course of this study.

A. SAB Recommendations to OGAC for PEPFAR Research and Evaluation

At the PEPFAR SAB's inaugural meeting on January 6-7, 2011, OGAC requested that the SAB develop recommendations for Ambassador Goosby on directions for PEPFAR's future research and evaluation agenda. Over the course of the two day meeting, the SAB generated recommendations for six areas needing in-depth review and discussion including: overarching issues, care and treatment, bridging care and treatment with prevention, data sharing, and streamlining funding modalities (PEPFAR SAB, 2011). Essentially, these recommendations served as advice to the Ambassador on what topics the SAB should address going forward.

Broadly, the overarching issues identified by the SAB related to the management, coordination, and rigor of future PEPFAR-funded research. The SAB noted that a research agenda, consisting of identifying priority research studies, should be planned strategically in coordination with other agencies. The SAB recognized that some of these studies would need to be centrally managed while others could be decentralized and managed by individual agencies. Finally, the SAB recommended that the speed with which study protocols were reviewed be greatly increased while simultaneously recommending that the rigor of those protocols also be improved.

In the area of care and treatment, the Board identified improving the efficiency of service delivery and improving the implementation cascade as the two priority areas. The "implementation cascade" refers to the spectrum of services, from testing to retaining individuals on treatment, that are needed to improve programmatic and health outcomes.

The second area of recommendations concerned the need to bridge care and treatment with prevention. Specific issues the SAB thought should be addressed were the prevention benefits of treatment, how to generate and sustain demand for treatment, and the need to improve data

collection and use. Relatedly, in the area of prevention, the SAB recommended that several priorities be pursued, including strengthening the implementation, scale-up, and evaluation of proven interventions (e.g., PMTCT), behavioral interventions, and new interventions.

Finally, a number of cross-cutting areas were identified by the SAB as needing additional attention, such as linkages to care for those co-infected with HIV and associated diseases (e.g., tuberculosis) and how best to address key populations such as PWID and men who have sex with men (MSM) who may be in need of specialized programming.

B. SAB Recommendations to OGAC for Treatment as Prevention

In April 2011, the findings from the HIV Prevention Trials Network's (HPTN) study 052, which assessed the efficacy of ART as a method to prevent or reduce the rate of transmission among sero-discordant, heterosexual partners in sub-Saharan Africa, were released. More specifically, the trial results showed that the sexual transmission of HIV was reduced by 96 percent when the infected partner was treated with ART, and the couple received counseling and used condoms (Cohen et al., 2012). Given the relevance of these findings to PEPFAR, Ambassador Goosby called a meeting of the SAB after which a working group was established specifically to discuss the science of the trial and implications for PEPFAR. The "052 subcommittee" presented its recommendations at the SAB meeting held on September 14-15, 2011. Over the course of the two days, there was extensive and vigorous debate among the SAB members about the recommendations, particularly with respect to their external validity. Ultimately, the SAB reached consensus on the scope and priority of the recommendations. The subcommittee issued a detailed report on behalf of the SAB, which includes the scientific rationale for each recommendation, estimated financial implications, public health impact, and implementation issues (PEPFAR SAB, 2011b). This section focuses on the recommendations identified in that report and the actions taken

by OGAC in response.

The SAB issued the following six recommendations to OGAC regarding the use of ART as a method to prevent the transmission of HIV or substantially reduce the risk of transmission:

1. Accelerate the support of the scaling up of ART to all HIV-infected people with CD4+ cell count < 350 cells=mm3, irrespective of WHO disease stage for treatment and prevention (goal: 90% provision of ART)
2. Offer ART to all patients with HIV-related TB, irrespective of CD4+ cell count, and integrate during TB treatment.
3. Endorse WHO guidelines for PMTCT in pregnant and breast-feeding women with a CD4+ cell count > 350 cells=mm3, with a preference for option B (ART throughout pregnancy and breast-feeding) where locally appropriate.
4. Support use of ART in specific populations with mid-level cell counts (CD4 > 350) to prevent transmission to others based on the results of HPTN 052. The benefit of this intervention has been demonstrated for heterosexual discordant couples. Careful evaluations, including assessment of benefit/risk/impact/feasibility and modeling exercises are urgently needed to identify populations to be prioritized for this intervention.
5. Intensify efforts to establish effective programs for key affected populations in HIV programs. Take particular care to ensure key populations eligible for treatment receive ART in an enabling environment that supports their human rights.
6. Seek and secure sufficient resources to implement the recommendations, given the scientific basis for, and potential impact of, their implementation.

The recommendations are listed in the order of how they were prioritized by the SAB, with the first recommendation taking precedence over the others. WHO changed its guidance for treatment as prevention in April 2012 to align with the first recommendation.

C. SAB Recommendations to OGAC for Key Populations

As noted above, at its inaugural meeting the SAB recommended to OGAC that key populations[13] (KP) be included as one of the topics it addressed over the course of its tenure. A subcommittee was formed following that inaugural meeting and it presented its recommendations to

[13] The SAB chose to use the term "key populations" instead of the often-used "Most At Risk Populations (MARPs)" because it felt "key populations" is less stigmatizing. Broadly, these populations include groups who are at high-risk for acquiring or transmitting HIV and/or face structural barriers to receiving prevention, care, and treatment services.

the SAB at the SAB meeting held on September 14-15, 2011. The SAB accepted the following recommendation put forward by the subcommittee (PEPFAR SAB, 2011a):

> The KP sub-group, on behalf of the PEPFAR SAB, recommends that PEPFAR intensify programmatic activity and implementation science that addresses focused prevention, treatment and care programs for key populations. These key populations include PWID, MSM, and sex workers and their clients in PEPFAR partner countries.

Two years later, at the PEPFAR SAB meeting held on October 2-3, 2013, a presentation was given on prevention and treatment for key populations (Beyrer, 2013). The presentation concluded by offering the following "bottom lines":

1. KPs need tailored prevention services, *and treatment*, from which they are often excluded
2. Many are in couples, some discordant
3. Women who sell sex and are living with HIV need PMTCT
4. We need to study the continuum of care for these people, identify barriers, and intervene to make real headway

These "bottom lines" are relevant here because they suggest that the Key Populations subcommittee felt that there was still room for OGAC to more completely adopt the original recommendations on key populations offered in 2011.

D. SAB Recommendations to OGAC on PEPFAR Data

The recommendations to OGAC from the Data Working Group (DWG) were provided at the last SAB meeting held under Ambassador Goosby's tenure in October 2013 and include the following:

1. Establish and maintain a PEPFAR public access knowledge portal
2. Strengthen, streamline and publicly disclose PEPFAR's collection and management of key program indicators
3. Establish, collect and publicly disclose activity-based budget, expenditure and cost data
4. Require each future grantee and contractor to submit a "Data Management Plan"

The DWG developed their recommendations using a set of five principles, which were informed by President Obama's Open Government Initiative, which emphasizes transparency, participation, and collaboration in government (Orszag, 2009). First, the DWG believed that the monitoring and evaluation of USG spending on HIV/AIDS programs could be improved through the use of good data on an appropriate set of indicators. Second, the DWG operated under the assumption that data are a public good that could benefit both US nationals but also individuals in other countries. Third, the DWG emphasized the importance of public disclosure of relevant (an anonymized) data to enhance the transparency and accountability of US-funded programs such as PEPFAR. Fourth, any data made publicly available should be accessible to both the government and other researchers through a common interface or "platform" which uses the same units of observation. Finally, the DWG emphasized the importance of the replicability of data analysis by the public research community.

In summary, the recommendations provided by the SAB to OGAC between 2011 and 2013 address a number of issues the SAB, in collaboration with OGAC, believed to be priorities (Table 5.2). As described above, some of the recommendations have been implemented with greater speed and fidelity to what the SAB recommended than others. As discussed in Chapter 4, the second aim of this study is to understand the contextual factors which affect whether recommendations put forward by advisory committees are taken up by government agencies. The findings in this area are discussed in depth below.

Table 5.2. Summary of PEPFAR SAB Major Recommendations to OGAC

Topic Area	Working Group	Date of Recommendation	Recommendation(s)	OGAC Action (if known)
Future Direction of Evaluation and Research within PEPFAR	Whole SAB	January 6-7, 2011	*1. Overarching Issues* • Plan a research agenda in coordination with other agencies and identify which studies should be managed centrally versus decentralized. • Reduce review time and improve rigor of study protocols. *2. Care and Treatment* • Improve efficiency of service delivery and the implementation cascade *3. Bridging care and tx with prevention* • Investigate how tx can be optimized for prevention • Investigate how to generate and sustain demand for tx • Improve data collection and use. *4. Prevention* • Strengthen the implementation, scale-up, and evaluation of proven interventions, behavioral interventions, and new interventions. *5. Cross-cutting areas* • How to integrate tx for associated diseases (e.g., tuberculosis) with ART • How best to address key populations	
Treatment as Prevention	HPTN 052 Subcommittee and HPTN 052 Writing Group	September 14-15, 2011	1. Expand ART to all HIV-infected people with CD4+ cell count <350 cells=mm3, irrespective of WHO disease stage. 2. Offer ART to all patients with HIV-related TB, irrespective of CD4+ cell	1. Expand treatment according to WHO recommendations; 2. Support large-scale, community-based trials of combination prevention, with treatment as prevention as the foundation.

Topic Area	Working Group	Date of Recommendation	Recommendation(s)	OGAC Action (if known)
			count, and integrate during TB tx. 3. Endorse WHO guidelines for PMTCT in pregnant and breast-feeding women with a CD4+ cell count > 350 cells=mm3, with a preference for option B[14] where locally appropriate. 4. Support use of ART in specific populations with mid-level cell counts (CD4 > 350) and conduct evaluations on benefit/risk/impact/feasibility and modeling exercises to identify priority populations 5. Intensify efforts to establish programs for KPs. 6. Seek and secure sufficient resources to implement the recommendations.	3. Promote implementation science in a number of countries throughout Africa and Asia, with a focus on use of treatment for prevention.
Key Populations	Key Populations Working Group	September 14-15, 2011	1. KPs need tailored prevention and tx services 2. Women who sell sex and are living with HIV need PMTCT 3. Study the continuum of care for KPs, identify barriers, and intervene	Melbourne Declaration signed at 20th International AIDS Conference in July 2014 http://www.aids2014.org/declaration.aspx
PEPFAR Data	Data Working Group	October 2-3, 2013	1. Establish and maintain a PEPFAR public access knowledge portal 2. Publicly disclose data on key program indicators and; 3. on activity-based budget, expenditure and costs 4. Require each future grantee and contractor to submit a "Data Management Plan"	

[14] Option B refers to the provision of ART throughout pregnancy and breast-feeding.

VII. Interview Findings

This section discusses the results of the in-depth interviews conducted between March 2013 and September 2014 with PEPFAR SAB members, OGAC staff, and managers or staff employed by advocacy groups active in the HIV/AIDS community. These results are presented in relation to the aims and research questions described in Chapter 4. The results are presented in this way to ensure that there is a parallel structure between this case study and the NCADAC case study and to facilitate the cross-case analysis, which is presented in Chapter 7. In addition, presenting the results by aim, rather than by category of respondent, helps to maintain the confidentiality and anonymity of the interviewees.

A. Aim 1: The Role of the PEPFAR SAB in the Policy Process

Given the history of the PEPFAR program's relationship with scientific evidence and research, particularly as it related to the allocation of funding for the prevention of sexual transmission of HIV, the creation and implementation of the PEPFAR science advisory board represented a substantial shift in OGAC's perspective on the importance of using evidence to inform their policy decisions. The use of a FACA committee by PEPFAR was unprecedented in the history of PEPFAR as well as in the history of other large-scale global health programs in the United States (e.g., the President's Malaria Initiative). Thus, the PEPFAR SAB provided empirical evidence for how FACs function, the extent to which the literature on the role of evidence in the policy process has support in practice, and how FACs can facilitate or impede the use of evidence by policymakers.

1. RESEARCH QUESTION 1: WHAT ARE THE MECHANISMS AND PROCESSES BY WHICH SABS FUNCTION, INCLUDING HOW THEY ARE STRUCTURED, IMPLEMENTED, CONVENED, AND OPERATE?

i. Implementing the PEPFAR SAB

a) Navigating State Department and FACA Rules

The decision to establish an SAB constituted of external advisors triggered the process of creating a FACA committee which in turn, necessitated the involvement of four different bureaus at "Main State" (which refers to the Harry S Truman building in Washington, DC), including the Bureau of Resource Management (RM Bureau), now called the Bureau of Budget and Planning (BP Bureau), the Office of the Legal Advisor (L Bureau), the Bureau of Legislative Affairs (H Bureau), and the Office of the Under Secretary for Management (M Bureau). The BP Bureau assisted with posting a public notice of the intent to establish the PEPFAR SAB in the FR, ensuring PEPFAR SAB meetings were announced in the FR, as well as renewing the SAB Charter. The L Bureau advised OGAC on the legal processes involved with establishing the SAB, given that it fell under FACA. The H Bureau liaises with Congress and sent letters notifying Congress of the PEPFAR charter and charter renewal. Finally, the M Bureau assisted with vetting SAB members.

A key finding related to the implementation of the PEPFAR SAB is that the staff directly involved with the day-to-day management and administration of the SAB could not access the State Department training on FACA committees. At the State Department, the training on FACA committees is open only to employees who are "direct-hires" which is a hiring authority that can be invoked by any government agency when the Office of Personnel Management (OPM) determines that there is a "severe shortage of candidates" or a "critical hiring need". The agency must demonstrate either of these two circumstances to OPM. While this type of authority allows the agency to hire personnel without regard for certain federal regulations governing hiring procedures,

there remains a considerable burden on the agency to justify the need for a direct hire. Thus, across the US government direct-hire staff are few and far between. Positions are filled primarily by individuals who are technically employed by government contractors. The FACA training, as well as others, are not open to these individuals because agencies view their direct hires as an investment in the future of the agency whereas the contractors are considered to be more temporary staff (although many contractors have worked at their agency for decades).

One implication of this was that no OGAC staff attended any State Department training on FACA committees when the SAB was being established. As a result, OGAC was not aware that any and all conference calls held for the whole SAB were subject to FACA and were thus required to be announced in the FR and open to the public, just like the in-person meetings, until Spring 2013, two years after the SAB met for the first time. While information on FACA committees was sent to the DFO, respondents reported that it was challenging to understand the legal information and how it applied to OGAC.

b) PEPFAR SAB Member Selection

While he could have chosen to create a USG-only advisory body, Ambassador Goosby was intent on tapping into the expertise of individuals outside of the U.S. government. While there was some discussion about keeping the advisory body internal to the U.S. government, one respondent reported that there was a "quick conclusion was there are a lot of great people in government but there's a lot more talent out there that we don't tap into. So it really was we could always go to USG but we can't always go to the outside unless we organize it somehow." A key theme which emerged from the interviews regarding the selection of SAB members was the importance of long-standing relationships between Ambassador Goosby, OGAC staff, and the potential SAB members. While there was a formal request made to other government agencies such as USAID, CDC, and DOD for

suggestions of who to nominate to create an initial pool of potential SAB members, the process for making the final selection of individuals to nominate was far less formal and based on professional and personal relationships. When asked what factors influenced the narrowing of the overall pool, a respondent replied:

> Kind of what they represented in the research arenas. We wanted enough breadth to cover the breadth of PEPFAR, but also kind of leaders in their field. And recognizing that maybe of the 10 leaders in such and such a field, I happen to like these three. The other ones are great but I don't like them so that certainly influences who gets identified.

Further, there was some attention given to whittling the initial pool down to a reasonable number of people.

> The vetting was a little bit kind of you want to get down to a certain number and so who do we give up in this particular arena of research…we can only use two of these people and we've got five, so what's the preference, chop, chop, chop. And then the next level would be are you willing to participate. I don't recall that a lot of people said no.

Given the already-existing relationships that OGAC had with the potential SAB members, the next step involved OGAC staff approaching the potential members informally to assess their interest in and willingness to serve on the SAB.

> It was kind of 'we're [OGAC] thinking of doing this, is this something you think would be good and if so would you be prepared to serve on it'. We agreed and then the formal letter came some weeks later and we'd already been primed. I think it you know, it was a lot about relationships. As I say I had this mutual respect with Ambassador Goosby for a long time and so it was one feeling very honored to be part of this but also wanting to contribute what was in our opinion quite a tough job.

Similarly, another respondent noted that "there are a lot of people here who have had relationships over the years with Eric Goosby" when looking at the list of SAB members. However, it should be

noted that the pattern of selecting individuals who had long-standing relationships with Ambassador Goosby was not the only criterion. One respondent noted that "We all made recommendations with the same lens, which is what does the program need? Does the program need expertise here? Does the program need expertise there? Ultimately it's the Ambassador's decision."

c) PEPFAR SAB Membership Bias and Balance

As mentioned above, the primary area of concern about bias among the PEPFAR SAB stemmed from the fact that many SAB members received PEPFAR funding. Respondents had mixed opinions about the extent to which this affected the advice and guidance the SAB provided. One respondent noted that:

> I think everyone feels constrained, right? They've all got a reputation. They don't want to be the troublemaker. They've got a lot of relationships a lot of them having to do with funding that they don't want to mess with. Criticizing the program is deadly in terms of so many things including money.

This suggests that rather than members making recommendations that would eventually lead to OGAC directing funding to their own areas of expertise, which could also be a potential source of bias, the PEPFAR SAB members were reluctant to be candid about their critiques of the PEPFAR program for fear of retribution in terms of the amount of funding they received as well as other issues. A respondent suggested that the PEPFAR SAB "need[s] more rabble rousers. They need more people that aren't getting paid by the machine." However, others felt differently:

> I think that the scientific advisory board could not care less who's in the room. Nobody is censoring what they're going to say. And I don't know, I don't care who's in the back of the room. If they get mad at me I'll probably hear about it in the coffee break. But I like to share what I think about the issue.

Another participant echoed the same sentiment:

> So, when I'm in this SAB, when I can say what I actually believe, there is no inhibition. We take our role as advisors to the Ambassador a lot more seriously than we take the fear factor into account that some loony bin might be in the audience who would think ill of us.

Interestingly, both of these respondents interpreted the question about whether they tempered their advice in any way as addressing a concern about the reactions of individuals in the audience, rather than possible repercussions from OGAC. Others, however, understood the concern about SAB members feeling squelched in giving candid feedback to be related to the fear of retribution as discussed above:

> We have private sector and advocacy community [but] there are more academics than anything else, and many of the academics also do PEPFAR implementation, I mean they have programmatic associations so they are very familiar with some of the issues…In academia it is a very comfortable space to throw things out there and yell at each other so I don't feel like it's a real reticent, controlled…I think people say 'No, Bob, I think you're wrong' and they do say that in public which might be different from other kinds of discussions that go on in government policy settings …the debate is pretty robust and I feel like if people have a concern with things people feel comfortable saying that right out. So the meat of the discussion really is represented for the public there and in the final documents that are produced.

The sentiment that little could be done about potential conflicts of interest was also expressed:

> You know, the experts that you should have around the table are also the people you should probably wind up funding. And they're certainly going to agree with that. But you can't not have them at the table. They're the experts. So you have to just go in and say this is a deeply conflicted situation but let's go in and be as good as we can be.

This statement suggests that there was some resignation to the fact that there would always be some conflict of interest on an advisory committee if the "right" people are committee members.

More specifically, one could argue that the optimal level of conflict of interest on federal advisory committees is not zero, because an absence of conflicts of interest would indicate that the committee is not comprised of the appropriate experts.

A respondent also noted that among the pool of potential SAB members, there were others that could have been selected who would have been less likely to be honest in their advice and recommendations:

> There are a lot of folks who….I think there's a fair number who get a lot of PEPFAR funding…I think those that they've chosen have been relatively independent people who get a lot of funding. I could imagine a sub-set of people who get a lot of PEPFAR funding who don't challenge PEPFAR ever. I think a bunch of the people who they put on the committee actually are the opposite of that. They may have major treatment programs but I think they just say what they want…I do think that [OGAC] did that pretty well and did that nicely.

In terms of balance of the PEPFAR SAB membership, respondents generally agreed that the appropriate and relevant areas of scientific expertise were well-represented on the SAB. However, there were doubts about whether there was adequate representation from PEPFAR focus countries. One respondent summarized the complexity of the country-representation issue, noting:

> It's a tricky one because I think it's an unusual situation where the activity is all happening offshore but the money is all being generated in country. So there's an element of accountability for what's being spent on the one hand where I can absolutely see that OGAC has a requirement to be accountable for it, that it's spending wisely and in a way that is in the best interests of everyone. But then there's a perception that if this is happening in other countries shouldn't those countries be represented? You could argue that well, we needed fair representation of the taxpayers versus we needed fair representation of the international side.

Unfortunately, while there were SAB members from institutions in South Africa, Uganda, and Zimbabwe, these individuals were not always able to attend the annual SAB meetings because of

scheduling conflicts and difficulties arranging travel.

ii. Managing the PEPFAR SAB

OGAC did not have a staff dedicated solely to the management and administration of the SAB. As a result, any time OGAC staff did dedicate to the SAB was in addition to their other work. As one respondent noted, "the first year was a huge struggle because it was just another of the many jobs we try to balance." The "unfunded mandate" nature of managing the SAB had negative implications for both OGAC staff and SAB members. Initially, it was conceived that the SAB would meet in-person biannually, but this proved to be too time consuming for OGAC to manage and too difficult for SAB members to incorporate into their schedules.

> It was originally intended that this would be a twice a year meeting but we soon found that it worked better as a once a year meeting with a semi-annual call just given the number of people involved and the burden of trying to plan for face to face meetings.

The lack of a full-time staff or secretariat at OGAC dedicated to the oversight of the SAB seems to have compromised the ability of OGAC staff to devote adequate time to the SAB: the SAB was marginalized as a priority due to the many other professional commitments of OGAC staff.

Respondents identified two ways that SAB members experienced the "unfunded mandate" element, namely through receiving SAB meeting agendas just a few days in advance of the meetings, which left little time to prepare, and through poorly conceived meeting agendas. The week before one of the SAB meetings, one respondent noted that:

> The one area where I think that it doesn't work so well is in the planning of the meeting. For example, I don't have an agenda for next week's meeting yet. And I know that they're over there at OGAC…and they're all fighting over what it's supposed to be and how to do it. Because I haven't seen a draft, I don't know what we're discussing and I haven't been able to give input.

In addition, SAB members were often not able to participate in the conference calls that were held in between in-person meetings because of other professional commitments and sometimes, were not able to travel to Washington, DC for the annual in-person meeting for the same reason.

a) PEPFAR SAB Working Groups

As discussed in more depth in Section VI, several Working Groups were established to develop recommendations on key issues the SAB and OGAC determined to be priorities. Respondents indicated that these Working Groups were established because Ambassador Goosby specifically requested a sub-group of the SAB address a specific issue or because SAB members requested that a Working Group be established. In terms of who sat on the Working Groups, a respondent indicated that:

> Pretty much the working group decides. Or if it's something the Ambassador comes up with he might say be sure to get so and so on it or something like that. And they can bring people into the working group who are not part of the scientific advisory board. And that happens all the time.

Given the large size of the SAB and the varied expertise of its members, establishing these Working Groups was necessary to ensure that the SAB fulfilled the requests made of it in a timely way, the only way to manage workflow, and the best way to tap the specific expertise of its members. However, for OGAC staff, managing the outputs of the Working Groups was particularly time consuming:

> Well, it depends on the group…they're tasked with something to do, so you need to facilitate that and make sure it happens in a timely way. And unless…I don't know about this, but, I'm not sure if in order for that to happen it requires our input or whether it's just easier if it does. We're the people who are integrating the comments

> into the recommendations. When the SAB gives comments back, we're the people who are integrating it, we're the people who are sending it out. We're the people who are convening meetings of the working group. Right now I have like three million working group things to do before our next meeting. So it's a lot of work. And actually it's worse…the person who sort of administrates it…it's time consuming for me and for her it's really time consuming.

Importantly, any recommendations developed by a Working Group were presented first to the SAB as a whole. Under FACA law, the Working Groups are not permitted to make recommendations directly to the government agency which created the FACA committee because they are a subset of the committee and only the committee as a whole can make recommendations to the establishing agency. In the case of the PEPFAR SAB, draft recommendations were presented and then discussed. SAB members also had the opportunity to provide written comments on the draft recommendations, which the Working Group would have to address. Respondents indicated that some SAB members provided comments on all recommendations while most SAB members only commented on the recommendations that were of interest to them or fell under their area of expertise. Once finalized, the recommendations were submitted to OGAC and Ambassador Goosby. The specific recommendations made by the SAB and formally submitted to OGAC under Ambassador Goosby's tenure are discussed in Section VI.

b) PEPFAR SAB Chair

A critical element to the management of the PEPFAR SAB is the Chair. Three key findings emerged from the interviews about the role of the Chair related to OGAC's interpretation of the FACA law about who could be appointed as Chair and the implications of this interpretation for the perceived independence of the SAB's recommendation, the lack of clarity among SAB members about who officially was Chair of the SAB, and the relationship between the Chair's management

style and the efficiency of SAB meetings.

When establishing the PEPFAR SAB, OGAC interpreted the FACA law to require the Chair to be someone different than the DFO. In fact, this is not the case: the DFO – who is required to be a government employee or official – can technically also serve as Chair. Importantly, no FACA committee meeting can occur in the absence of the DFO and the DFO has the authority to adjourn any meeting he/she is designated to chair or attend. In the case of the PEPFAR SAB, the chair was a Professor at an academic institution who was contracted by OGAC as a consultant to serve as a special advisor to Ambassador Goosby.

While the Chair of the SAB is information that is publicly available through the FACA database, many SAB members were confused about who actually was their Chair. This uncertainty resulted partly from how SAB meetings were administered: respondents indicated that different people would facilitate discussions for different sections of the agenda. Thus, there was no consistency in who was facilitating or chairing the meetings. One respondent noted that there was no Chair of the PEPFAR SAB.

Those who were aware of who the Chair was had strong opinions about the fact that the role was filled by someone who was a consultant to OGAC in addition to serving as Chair. One respondent noted the following:

> I think the best approach to a SAB is not to have it chaired by the people who are getting the advice. And [the Chair] was working under contract to OGAC at that time and so [the Chair] was one of the people getting advice. So I think that was a mistake.

The implication of having a Chair who was also a consultant to the agency which established the board is that there could be the perception that the recommendations provided are not independent. "The nice thing about that then is that when you have a consensus or a recommendation you can

say it's an outside recommendation rather than an inside recommendation."

The findings also indicate that the management style of the SAB Chair is a critical influence on how discussions at SAB meetings are structured and on the extent to which certain SAB members dominate the discussion. One participant offered the following suggestion for the type of experience and character a SAB Chair should have:

> I think what they should have done is picked somebody who is very experienced in advisory boards and has a track record and can help the discussion both stay on time and on topic. And if that means interrupting the dean of the school of public health of elsewhere, so be it. And if that means cutting off discussion with the WHO person speaking, so be it. I mean you gotta have the guts to run these things with some discipline.

iii. Convening the PEPFAR SAB

a) Setting PEPFAR SAB Meeting Agendas

The process of setting the agendas and convening SAB meetings, both in terms of the work that needed to be done in advance of the meeting by OGAC staff and SAB members as well as the process of administrating the meetings themselves, proved to be time consuming for all involved and at times, wrought with frustration.

Respondents indicated that the process for determining which issues were on meeting agendas was driven both by Ambassador Goosby as well as SAB members.

> Setting the agenda is mostly driven by the Ambassador's priority questions although when we do our quarterly calls, SAB members can bring up and ask for those and the Ambassador is generally very responsive about what the SAB sees as priority issues and they tend to be the same thing in terms of what are priorities.

It appears that this system of accepting all suggestions for agenda items was not effective. There was broad agreement among respondents that the agendas were too full:

> And even the agendas that are put forth to them like this last one in particular it was just packed and yet there was no time…no time isn't correct. There was much too little time to actually let them talk. Okay you've got 15 minutes okay move on to the next thing. It really doesn't make good use of them. Didn't prepare them well in advance.

This response suggests that determining what and how many items should be included on SAB meeting agendas should be weighed in terms of the anticipated time needed to discuss each agenda item in a robust and open manner which in turn involves consideration of the personalities of the committee members. The idea that the ability of the SAB to be effective is influenced by not only the number of items on the agenda but also by how the meeting discussion is managed suggests that the agency which establishes the SAB has an important role to play in ensuring that it obtains actionable, relevant recommendations based on the conclusions of robust SAB discussions.

b) Managing PEPFAR SAB Meeting Discussions

Several respondents noted that the discussions at the SAB meetings were not managed in an optimal way. Respondents had mixed opinions about the implications the size of the SAB had for the management of discussion. While respondents recognized that the board was quite large – nearly double the original estimate for the number of members – some did not think this created challenges for the management of discussion, while others did. One respondent questioned the utility of even creating a board of the PEPFAR SAB's size, noting:

> Well I'm not sure that sure that convening a board of 40 people is ever particularly useful. The way I look at it, within the board you have immense expertise but it's highly diverse. So if you can do what we did to some extent, which is break the board into working groups, and give them a tough assignment…[and] for us to then work on that between meetings and have a series of calls and actually present a report, that was the SAB work process at its finest in my judgment.

This respondent suggested that an alternative way to run the meetings would be to have "a half-day

information exchange and then [break] up into groups where detailed issues could have been hammered out with OGAC, CDC, [US]AID, whomever, personnel that would have been perhaps more meaningful to everybody in the room." Similarly, another respondent suggested that materials to be discussed at the meeting should have been distributed electronically in advance of the meeting to maximize the productivity of the meeting itself. With time managed in a stringent manner, there should have been "the invitation that everyone with a further point to make - everyone - make it to both the committee chair in the writing and the appropriate PEPFAR staff member copied. And those comments would all be collated as inputs from the scientific advisory board."

Others indicated that the personalities of the SAB members themselves were partly to blame for the difficulty in managing meeting discussions. One respondent noted, "Working with a lot of strong personalities, whether or not they can be managed is a good question, but we'll go off on tangents that we've never successfully pulled them in. Say great, great, okay, next time and pull it back so they will kind of get scattered." However, it is difficult to separate SAB members' personalities from the Chair's ability to control the meeting:

> But when you let meetings run on and run over, because in general whoever is chairing - and different people were chairing at different times - but it always ran over, again because you had such strong people in the room, …that you really have people that think that their word is the last word on this topic and need to be heard. And as I say, me included. With no shrinking violets, the leader has to exert a strong hand and say 'sorry guys time's up, I didn't call on you, I know you have these 5 people waiting to talk'.

Interestingly, others felt that discussion of some specific issues was not permitted to be as robust as it should have been.

> I think it was too managed to reach the conclusions that CDC wanted to reach. CDC and OGAC. So, I think that made it useful to Ambassador Goosby because he knew where he wanted to go and so by choosing the people who present and the views

> that were presented, he could be more certain to get there. I think that basically the downside of raising the CD4 threshold was not given sufficient attention. And by that I mean partly cost, partly feasibility, and partly really a serious issue that people start too early. They may not adhere. So those issues of course we don't have enough empirical data even now, but I think those issues were largely swept under the rug much more than they should have been.

These findings suggest that the task of implementing, managing, and convening the PEPFAR SAB was challenging.

2. Research Question 2: To What Extent Does the Theoretical Disconnect Between the Literature on the Health Policy Process and the Literature on Evidence-Based Policy Have Empirical Support?

As discussed in Chapters 1 and 2, the traditional model of the policy process assumes that policymaking is inherently linear, with policymakers engaged at each stage as rational actors. The push for policy to be more evidence-based or even evidence-informed relies heavily on these assumptions. Critics suggest these assumptions are flawed and argue that any call for policy to be evidence-based ignores the reality of the policy process, including that it is inherently irrational and political. This case study provides an opportunity to assess whether this disconnect has any bearing in practice. Overall, the evidence suggests that at times, the disconnect does bear out in practice, but at other times, it does not. There is support for a number of the different theories of the policy process as well as different models of the research-policy relationship.

The inherent assumption of the step-wise or cyclical models of the policy process is that policymaking occurs in a series of stages and that policymakers are capable of making rational decisions at each stage. With respect to the use of research findings or evidence, an implication of these models is that a problem is defined, and research is conducted which then informs the policy solution to that problem. Findings from the in-depth interviews suggest that there is support for

these assertions. Respondents suggested that part of the reason why the SAB was established was to lend credence to the argument for investing more in HIV treatment because there were skeptics across the U.S. government who were questioning the cost-effectiveness of ART and arguing that funding should be directed away from treatment and towards prevention. At the time, the results of the HPTN 052 trial had not been released, but a number of observational studies had already indicated that ART can be effective in reducing the risk of transmission of HIV among sero-discordant couples (Bunnell et al., 2006; Del Romero, Castilla, Hernando, Rodriguez, & Garcia, 2010; Donnell et al., 2010; Reynolds et al., 2011). Thus, the problem was the conflict between stakeholders within USG about how funding should be allocated. While HPTN 052 was not commissioned by PEPFAR, it was already underway, and when the trial results were released on April 28, 2011, Ambassador Goosby requested that the SAB form a working group to assess the study's findings and make recommendations.

Between April and September 2011, the working group developed draft recommendations which were debated vigorously for two days at the September 2011 SAB meeting. Those recommendations, which are detailed in Section V.B, were adopted as PEPFAR policy following the SAB meeting. This example of PEPFAR changing its policy for ART based on the results of the HPTN 052 trial results lends support to the idea that the policy process can be linear. Further, it seems to refute Simon's satisficing concept, which suggested that policymakers will choose the solution that is merely adequate rather than the optimal solution (Simon, 1957). It could be argued that OGAC was opportunistic by waiting for the HPTN 052 trial results to be released before changing its treatment guidelines. Indeed, the SAB was scheduled to meet in the Spring of 2011 but the meeting was postponed until September of that year so that the committee had adequate time to prepare recommendations based on the trial results. On the other hand, the HPTN 052 results do

confirm through a randomized control trial what had already been reported from observational studies. This suggests that it may have in fact been the optimal solution for OGAC to enact policy in response to the 052 findings. Similarly, Lindblom's model of incrementalism, which suggests that policy change is optimal when it occurs gradually because this simplifies the process, and Cohen's garbage can model, which suggests that it is not feasible to be proactive about changing policy because solutions arise when problems emerge from a metaphorical garbage can, both seem to be refuted by this example. PEPFAR policy was changed quite substantially, not incrementally, and it was changed pro-actively (Cohen et al., 1972; Lindblom, 1968). In contrast, Kingdon's multiple streams model, which posits that a favorable political environment is a necessary ingredient for issues to rise to the policy agenda does seem to have some support: the issue of how to change PEPFAR's treatment policy rose to the agenda of the SAB because Ambassador Goosby requested a working group address the findings of HPTN 052, which provided the data needed to propose a recommendation for PEPFAR (Kingdon, 1984).

In terms of models of the research-policy relationship, the example of the PEPFAR SAB case provides support for some models and not for others. There is strong support for the problem solving model, which suggests that research findings help solve policy problems by applying empirical evidence directly to a specific policy issue, which is then resolved because the gap in knowledge is filled (Weiss, 1979). Similarly, there is also strong support for the linkage and exchange model which suggests that when the interface among researchers, policymakers, research funders and knowledge purveyors – all of whom are stakeholders involved with the PEPFAR SAB – is strong, research will be used (Lomas, 2000). One way this interface occurs is when policymakers ask researchers for advice on pressing policy problems and researchers aim to provide solutions.

The general utilization theory model posits that there must be a change in social context

which leads to a change in policy issues for policymakers and researchers to interact (Nutley, 2007). It could be argued that the change in the Administration and its new approach to using data to inform policy was a change in social context that allowed certain policy issues to be brought to the fore, which were then discussed by the SAB. Further, the SAB "adapted, recreated, [and] transformed" the research findings from the 052 trial into recommendations appropriate for OGAC (Nutley, 2007, p.100).

The two communities model, which is based on the premise that policymakers rarely use research and exist in two almost irreconcilable cultures, can almost be dismissed out of hand, simply because the establishment of the PEPFAR SAB indicates that PEPFAR policymakers do, in fact, use research. Similarly, there is little support for the enlightenment model, which suggests that policy is not changed due to the findings of a specific study but rather because general ideas rooted in research almost unconsciously enter the policy sphere, and the knowledge-driven model, which suggests that basic research provides an opportunity for applied research to assess whether the initial findings are relevant for practical application (Weiss, 1979).

Findings from this case study support the assumption proposed in Chapter 2: the linkage and exchange model does appear to be relevant to this study given its specific acknowledgement that an interface between policymakers and researchers is needed for research use to occur, and that this interface can be created when policymakers request the advice of researchers. Although Lomas does not suggest it, a FAC would be a natural example of an interface through which researchers can provide advice at the request of policymakers. In addition, the problem solving model is relevant as well, particularly given how the findings from the 052 trial were used.

3. Research Question 3: How do SABs Facilitate and Impede the Use of Evidence by Policymakers?

Respondents noted that a key way for the PEPFAR SAB to facilitate the use of evidence by policymakers at OGAC or USG more broadly is to provide scientific justification for a policy decision.

> First of all, just the discussion, from some of the best HIV minds around, is just extremely useful to hear the opinions, the different stands on things articulated, to have the resource of people who can be tasked with 'this is an issue based on some new evidence, lay out for us what's there', which has been very useful. And then I think being able to ensure that we demonstrate both of those things. That we are using that evidence when we look at programming decisions is extremely useful to policymakers. It's legitimizing, it's also just consonant with a science-based approach to PEPFAR programming, it helps us be able to prioritize with that evidence purpose. So I think in that sense it's extremely useful for policymakers, it gives us cover in how we respond to Congress, to our overseers about how we do things, having that objective basis. And so by having that SAB these ideas are vetted and discussed and really gives us that validation…gives us the evidence base and validates it.

A related but distinct finding was that the SAB provided a way for OGAC to remove itself from arguments about policy directions and defer to the experts on the SAB. One respondent noted that the SAB "gives us traction we wouldn't have had on our own, a place to fall back." Yet another noted that "PEPFAR is able to invoke the guidance of this scientific advisory board as sort of external validation."

Respondents also noted that HIV prevention, care, and treatment is wrought with political and ideological debates that are not always based on sound scientific evidence. Interviewees noted that an SAB constituted by renowned and respected academics can help to resolve ideological differences.

> …I also think that [the SAB] helped at various times to settle inter-USG and

> certainly even inter-PEPFAR disagreements at times. Because as you know very well I'm sure after all these interviews and after advocacy work as well, these are not monolithic entities. And given different currents within them especially when it comes to how do you spend $6 billion dollars a year, the prioritization fight is an essential question within PEPFAR at all times. And I think there was and continues to be struggles within PEPFAR for turf, struggles between agencies for funding, and I think things that the SAB did and in fact was established to do was to help answer some of those questions. Sometimes because they were genuine questions or sometimes because subjects within PEPFAR wanted legitimacy for what they wanted to do versus what others wanted them to do.

Respondents had considerable difficulty conceiving how a SAB – either the PEPFAR SAB or a generic SAB – could impede the use of evidence by policymakers. Across all categories of respondents, there was a strong belief that policy should be informed by evidence, at a minimum, if not based on it, and that in the area of HIV prevention, care, and treatment in particular, scientific evidence in support of policies that have been politically controversial (e.g., needle-exchange programs) could help to mitigate ideological differences and facilitate the development of policies that are beneficial for public health.

Respondents noted that if SAB members do not understand the intricacies of the PEPFAR program and how it operates, their recommendations could be inappropriate for PEPFAR's mandate or impossible to implement. "There could be times when advisory board members who aren't as familiar with the PEPFAR program and with the structures that PEPFAR…might serve as at least a temporary barrier to saying 'here's the research and here's what the evidence base shows, how do we actually build programs that rely on that'". This relates to the issue of conflict of interest and reinforces the idea that a "good" FAC is comprised of implementers and researchers. It was noted that to some extent, the establishing agency has a duty to be clear about what priorities and questions they expect the advisory board's guidance as well as to reign in SAB meeting discussions if

it spirals out of control.

B. Aim 2: Contribution of Contextual Factors to Adoption of PEPFAR SAB Recommendations

While the institutional environment at OGAC is the most relevant context that influenced whether and how the SAB's recommendations were adopted, the broader policy context of the US government during Ambassador Goosby's tenure at OGAC was identified by many interviewees across respondent categories as a critical influence on OGAC. Several respondents noted the different tenor of how science and research were treated under the Obama Administration relative to the Bush Administration. One participant described this historical context in depth, noting that:

> It definitely was a different tenor for the Bush-era PEPFAR and the Goosby-era PEPFAR or the Obama-era PEPFAR under Goosby in that at least the rhetoric and the public discussion [has been] much more about science and 'we're going to follow the science'. This is not to say that Mark Dybul did not follow the science. But there [has been] less of a political overtone in how PEPFAR was talked about by the new Administration. And it's not that there wasn't science in the first few years, but a couple things: one it was an emergency response and I think in retrospect everyone agrees that there should have been much more embedded in it – evaluation and all kinds of things, but I think given the emergency nature and that was an era in June 2003 [when] we just didn't have all the proven interventions. By 2009 and 2010 we had a lot more. And we also had an IOM report that had come out that basically said that politics shouldn't trump science so that was a key thing. Several GAO reports kind of said the same thing and basically said that politics was driving some of the decision-making and it should be driven by science. Those independent bodies said that, you had a president [Obama] who was much more focused on that as an idea, and Eric as well. And before that, my understanding was that most of the scientific stuff – they had the public health evaluations, which nobody ever saw or anything but they had those.

OGAC's new and heavy emphasis on funding research and using the results of scientific studies to inform PEPFAR policy was viewed by many as being not only aligned with the Obama

Administration's focus on transparency, accountability, and evidence-based policy but also encouraged by it. According to one respondent, "it starts with the President. I mean he's a law professor. There's an evidence-based ethic." In addition to the overall approach of the current Administration to the value of science, participants noted the timeliness and importance of scientific evidence that was generated during the course of Ambassador Goosby's tenure at OGAC. One participant noted that:

> I think this Administration is way more interested in being evidence-based but then also they've benefited from a time in history when the science has been absolutely terrific…I mean, the science of the last few years would just drive you to pay attention because it's so startling.

More proximate to the SAB was the context of OGAC itself under Ambassador Goosby's leadership. Respondents unanimously identified Ambassador Goosby as the driving force behind not only the creation of the PEPFAR SAB but also the utilization of its recommendations to inform and change PEPFAR policy. Interviewees viewed the Ambassador as someone who has a long-standing and deep commitment to ensuring that policy is evidence-based:

> He comes from academic medicine. And he himself sort of is that way. So I think he's used to that. He's used to functioning in an academic environment. He always thought that not necessarily academic medicine but academic science absolutely had a role to play. That was his vision from day one.

When asked specifically about the factors that influenced OGAC's adoption of the SAB's recommendations, several themes emerged from respondents' answers. Interviewees indicated that the ability to link the recommendation very clearly to scientific evidence would be important because such a connection would establish the legitimacy of the recommendation and assist OGAC in defending any action based on the recommendation, should critiques arise.

> I think scientific rigor and really getting that input from the scientific community was the first priority. And then I think demonstrating that in fact those things were brought in because programmatic realities are sometimes…so as we look at if there are new WHO normative guidelines then those are often an ideal, and when we look at them from a PEPFAR standpoint, how should we tell our countries about how we should move forward with this knowing that individual countries may not be where the Ministry of Health has chosen to go? Or your guidelines are different and how do we work these. And to really have a dialogue with the scientific community about how we approach that and to have this transparency and documentation that those discussions did happen and that PEPFAR policies aren't arbitrary in that sense or weren't taking that science into consideration.

In addition, the extent to which the recommendations address a high-priority issue for OGAC and are feasible for OGAC to implement were noted as contributing factors. Participants noted that feasibility involves the availability of financial resources to implement the recommendation as well as the political mandate to do so. For example, one participant noted that:

> The two things that immediately come to mind is that one, [OGAC does not] have the money to do it or we're proposing a much larger research agenda than OGAC can really take responsibility for. [OGAC] may not disagree with what we're talking about but it's beyond the scope of what they can do. Or it may not be politically feasible, what we're suggesting. An example there would be I had no doubt that the scientific advisory board – we certainly discussed this – supports funding syringe exchange programs. The Administration also supports that. It's not feasible for them to do that.

In contrast to the issue of needle exchange programs, it was feasible for OGAC to react quickly to the SAB's recommendations following from the HPTN 052 trial results. The response by OGAC is well-documented by Cohen et al., who describe how the science of treatment as prevention evolved over time as well as how WHO and PEPFAR responded to the new evidence (Cohen et al., 2012). The article indicates that both institutions reacted quickly to the HPTN 052 results. In particular, PEPFAR took the following steps:

1. expand treatment according to WHO recommendations;
2. support large-scale, community-based trials of combination prevention, with treatment as prevention as the foundation.
3. promote implementation science in a number of countries throughout Africa and Asia, with a focus on use of treatment for prevention.

The factors which affect OGAC's uptake of the SAB's recommendations were addressed during the interviews conducted as a part of this case study and are discussed in depth below. However, it should be noted that the speed with which OGAC reacted to the 052 findings and the SAB's recommendations for how they could be integrated into PEPFAR programming is unique; the outcome of the recommendations from the other two working groups (described below) remains unclear.

Similarly, when asked what challenges might impede OGAC's adoption of the SAB's recommendations, there were several common themes that emerged, which largely echo those identified as being associated with the uptake of recommendations. Participants noted that recommendations would be unlikely to be adopted if they were not politically or financially feasible, or fell outside the scope of what OGAC could take on in terms of research. In addition, it was suggested that if there was not scientific consensus within the recommendation, it could challenge OGAC's ability to adopt the SAB's guidance. Finally, already-existing systems or guidance at various levels could challenge efforts to translate the SAB's advice into operationally-applicable actions.

C. Aim 3: Stakeholder Engagement with the PEPFAR SAB

When this study was initially conceived, the third aim was developed based on the investigator's assumption that there was a vibrant advocacy community actively lobbying and advocating for certain policies in both the HIV arena and that these groups would be actively engaging in efforts to influence the proceedings and outcomes of the PEPFAR SAB. In addition, in

the absence of knowledge about how the advisory committees functioned and the dynamics between the committees and their establishing agencies, it was assumed that SAB members themselves served almost as lobbyists, in addition to science advisors, in their capacity as committee members.

However, after conducting the first few interviews for each case study and attending PEPFAR SAB meetings, it became clear that there was little NGO or advocacy group engagement with the PEPFAR SAB and that the committee members took their role as science advisors quite seriously, and largely set personal agendas aside. Thus, the research questions originally defined for the third aim quickly seemed less relevant than originally anticipated. Instead, it became clear that there was a far more nuanced dynamic occurring between NGOs and the SAB involving both formal and informal mechanisms of communication. Further, the informal communication that was occurring was influenced heavily by already-existing and long-standing personal relationships. Finally, it was apparent that the mechanism built into FACA for engagement with the public – the mandatory public comment period held at FACA committee meetings – was ineffective. Chapter 7 will address these issues across the two case studies.

The key finding from this research related to stakeholder engagement with the PEPFAR SAB is the lack thereof. Respondents in all categories of interviewees expressed surprise at how little interaction there was between NGOs and advocacy groups working on global HIV/AIDS and the SAB. This seems to be due in part to the fact that the SAB meetings were not widely publicized.

> It's just not been well-publicized, well-shared, that it exists. I'm aware of other advisory boards where there is much more awareness of them and there's always public comment and there's always people posting this meeting is coming up and this hasn't happened with the SAB. I mean I could guess…it's relatively new, there's been some turnover, and all of that, but I agree with you. It's not well known.

While FACA requires that the meetings be announced in the FR, respondents indicated that no one ever checks the FR. Further, while meeting announcements were added to the PEPFAR SAB website they were not announced on the main PEPFAR website nor were they sent out via listservs. Thus, it was often the case that concerned stakeholders were unaware that SAB meetings were occurring.

Even if there was awareness about the occurrence of an SAB meeting, some respondents indicated that they felt that attending the meetings were not worth their time. One respondent identified the following as reasons for not attending: "Didn't have enough of a heads up, didn't think about it, one couldn't go, to be honest with you, I don't tend to go to meetings unless I'm presenting at this point. I just don't have the time." The only opportunity to comment on SAB proceedings is during the FACA-mandated public comment period that is only 10 minutes long and scheduled at the end of each day of a FAC meeting. However, this investigator noted from attending PEPFAR SAB meetings that in practice, the agenda for the SAB meetings were often re-arranged on the day of the meeting because discussion on various agenda items ran over the allotted time. This included the time scheduled for public comment, which meant that if someone was planning on attending at a specific time to make remarks, he may be too late.

Several participants expressed surprise at how little engagement there was during the public comment period and were puzzled as to why this was the case.

> I think it's obviously – in addition to being required – I think it's very important. I have been a little bit surprised at how little engagement there is on that front. I'm not if that's a reflection of a lack of concern, I mean a general supportiveness of what's going on…or if it's a bureaucratic issue, you know…it's a relatively small window. I think the public comment section has to be – if you're going to get these people into a room together to talk about the issues you do have to control some of the time limit. You're sort of stuck with that. There are requirements about posting it and having it out there so we do everything for that but I have been a little bit surprised

> that there aren't more public comments or larger attendance from some, but I don't know why.

Others noted that the public comment period may have been less effective than it could have been because the comments received from advocacy groups were not directly related to matters OGAC was considering or because the issues were diplomatically too sensitive for OGAC to approach.

> I think that my experience in our SAB has been that the comments from the advocacy community are often targeted toward particular issues of interest which are important [and] which we have an ongoing engagement on, but they are not necessarily related to the topics that have been put on the advisory board. So, maybe that means there's is a deficit in what comes up there. If your issue that you're concerned about relates to treatment of certain populations in various countries and we know there are human rights issues that are associated with these - if that's you're issue and that's what you're passionate about and what you work on, you will come to the SAB and you will discuss this. And it is not that the issue isn't important and it's not that we're not engaged on that issue, it's just that there may not really be anything that the SAB could discuss. It may be that the science is really clear but the policy implications in terms of the host nation government…we may just not have a lot of options. And so I think often the discussions that come out of the public comment tend to fall more into that category.

Some respondents perceived the public comment period to be a mere formality required by law rather than a time to productively engage with the SAB because there is no opportunity for the SAB to respond to comments received.

While the formal mechanism for stakeholder engagement (i.e., the public comment period) was rarely used, respondents indicated that already-existing personal relationships among the various stakeholders involved with the SAB enabled engagement through informal channels. One participant indicated that "If I felt I wanted [the SAB] to do a particular thing I would feel no resistance about weighing in or just going down the list and calling them. And I mean I probably contacted five people when I wanted earlier treatment initiation". The same respondent noted that

communicating directly with OGAC at the staff level 'off the record' provided an opportunity to understand the issues on which there was a difference of opinion between OGAC leadership and OGAC staff. Efforts were then made to influence the SAB to align with the OGAC staff position without actually involving OGAC staff.

> Sometimes I'll work with an OGAC staff member who…doesn't want his or her name used. But we're always… talking to insiders at OGAC who are just like stealth people. The system depends on that. Disgruntled employees. I mean it's interesting though not everybody thinks about that. I said to somebody from the White House the other week that you need to know that you're hearing one thing from OGAC leadership and the people below that completely disagree with that. And they're like "really?" And I'm like "yeah."

Others indicated that they would contact SAB members directly in advance of meetings to try to influence them to raise or support certain issues at the SAB meetings. Respondents also noted that SAB meetings were only one venue at which current issues related to HIV prevention, care, and treatment science and policy were being discussed: other conferences, such as the Conference on Retroviruses and Opportunistic Infections (CROI) and to some extent, the International AIDS Conference, as well as meetings held by the World Health Organization (WHO), also provided opportunities for stakeholders to engage with each other.

It was also noted that the topics of discussion during SAB meetings may not be appealing or interesting to a wide audience. The amount of funding appropriated for PEPFAR by Congress receives a lot of attention, but that issue was not the subject of debate at the SAB meetings. As discussed above, the SAB focused much more specifically on scientific evidence and implications for the operational aspects of PEPFAR programs. Respondents suggested that this type of discussion may not be perceived as politically important beyond a small group with highly specialized knowledge of a very technical and complex funding system. Further, the primary beneficiaries of

PEPFAR programs are individuals living in focus countries, who obviously cannot attend SAB meetings held in Washington, DC.

VIII. Conclusion

Since its inception in 2003, the PEPFAR program has evolved considerably from one focused on responding to the emergent nature of the HIV pandemic in ways that partly ignored scientific consensus, to a program intent on using scientific evidence to inform its policies and evaluating the impact of its efforts. The shift in how the PEPFAR program and OGAC viewed the value of research and evidence seems to have coincided with the change in Administrations between President George W. Bush and President Obama and correspondingly, with the change in OGAC leadership. Thus, while the State Department is only one of many government agencies, it seems clear that the overarching policy environment of the executive branch was a critical influence on the institutional environment at OGAC. In addition, and more proximally related to PEPFAR, was the importance of Ambassador Eric Goosby's commitment and dedication to evidence-informed policy. His decision to create the PEPFAR SAB is perhaps the prime example of this.

Over the course of Ambassador Goosby's tenure at OGAC, the SAB discussed a number of issues that they were requested to provide guidance on by OGAC and that were added to the agenda by the SAB itself. The synergy between the priorities raised by the "demand side" (i.e., OGAC) and the "supply side" (i.e., the SAB) seems to have been a key contributing factor to the uptake of the SAB's recommendations. Although there were challenges with implementing, managing, and convening the SAB, findings suggest that having a staff dedicated full-time to the SAB, as well as prioritizing meeting agenda items more judiciously and managing SAB meetings more effectively could help to ameliorate some of the problems noted by respondents. However, to some extent these challenges are to be expected, given that this SAB was the first of its kind.

Although there appear to be some changes that could be easily implemented to facilitate more frequent and robust engagement between the SAB and civil society, such as more widespread announcements of the SAB meetings, the FACA-mandated public comment period remains a substantial barrier to real-time and meaningful interaction. With only 10 minutes and no response from the SAB or OGAC, it is not immediately obvious how to encourage greater engagement. However, findings suggest that informal communication has provided a sufficient if not preferred substitute to the opportunity to make formal comments during SAB meetings.

The PEPFAR SAB offers a striking contrast to the NCADAC (discussed in the next chapter) on many levels. However, these differences as well as the similarities between the two committees also offer interesting points for comparison, which are discussed in Chapter 7.

CHAPTER 6: THE NATIONAL CLIMATE ASSESSMENT AND DEVELOPMENT ADVISORY COMMITTEE – A CASE STUDY

I. Introduction

This case study provides empirical evidence about the role of the NCADAC in the drafting of the Third NCA. The evidence focuses on the operational elements of the NCADAC because while the final version of the NCA was released by the NCADAC in May 2014, it was technically submitted to President Obama and Congress, and then became a government document. Thus, given the boundaries of this case study, which span from April 2011, when the charter was signed, to May 2014, this case study does not address any policy actions taken after the release of the NCA[15].

The evolution of the program responsible for overseeing the drafting of climate assessments – the United States Global Change Research Program (USGCRP) – is described, beginning with the first announcement of a presidential initiative on global climate change made by President Ronald Reagan in January 1989, and including the relevant legal history related to the findings of assessments released prior to the 2014 NCA. This background information is discussed in Section II, and precedes a brief overview of the state of climate change science, which is presented in Section III. Core components of the NCADAC as it existed between 2011 and 2014 are discussed in Section IV, including the charter and committee membership. Section V addresses the findings from the in-depth interviews and NCADAC meeting documents. Section VI discusses the key

[15] While there have been several major efforts and actions by the White House related to climate change since the NCA was released, it is not possible to attribute those policy actions directly to the NCA because the endpoint of the case study precluded tracking such actions and more importantly, because establishing a causal link between the release of a report and a corresponding policy change is inherently challenging.

recommendations from the 2014 NCA with a focus on those related to research and public health. Conclusions are offered in Section VII.

II. Background

In January 1989, just before he left office, President Ronald Reagan announced a presidential initiative for fiscal year 1990 called the US Global Change Research Program. President George H.W. Bush reaffirmed the initiative when he took office and Congress passed the US Global Change Research Act (GCRA) on November 16, 1990 (P.L. 101-606). The purpose of the Act was to establish the USGCRP, which would understand and respond to "global change[16], including the cumulative effects of human activities and natural processes on the environment, to promote discussions toward international protocols in global change research, and for other purposes.

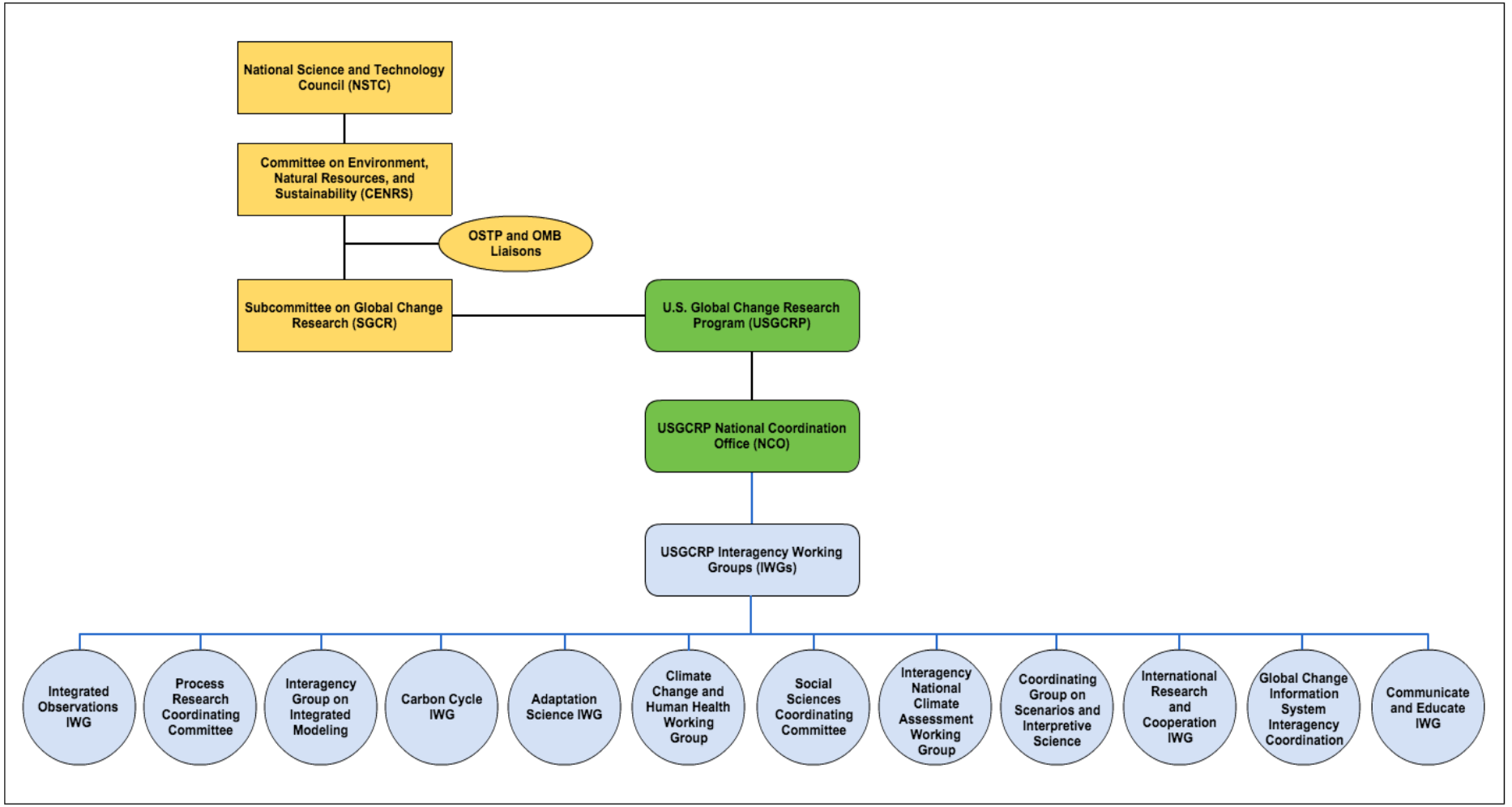
More specifically, the GCRA stipulated that the Federal Coordinating Council on Science, Engineering, and Technology in the Office of Science and Technology Policy (OSTP) in the Office of the President establish a Committee on Earth and Environmental Sciences (CEES). In turn, CEES was charged with developing a plan for how the USGCRP would be implemented, which was to be submitted to Congress one year after the GCRA was passed and at least every three years thereafter. As guidance, the GCRA did specify seven over-arching program objectives of the USGCRP plan, and an additional five elements for research, and three elements for coordinating across the US government and collaborating with other countries. Importantly, and most relevant to this case study, the GCRA also specified that an assessment should be prepared and submitted to the President and Congress every four years that:

[16] Global change was defined as "changes in the global environment (including alterations in climate, land productivity, oceans or other water resources, atmospheric chemistry, and ecological systems) that may alter the capacity of the Earth to sustain life".

- Integrates, evaluates, and interprets the findings of the Program and discusses the scientific uncertainties associated with such findings
- Analyzes the effects of global change on the natural environment, agriculture, energy production and use, land and water resources, transportation, human health and welfare, human social systems, and biological diversity
- Analyzes current trends in global change, both human- induced and natural, and projects major trends for the subsequent 25 to 100 years.

Currently, USGCRP coordinates the research arms of 13 government agencies which support the United States' response to global change. It is now overseen by the Subcommittee on Global Change Research, which is a sub-group of the National Science and Technology Council's Committee on Environment, Natural Resources, and Sustainability, which is, in turn, a committee of the OSTP. Thus, while there have been changes in the names of the entities involved in the oversight of USGCRP since its inception in 1990, the program is still responsible for managing relationships with a diverse array of government agencies and there remains a complex hierarchical layering of oversight, which ultimately begins in the Office of the President. The organizational structure of USGCRP can best be described with a diagram (Figure 6.1) (U. G. C. R. Program, 2014). This structure is important because of the implications it has for the government agencies, offices, and officials who have been involved in legal challenges to the conclusions of previous assessments.

Figure 6.1. Current organizational structure of USGCRP



III. National Climate Assessments in Historical Perspective

Although the GCRA did not mandate that USGCRP establish a FACA committee to develop the climate assessments, each assessment to date has been written by a committee that fell under FACA's purview. The 2014 NCA is no exception. In fact, the NCADAC was not only the largest committee established to draft a NCA to date, but was involved with the most comprehensive effort thus far to engage stakeholders across the country throughout the Assessment process. The first two climate assessments, issued in 2000 and 2009, respectively, were met with substantial backlash from conservative public policy groups and politicians which fueled legal action. In turn, these experiences led USGCRP and the NCADAC to engage in special efforts to comply with FACA and ensure that all meeting proceedings and NCADAC decisions were as transparent as possible. The relevant legal history and related events are discussed below.

There is some debate about the number of assessments which have been issued since the GCRA was passed in 1990. As mentioned above, the Act stipulated that an Assessment should be submitted to Congress and the President every four years. If this requirement had been adhered to, the latest Assessment would be the sixth NCA[17]. However, according to USGCRP, the 2014 NCA is the third assessment.

Previous assessments were drafted by FACA committees, but the name of the committee has changed over time. The first assessment was written by the National Assessment Synthesis Team (NAST), which was established by the National Science Foundation (NSF) as an independent FACA committee. Consisting of 14 members with an additional 10 individuals as lead authors, the NAST initiated the process of drafting the first NCA in 1997 by conducting 20 workshops around the country involving academics, representatives from manufacturing, power generation, and

[17] If one assumes that a national assessment would be issued every four years from the inception of the USCGRP in 1990, then there should have been assessments issued in 1994, 1998, 2002, 2006, 2010, and 2014.

tourism, and people who work closely with land and water ecosystems including resource managers, ranchers, farmers, foresters and fishermen. Scientific, university-led regional studies were initiated after most of the workshops, the results of which were then used to inform the National Assessment Report. The NAST released the "Climate Change Impacts on the United States: The Potential Consequences of Climate Variability and Change" report in June 2000.

On the day of the Assessment's release, the Competitive Enterprise Institute (CEI), a libertarian think tank, issued a press release stating that the Assessment was a "scientifically dishonest, alarmist document based on junk science and intended to advance a political agenda rather than provide a sober look at the state of the science and its uncertainties involving the theory of climate change" (Institute, 2000). On October 3, 2000, CEI and several other plaintiffs filed a lawsuit against President Clinton and Neal Lane, who was then the Director of OSTP (*Competitive Enterprise Institute v. Clinton, D.C. Cir., 1:00-cv-02383*). Given the hierarchy of supervision of the assessment process, President Clinton and Neal Lane were named as defendants. The lawsuit alleged that President Clinton and Neal Lane had violated FACA because the NAST held closed meetings and meetings without the DFO present. In addition, the lawsuit alleged that the GCRA had been violated because the NAST report had not been filed in the timeframe required by the GCRA and was incomplete. The third count named in the suit was an alleged violation of Public Law 106-74, which requires that if appropriated funds are to be used in completing assessments under the GCRA, any reports should be subject to peer review and released for a public comment period, neither of which occurred.

In spite of this lawsuit, the White House proceeded with steps to release the report. President Clinton sent a pre-publication version of the report to key members of Congress on November 11, 2000. A PDF of the document was put online on the same day, and printed copies were sent to Congress in early December with a cover letter signed by Neal Lane. In April 2001, the

final version of the report was sent to Congress and it was posted online in July 17, 2001. Ultimately, the lawsuit against Clinton and Lane was dismissed in September 2001 following a statement issued by Rosina Bierbaum, the then Acting Director of OSTP, stating that the information included in the NAST report was not a policy position or official statement of USG.

Two years later, on August 3, 2003, CEI filed another lawsuit, this time against President Bush and George Marburger, who was then the Director of OSTP. The suit alleged that the NAST Assessment violated a different law, the Federal Data Quality Act (FDQA), because the NAST used "demonstrably inaccurate computer models, and dissemination of historical temperature data that it modified to inaccurately omit the occurrence of recognized climatic periods" (*Competitive Enterprise Institute v. Bush* [D.D.C. No.03-1670]). Again, Bush and Marburger were named as defendants because of the oversight structure of the assessment process. The suit was dismissed after the White House settled with CEI, on the condition that the USGCRP website include language stating that the NAST and the reports it issued were not subjected to OSTP's Information Quality Act Guidelines. Essentially, this discredited the assessment and provided fodder for CEI to issue a statement that the NAST assessment was propaganda, not science. However, it should be noted that the FDQA did not exist when the NAST report was issued in November 2000: the FDQA was passed in 2001.

According to the schedule outlined in the GCRA, the next assessment should have been issued in November 2004. The NAST no longer existed under the NSF, so it could not be responsible for drafting the report. Instead, the Climate Change Science Program (CCSP), created by President Bush in 2002, was the entity which coordinated and directed US government responses to climate change and thus was responsible for issuing the 2004 assessment. CCSP issued a strategic plan in July 2003, which included a schedule for preparing 21 reports on specific topics related to climate change. CCSP thought these distinct reports would satisfy the GCRA's requirements for a

national assessment. The schedule indicated that all 21 reports would be completed by 2007, which was three years behind the schedule outlined in the GCRA and meant that seven years would have elapsed between the first and second assessments. Only two reports were completed by 2007 and by mid-2008, two reports were still outstanding. The distinct reports were compiled into one large report, titled the "Scientific Assessment of the Effects of Global Change on the United States", and was submitted to the President and Congress as being in compliance with the requirements of the GCRA (USGCRP, 2008).

In June 2009, the USGCRP issued another national assessment, titled "Global Climate Change Impacts on the United States". Initially, USGCRP stated that this report was *not* being submitted in compliance with the GCRA (Karl, Melillo, and Peterson, 2009). However, that position was reversed. Currently, this 2009 assessment is referred to as the second national assessment, with no acknowledgement of the 2008 assessment. As stated above, the 2014 NCA is referred to as the third national assessment. Ultimately, it seems the 2008 assessment is not considered in compliance with the GCRA, even though there is clear language in the front matter of the report stating it is submitted under that act. Thus, according to USGCRP, national climate assessments have been issued in 2000, 2009, and 2014. It is unclear why there is contradictory information about whether the 2008 report satisfies the requirements of the GCRA.

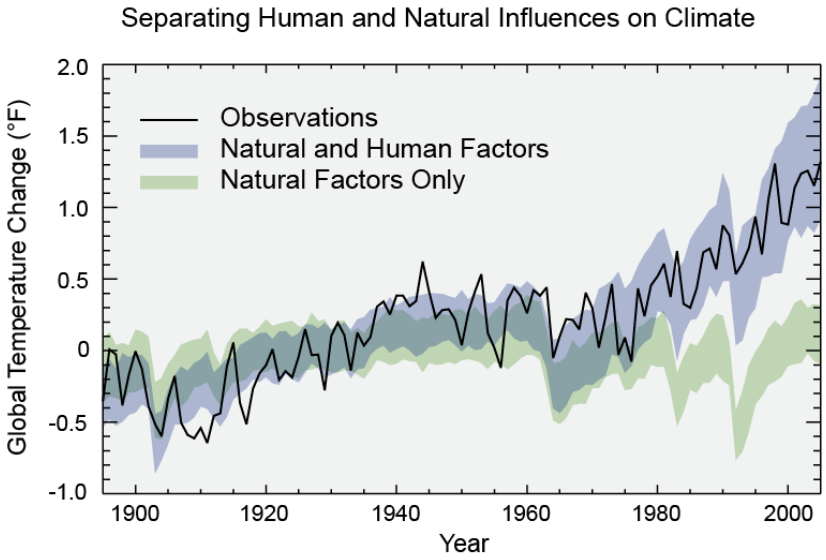
IV. Climate Change Science: A Summary of the State of the Field

There is global consensus that the planet is warming and that human interaction with the environment is the primary cause of global warming over the past 50 years (Figure 6.2) (IPCC, 2014; USGCRP, 2014). The Intergovernmental Panel on Climate Change (IPCC)[18], the international body

[18] There are 195 countries which are members of the IPCC, which was established in 1988 by the World Meteorological Association and the United Nations Environment Program. The objective of the IPCC is to provide policymakers with assessments of climate change science, the impacts and risks of climate change, and options for mitigation and adaptation, on a regular basis. The entire panel of 195 countries meets in plenary sessions to make major decisions while

which assesses the science related to climate change, issued its fifth assessment report in stages between September 2013 and November 2014, with three key messages: the influence of human activity on climate change is clear and increasing; urgent action is needed to avoid deleterious outcomes; and there are options available for the mitigation and adaptation of climate change (IPCC, 2013).

Figure 6.2. Influence of human and natural factors on global temperature, 1900-2000



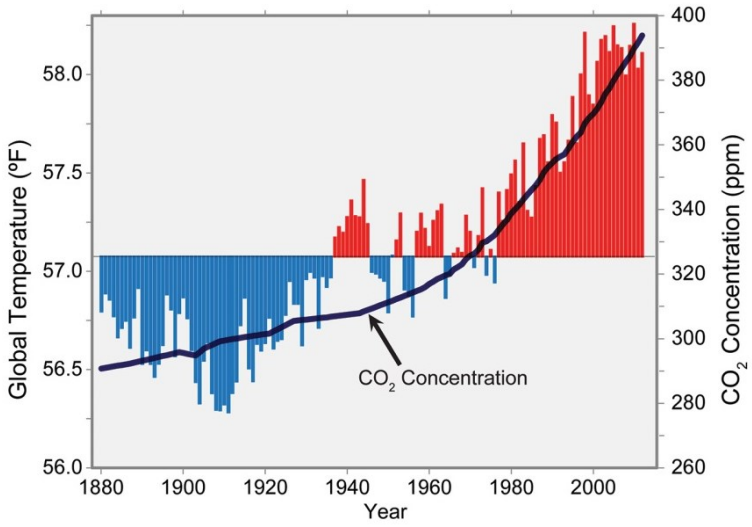
Source: Huber, M., and R. Knutti, 2012: Anthropogenic and natural warming inferred from changes in Earth's energy balance. Nature Geoscience, 5, 31-36, doi:10.1038/ngeo1327

While the NCA issued by the NCADAC focuses on climate change in the United States and the IPCC Assessment has a global focus, the messages from the IPCC and the NCA are mutually reinforcing. Thus, it seems clear that any debate about the causes of global warming exists among those who are on the fringe of mainstream science and deny what multiple sources of independent evidence have confirmed to be the case: the burning of fossil fuels, deforestation, emissions from agriculture and other human activities have increased the concentration of carbon dioxide in the

a smaller group of countries, elected by member governments, provides guidance and advice to the overall Panel on scientific, technical, and managerial issues.

atmosphere by over 40 percent since the industrial revolution (Figure 6.3) (U. S. G. C. R. Program, 2014).

Figure 6.3. Global temperature and carbon dioxide concentration (ppm), 1880-2000



Source: Karl, T. R., J. T. Melillo, and T. C. Peterson, 2009: *Global Climate Change Impacts in the United States*. T.R. Karl, J.T. Melillo, and T.C. Peterson, Eds. Cambridge University Press, 189 pp.

The implications of climate change both in the United States and in other countries are too numerous to name, but illustrative effects involve an increase in extreme weather events, projected decreases in agricultural yields, substantial adverse effects on marine ecosystems, and most germane to this study, threats to human health and well-being.

The key ways that climate change affects human health are through extreme weather events and wildfire, decreased air quality, and diseases transmitted by insects, food, and water (Alexander, Carzolio, Goodin, & Vance, 2013; Patz, Frumkin, Holloway, Vimont, & Haines, 2014). Extreme weather events such as Hurricane Sandy can be associated with mental health disorders such as depression and post-traumatic stress disorder, but also with adverse effects on a household's healthcare seeking behavior if finances are re-allocated to deal with other pressing concerns, such as re-building a house. Wildfires can impact air quality even thousands of miles away from the fire site.

For example, smoke from forest fires in Quebec in 2002 resulted in a 30-fold increase in airborne fine particle concentrations in Baltimore, Maryland, which is located over 1,000 miles downwind of (Luber, 2014). The length of the pollen season has increased in parts of the United States from 11 to 27 days between 1995 and 2011, which has effects on respiratory health, including allergies and asthma. Vector-borne and water-borne diseases such as malaria and gastrointestinal illnesses can be seasonal but have been shown to increase in incidence following changes in temperature and rainfall patterns (Alexander et al., 2013).

V. The NCADAC

On December 27, 2010, the FR announced that the NCADAC was being established by the DOC, which oversees NOAA. The notice indicated that the committee would consist of approximately 50 members total, 35 of whom would be scientists, educators, and other experts with expertise in "the full range" of scientific issues pertaining to climate change. In addition, there would be 15 individuals representing each of the government agencies in the U.S. Global Change Research Program. The notice also indicated that the NCADAC would be holding its first meeting on February 3-4, 2011, to discuss initial plans for the NCA.

A. NCADAC Charter

The first NCADAC charter was signed on January 11, 2011 and was renewed twice before the NCADAC issued its final report in May 2014. Interestingly, the first charter renewal was only for a six month period: it was renewed on January 11, 2013 with a termination date of July 11, 2013, even though at the time, the NCA was not scheduled to be released until mid-2014. It is unclear why the first charter renewal had a termination date six months from its renewal date given that all concerned stakeholders were aware that the NCA would not be delivered until nearly a year after the new termination date. The charter was renewed for a second time on June 24, 2013 and was set to

expire 90 days after the Third NCA was released to the public or on June 24, 2015, whichever came first.

As outlined in the charter, the NCADAC has three objectives: to synthesize and summarize the science on the impacts of climate change in the United States; to make recommendations for a sustainable national assessment of the impacts of climate change globally, and for adaptation and mitigation efforts in the United States; and to develop a National Climate Assessment. More specifically, the charter indicates that the NCA should be a report that:

1. "Integrates, evaluates, and interprets the findings of the U.S. Global Change Research Program (USGCRP) and discusses the scientific uncertainties with such findings;
2. Analyzes the effects of current and projected climate change upon ecosystems and biological diversity, agriculture, energy production and use, land and water resources, transportation, human health and welfare, and social systems, including in a regional context;
3. Analyzes current trends in global change, both human-induced and natural, and projects major trends for the subsequent 25 to 100 years;
4. Is a continuing, inclusive National process that synthesizes relevant science and information about changes in the Earth system as they affect the Nation's climate, and about how such changes relate to and interact with changes in social, economic, ecological, and technological systems; and,
5. Supports climate-related decisions by providing an information base in multiple formats, including Web-based and hard copy formats."

Ultimately, the major focus of the NCADAC was to develop the NCA. The other objectives, while important, were essentially components of the larger NCA effort.

The Charter indicates that the NCADAC shall comply with FACA, FACA implementing regulations, the Information Quality Act, and other applicable DOC regulations as it developed the NCA. The NCADAC reported to the NOAA Administrator, and per FACA rules, served in a purely advisory capacity.

The non-federal members served at the discretion of the Secretary of Commerce and were appointed for a term of three years, with the possibility for reappointment. This term length is

longer than the usual two-year appointment under FACA, but this was done to ensure continuity in NCADAC membership as the NCA was being developed.

The NCADAC organizational structure was outlined in the Charter, which states that the Under-Secretary of Commerce or her designee would appoint a Chair, two Vice-Chairs, and an Executive Secretariat, all of whom would then be responsible for managing the work of the committee. In addition, the Charter specifies that subcommittees can be created from among the NCADAC members as well as non-members, should specific subject-matter expertise be required. This structure is discussed in more depth below.

The Charter allows for the frequency of NCADAC meetings to occur as needed, as determined by the Under Secretary, Chair, and Vice Chairs. Over the course of its tenure, the NCADAC met in-person at least once a year, usually in Washington, DC, and held a number of conference calls in between the in-person meetings. Both types of meetings were open to the public. This investigator attended nearly all of the NCADAC in-person meetings and conference calls during the study period. Some members of the NCADAC attended the conference calls in person, which were organized by the USGCRP coordinating office, which is based in Washington, DC.

As stipulated by the Charter, NCADAC members served without compensation, although travel expenses and per diem were covered by the DOC upon request and subject to the availability of funds. As discussed below, there was a substantial staff supporting the NCADAC, which was paid for by NOAA's National Climatic Data Center. The Charter estimated that the annual operating cost for the committee was $1 million, and that 2.5 years of staff support[19] would be needed on an annual basis. However, the Charter also notes that additional funds may be available

[19] While the Charter does not specifically refer to full-time equivalent (FTE) units, the request for 2.5 years of staff support on an annual basis refers to 2.5 FTEs. This translates into two people working full time and a third person working half-time to support the NCADAC or some other combination of work by a number of individuals that adds to the equivalent of two and a half full-time employees.

through NOAA by contract or other means.

B. NCADAC Membership

A request for nominations for NCADAC committee members was announced in the FR on March 2, 2011. The announcement indicated that nominations would be evaluated and accepted if they benefited the overall composition of the committee. A lengthy list of criteria for the characteristics of nominees was included. In addition to specific areas of expertise, the FR notice indicated that the DOC was seeking members from a wide range of employers (e.g., private industry, government) and geographic regions within the United States, as well as members from a diverse array of backgrounds. Nominees were requested to submit a two-page resume as well as a statement about how they would assist the committee in meeting the goals outlined in its charter.

The March 2, 2011 FR notice also included a list of 49 individuals who had already been nominated to serve on the NCADAC, 33 of whom were non-federal members and 16 of whom were ex-officio members.[20] Thus, the request for nominations *in addition to* the already-named members was a departure from the December 27, 2010 FR notice which suggested there would be 50 members total. As discussed in more depth below, the member selection process was highly political: interview findings revealed that an initial list of members was compiled by OSTP and the Administrator of NOAA, with input from USGCRP, and subsequently submitted to the Secretary of Commerce who then requested that the nomination process be opened up through the FR. The initial list most likely consisted of approximately 50 individuals total, which is the number referenced in the December 2010 FR notice, while the March 2011 FR notice was most likely placed in response to the request from the Secretary of Commerce.

Of the 49 individuals named in the March 2011 notice, all but one of the 33 non-federal

[20] In general, FACA permits employees of federal government agencies to serve on advisory committees as ex-officio members to represent their agencies' interests. Whether these ex-officio members have voting rights is determined by the committee's charter or by statute. In the case of the NCADAC, ex officio members were *not* allowed to vote.

members served on the NCADAC, although it is unclear how or why this individual was excluded. Of the 16 nominees for ex-officio members, 10 did not serve on the committee, although another individual from their agency served in their place. Thus, all of the original 16 government agencies that were listed in the March 2, 2011 FR notice did have representatives on the NCADAC. The final NCADAC committee was comprised of a total of 60 representatives, which indicates that the nominations of an additional 12 non-federal members were accepted after the March 2, 2011 FR notice. Table 6.1 provides summary data on the organizational affiliations of the NCADAC members.

Table 6.1. Summary of NCADAC Members' Organizational Affiliation

Organizational Affiliation	Number of NCADAC Members *of which* (not US based)
University	22
US Federal Government Agency	16 ex-officio
Private Sector Company	7
Consulting Firm	6
State Government (e.g., public utilities)	5
Research Institution (not affiliated with a university)	2 (1)
Foundation	1
Non-Profit	1
TOTAL	**60**

All but one of the NCADAC members is based in the United States, although many serve on the IPCC.

VI. Interview Findings

This section discusses the results of the in-depth interviews conducted between March 2013 and September 2014 with NCADAC members, USGCRP staff, and managers or staff employed by advocacy groups active in the climate change community. In addition, materials from all NCADAC meetings between April 2011 and May 2014 were reviewed as part of the preparation for the interviews and attending the meetings as an observer. Relevant information from these documents is

included below.

The results are presented in relation to the aims and research questions described in Chapter 4. The results are presented in this way to ensure that there is a parallel structure between this case study and the PEPFAR case study and to facilitate the analysis across the two cases, which is presented in Chapter 7. In addition, presenting the results by aim, rather than by category of respondent, helps to maintain the confidentiality and anonymity of the interviewees.

A. Aim 1: The Role of the NCADAC in the Policy Process

The NCADAC is a different model of a federal advisory committee relative to the PEPFAR SAB and other FACs that were initially reviewed for inclusion in this research because its primary objective is to develop and deliver the national climate assessment to the President and Congress, rather than to provide general scientific advice and guidance to a government agency. One interviewee described the NCADAC in the following manner:

> This is a co-production model. It's not a model where the advisory board tells the agency a bunch of stuff and then goes home. Rather, the agencies are part of it, the committee is part of it, the public is part of it, the experts are part of it, and they all have a role and essentially the advisory committee has been in the driver's seat in terms of actually putting the report together.

Procedurally, this means that once the NCADAC delivered the final version of the NCA in May, 2014, it became a government document. Although representatives from 16 different government agencies served as ex-officio members on the NCADAC and were responsible for vetting drafts of the NCA with their respective agencies, and there was a 90-day period during which comments on the draft NCA were accepted anonymously from anyone, including government agency staff. Once the NCA was delivered, it was possible that the document could be changed without conferring with NCADAC members, USGCRP, or chapter authors. Thus, the potential for the NCADAC itself, as a federal advisory committee, to influence the policy process really occurs through the NCA. More

specifically, the potential for the NCADAC to influence policy depends substantially on whether the government accepts the NCA as delivered and then whether it decides to take action based on the findings and recommendations contained therein.

1. RESEARCH QUESTION 1: WHAT ARE THE MECHANISMS AND PROCESSES BY WHICH SABS FUNCTION, INCLUDING HOW THEY ARE STRUCTURED, IMPLEMENTED, CONVENED, AND OPERATE?

i. Implementing the NCADAC

The first meeting of the NCADAC was held in April 2011 but the strategic planning process for the 2014 NCA began in 2010. In January 2010, a draft outline of the NCA was circulated and served as the basis for four different meetings held across the country that year. Feedback from those meetings was incorporated into the draft outline before the first of three FR notices was published, which also solicited feedback on the topics to be addressed by the assessment. Throughout 2010, there were a series of meetings, workshops, scoping sessions, and other efforts which generated robust feedback that served as inputs for the NCADAC to use as the 2014 NCA was drafted.

a) NCADAC Adherence to FACA and Other Rules

At its first meeting in April, 2011, the NCADAC was presented with a number of background and briefing materials focused on the rules and regulations related to serving as a member of a FACA committee. The first substantive session of the meeting was a briefing provided by the Chair of the Subcommittee on Global Change Research on previous national climate assessments (USGCRP, 2011b). While there was no explicit mention of the legal challenges in years past, the briefing concluded by noting that the key issue for the NCA was adherence to the Information Quality Act (i.e., the FDQA), which meant that there were new demands for the use of data to be transparent and traceable to its source and for the NCA to go through a rigorous peer

review process that was itself transparent (Karl, 2011). Subsequent sessions were led by attorneys from the DOC's Office of General Counsel on FACA and the NCADAC Charter, ethics rules for NCADAC members, and the bylaws for the NCADAC (USGCRP, 2011b). Undoubtedly, the emphasis on the importance of adhering to FACA and other rules so early into the NCADAC's lifespan was related to the experiences of previous committees and their related assessments.

At times, adherence to FACA has created procedural challenges and additional work for both NCADAC members and USGCRP staff.

> I think FACA itself is severely flawed. One of the pieces of evidence is you know what we had to do in order to get the advisory board to a place where they were willing to vote to release the document. Essentially it has to be a public document for them to vote to release the document. And we would have had to make it public for them to approve it before they had approved it. That's crazy. And so they had to all individually sign in to webinars – a series of webinars – where they never all met together and talk about their issues individually. And then we had to sort of synthesize and respond to them over…we did it I think nine times. Nine times four or five because we did it four or five times for each [draft] between July and December to try to get them to a place where we could release the document for public review because we couldn't let it out as a public document before they had approved it. I mean that's crazy and ridiculous. So, there's some pretty serious problems with it. BUT, you know, the spirit of it is a useful thing.

The NCADAC bylaws are of particular interest because neither FACA nor the GCRA requires that bylaws be developed for its committees. The bylaws contain five articles: Oversight, Administrative Provisions, Membership, Committees, and Meetings. Article 1 draws verbatim from the NCADAC charter, as does part of Article 2. However, there is additional information contained in Article 2 which is not mentioned elsewhere, including that the DFO at NOAA be copied on all email communication between NCADAC members. In addition, Article 2 specifies how records and documents are to be maintained, noting that NOAA is responsible for keeping official copies of a variety of documents, including minutes of all NCADAC meetings and emails related to the

NCADAC. Article 2 also specifies how NCADAC members are to respond to press inquiries. Article 3, which addresses Membership, and Article 4, which addresses Committees, are discussed below. Article 5 discussed Meetings, including that they were to be called by the DFO and announced in the FR, which is required by FACA. However, the bylaws again departed from existing law by noting that a quorum was necessary for a NCADAC meeting to be held, and that decisions would be made by consensus (USGCRP, 2011a). Meeting materials were to be provided by USGCRP and NOAA staff to NCADAC members far enough in advance of meetings to allow members time to review any relevant documents. The bylaws suggested that USGCRP be permitted to develop processes for sharing materials with the committee. The outcome of this suggestion was a secure web-based system with access restricted to committee members and relevant government staff. Members of the public were not permitted to access this system, although the system was displayed on a projector during meetings.

Ultimately, the bylaws reiterated the information in the NCADAC charter and expanded on some of the key elements of the FACA law. In addition, they served as a reference for NCADAC members for how some of the operational and procedural elements of the committee should run so that transparency was maintained.

b) NCADAC Member Selection

As mentioned above, a FACA committee has been established for all previous national climate assessments. Respondents indicated that the rationale for establishing a FACA committee for the 2014 NCA stemmed not only from repeating what had been done in years past but also from recognition that the federal government did not have all of the expertise needed to develop a robust assessment. One interviewee described the rationale for using a FACA committee for each assessment in the following manner:

> I think there was a conclusion from the beginning which was essentially the Clinton Administration that the federal government didn't actually have all of the knowledge to do this properly. And also to properly assess the impacts on sectors we couldn't just have a government perspective. That there needed to be external sources of information and as soon as you sort of need to have ongoing input from an external bunch of people you essentially are in violation of FACA [if you have not already established a FAC]. So, I think it was essentially just…I don't know that it would have been done this way in the absence of FACA but in the presence of it there didn't seem to be any options.

Further, a respondent indicated that the credibility of the assessment would be enhanced by using a committee of external advisors:

> In addition, because climate change can be a controversial topic, they felt that it might be better to have an external body putting together the information and drafting the report so that it was felt to be less biased and more…independent essentially of any government opinion. So that was the reason for establishing a federal advisory committee for the initial drafting.

As mentioned above, the process for selecting the NCADAC members was highly political. One respondent described the following:

> But this was the first kind of effort at a 'what are the implications of the global warming program for the United States'. Having people who could represent [IPCC Working Group 1] but then moving on to the impacts and implicitly to the adaptation issues. Specifically at first not dealing with mitigation because it got into energy policy and it got so close to political controversy that the USGCRP was told to stay on the science side of the fence and let the policy people deal with mitigation issues. So at first it was a small group. It was a mixed bag of people…each one brought a different kind of expertise that seemed to well represent that area, that expertise, whether it was wetlands or climate modeling or observing systems. The NCADAC, now they wanted to also deal with issues of decision support. They wanted to deal with issues of mitigation. They wanted to start discussing adaptation policy implications a little bit more directly. They wanted to create a more substantial communications outreach. They wanted to create a sustained assessment process so how to deal with stakeholders is an expertise area; it's practically an academic specialization, a think tank specialization. They wanted private sector input. You wanted people who understood state and local. Then they started representing all the

agencies ex officio.

NCADAC member selection was also a lengthy process. One interviewee provided the following information about the timeframe and process for selecting the committee members:

> It took 18 months and it was ridiculous. I mean part of it was it was fairly early in the Administration and I don't think everybody understood how to do these things…and then it took a long time to get agreement on how to do the nominations and then after the nominations, the selection and then the back and forth about who and why and what the criteria were and all that kind of stuff. And I would say there were negotiations over the names for six months before we got to a point where there was even a list. Obviously [the members] had to be asked whether they would actually do it or not and if they said no, then there had to be back ups and blah blah blah. So it was pretty complicated. And then there was the second round where people were added.

One respondent described the process that occurred after the FR notice (the "second round" mentioned above) in the following manner:

> Once all the applications came in, there was a small committee made up of staff from the Commerce Department, OSTP because they're very interested in this and they have a role in the US Global Change Research Program, NOAA, and I think that's it. Those were the three main players. So there was a small committee that then went through all of the applications and looked at all of them and determined what the right mix was of people…and people with expertise, people with experience in serving on committees or people who might have served on the committees who did the previous national climate assessments. So that's how it was done for the NCADAC. And then they came up with recommendations and the Secretary of Commerce and the NOAA Administrator took that list and reviewed it and made their decision about who should be included on the committee.

Approximately 150 applications were submitted following the FR notice. Although interview respondents provided some mixed information about exactly which government entities were involved with decisions about member selection at which stage of the process, it is clear that the selection process was not only highly political but also involved very high-level officials in the US

government, specifically the White House OSTP, the DOC, and NOAA.

In terms of selecting a Chair for the NCADAC, respondents indicated that a number of qualities are important for the person in that position to possess. One respondent noted that:

> I think you generally want somebody who's going to work well with the staff; you want somebody who's going to work well with the other members…it's everything you could imagine for somebody who's a committee Chair. You want somebody who's good at building consensus but if the committee is struggling to reach consensus can sort of break it down into okay here's essentially where we need to go and can sort of push the committee when the committee needs to be pushed and knows when to step back when the committee needs a little more breathing room. I think you want somebody who's not too autocratic, who's willing to…somebody who also works well with the NOAA Administrator, but you know, so there's always this sort of dance because the Agency is not allowed to exert undue influence on an advisory committee but at the same time, the Agency wants to let the committee know what it's interests are and the committee wants to know what the Agency's interests are so you have to…you want to have somebody who can handle that sort of delicate balance.

c) NCADAC Membership Balance and Bias

Under FACA, the establishing agency is required to submit a balance plan to GSA when the request for approval for the advisory committee is accepted. The agency has some discretion about what criteria are included in the balance plan and the relative importance of those criteria. However, GSA reviews this plan and ultimately approves it. In the case of the NCADAC, a respondent indicated that the following criteria were important for balance:

> From what I recall from the NCADAC…I think the first criteria (sic) was expertise, scientific expertise in the area of climate and the specific areas of climate that the Assessment is looking at. Whether or not they had served on committees before, whether they had that experience was part of it, and there's also some consideration given to diversity which involves things like gender, ethnicity, other aspects of diversity, so that was sort of a final consideration that was given is there also a mix of people with diverse backgrounds who can bring diverse opinions in that respect… geographic representation was also important for the NCADAC in particular because they're doing regional chapters so we wanted to have people on the

> committee who would be able to look at California or the west and be able to serve as the experts on climate assessment in the Western United States or the northeast.

As discussed above, the NCADAC was initially conceived as a committee that would be comprised of approximately 50 members total, but ended up having 60 members. This increase was due to the request for nominations announced in the FR in December 2010, which in turn, was related to the apparent perception that the initial list of members was not optimally balanced with respect to the perspectives of committee members.

> There were internal discussions and concern that it wasn't as balanced as it could be or should be and at that point suggestions were made to add to the membership and those suggestions came both to the Federal Register notice and called for nominations or self-nominations and from particularly the lead agency NOAA and maybe others in the inner circle of politics…but it was the White House and top levels of NOAA who came up with additional names. Those nominations were then added to or considered and then there was an executive decision made by the co-chairs and by the top levels of NOAA because it's a NOAA federal advisory committee in terms of who should be on it. So it gets decided at that very, very high level but a lot of the leg work of pulling together the best of the best gets done at the staff level of the NCA.

By the time the bylaws were presented to the NCADAC at its first meeting in April 2011, the number of non-federal members had been revised to approximately 40, which is in line with the actual number who served on the committee (44). The bylaws make specific mention of the balance issue, stating that "to assure a balanced representation of views among preeminent scientists, educators, and other experts reflecting the full scope of issues addressed in the National Climate Assessment, the committee shall have approximately 40 non-federal members" (USGCRP, 2011a). The inclusion of 13 individuals from private sector companies or consulting firms suggests that special attention was paid to ensuring that there was both real and perceived balance of views represented on the committee. One respondent confirmed this:

> First of all there are NGOs represented on the advisory committee and so is Monsanto and a bunch of other people. So, I think there was a pretty deliberate and pretty successful attempt to have a balance of perspectives in the NCADAC and in the Executive Committee.

Ex officio members would be representatives from the 13 USGCRP agencies as well as the NSTC Subcommittee on Global Change Research, the Council on Environmental Quality, and the Department of Homeland Security. Ostensibly the participation of individuals from all of these agencies was part of an effort to ensure or at least facilitate buy-in to the NCA process by USGCRP partners. However, some respondents were concerned about this participation by representatives of federal government agencies:

> The ex officio feds are supposed to be independent of the advisory committee. It's not an arm of the government. It's advice to the government. The feds who are on the National Assessment Synthesis team for the first assessment were technical experts. But they weren't there to represent the government. They weren't there to represent their agencies' interest. But on the NCADAC it may have just been naively you know "we want to have the federal government as a stakeholder for this assessment". You know, "we want to have all the stakeholders' input". But they basically have some of the USGCRP principals, you know the agency representatives to the USGCRP – all people in similar positions being put on the NCADAC. These people have a tendency to be turf conscious. Their career is engaged not necessarily with intellectual honesty, it's with protecting their agency.

Ultimately, the concern about ex officio representation related to conflict of interest. According to one respondent, "now the NCADAC has members on it whose agencies are funding this study and to whom the National Climate Assessment is being delivered. It's too incestuous. I don't like it."

The issue of bias among non-federal NCADAC members was not raised by interviewees as a concern, at least with respect to members expressing views or pushing for certain agendas because of the potential for financial gain. The distal relationship between the NCADAC members' activities and any potential funding may have played a role in this: while the DOC, through NOAA, had

established the NCADAC, the committee was interacting most closely with the USGCRP, which coordinates the research arms of various federal agencies but does not have a readily apparent direct funding mechanism for individual climate scientists (USGCRP, 2014). Further, throughout the committee's existence, it was unclear whether and to what extent the recommendations contained in the NCA would be adopted by the government and thus whether any member could stand to benefit from additional or new funding for research, for example.

However, there is an interesting dynamic with the NCADAC membership given that the 2014 NCA is the third (or fourth, depending on whether the 2008 assessment is counted as complying with the GCRA) climate assessment. Many individuals who served on the NCADAC had participated in the previous assessments, either as members of the committees that drafted them or as government officials at OSTP or the USGCRP. Interviewees noted that many of the members had been involved with climate assessments previously, but the broaching of this subject was not attached to concerns that members were biased in any way. In fact, it was just the opposite. Participation in previous assessments was viewed as an asset:

> But the same core group has been involved in all of those. And I think as with Academy committees they are brought in in part because they have a track record for how these things get done. The scientific assessment is a genre of activity. It's an important intellectual creation in the science policy arena over the last several decades. It's not just a state of the science summary. It's a state of the science in terms of the implications for whom the assessment's being written. It's a large, cumbersome process that involves many inputs, many kinds of interaction. And in order to give these things shape they tend to draw on a similar cast of characters.

Given the timing of when the previous assessments were released – namely under two different Democratic administrations (Clinton and Obama), which have a proven track record of putting more stock in the science behind climate change assessments and acting on their recommendations – one could argue that re-appointing the same experts to successive assessment committees

introduces bias simply because the same perspectives are represented time and again. However, at least in the case of the NCADAC, it seems there was a concerted effort to introduce new thinking into the committee, as described in the section on Member Selection.

ii. Managing the NCADAC

a) NCADAC Staff Support

The National Coordinating Office (NCO) of USGCRP had a staff of 12 people dedicated to assisting the NCADAC develop the National Climate Assessment. There was additional staff at the National Climatic Data Center in Asheville, North Carolina. The volume of work with which this staff provided assistance was described as the following:

> It is a very complicated thing that involves lots of different people. We have an expert staff, we have about six people here, about 14 people in Asheville and what we've been doing is helping [the NCADAC] do what they need to do…help them with the writing, help them with the workshops…we've held 70 workshops in two years. We've written 14 methodology reports to help people use consistent methodologies, we've built an information system, we have an online resource for all the authors to engage. We've facilitated the nomination process for the authors – who are not the actual NCADAC authors – the 240 others. So, [there was] all kinds of administrative and technical support.

Funding for the NCA staff was contributed by the USGCRP agencies and the EPA and included detailees from NOAA, National Atmospheric and Space Association (NASA), Department of Energy (DOE), Department of the Interior (DOI), NSF and USDA. These funds were used for ongoing Advisory Committee support, publications, workshops, web support, data architecture, and training, among other activities. In addition, each agency provided extra funding to support Assessment staff, travel, the review of the NCA by the National Research Council (NRC), and contracts for writing/editing, data management and peer review. This commitment to funding the Assessment was made by the USGCRP Principles in October, 2010. This conglomeration of

funding from the USGCRP agencies was necessary to ensure that the NCA was completed. However, the program is not without challenges due to its design. One respondent offered the following:

> The USGCRP is a very disaggregated entity. It's the agencies…there's no hammer, there's no CEO, there's no unified budget. It's a synthesized budget out of the budgets of different agencies with different leadership and missions made to look like a program. It's really a composite of many things. The best people in it try to make sure that the key things get covered the best they can…

Given the sheer volume of work involved with developing the NCA, including the strategic planning process which started in 2010, as well as the size of the NCADAC, it seems that a large staff was a critical element that facilitated the day-to-day operations of the NCADAC as well as the production of the NCA. In the words of one respondent, the staff "ha[s] literally forced all the square pegs through the round holes to get everything done." It remains to be seen whether future assessments will require such a large staff given the focus through the NCA 2014 on developing a sustained assessment process, precisely to try to avoid having to reinvent the wheel every four years.

b) NCADAC Organizational Structure: Chair, Vice Chairs, and Executive Secretariat

Article 3 of the bylaws specifies that the NCADAC will be governed by one Chair, two Vice-Chairs, and Article 4 discusses an Executive Secretariat. One respondent noted that the impetus to use this structure was the large size of the board:

> And then because that became so big that's when the decision was made to have the smaller executive secretariat. It's representative. It has academia and so on and so forth. It's obviously much less diverse but by necessity. It needs to function.

The Chair was appointed by the NOAA Administrator and served as the chief executive officer of the NCADAC. His role included general supervision of the NCADAC, including presiding over NCADAC meetings. Additional specific duties outlined in the bylaws included the following:

- Liaison - Serving as a liaison with the DFO and staff assigned from NOAA and USGCRP;
- Communication - Maintaining communication with the NCADAC members;
- Key Issues - Framing questions for deliberation and articulating the scientific dimensions of key issues;
- Tracking Actions - Moderating and chairing deliberations of the NCADAC and tracking the actions;
- Tasks - Assigning tasks to subcommittees within the NCADAC;
- Results - Summarizing the results of deliberations to produce recommendations and articulating the "sense of the group" relative to reaching broad based concurrence; and
- Presentations - Responding to/ planning for potential presentations at select venues.

The role of the Vice-Chairs was to serve in the Chair's stead, should he be unable to act. In fact, the Vice-Chairs of the NCADAC played substantial roles in assisting with decision-making, contributing to the development of content to be discussed and decided upon at NCADAC meetings, and to the drafting of the NCA itself. The Executive Secretariat was to consist of between five and 15 members to be named by the NOAA Administrator. In fact, there were 10 members of the Executive Secretariat. Interestingly, the bylaws note that any meetings of the Executive Secretariat would be subject to the same FACA rules that govern the full NCADAC. However, it is not clear that this was carried out in practice, because there were no FR announcements of Executive Secretariat meetings, nor were minutes of these meetings made available to the public.

Aside from the specified duties of the individuals holding these leadership positions, respondents noted that the personal character and style of working are critical factors for ensuring assessments are completed:

> So there's kind of a screening process for how people get onto Academy committees and these assessment things. And it tends to weed out people who are highly idiosyncratic and bring kind of agendas that they're trying to cram down everyone's throat. People can see in their world of collegiality where the collaborative, collegial expertise is. And those kinds of people tend to end up on these. The Academy committees might be full of a little bit more academic raw edge, idiosyncrasy types but even there they have to understand the role of the National Academies senior

> staff in choosing these committees. It's a not well understood, under-appreciated role that they play because their job depends on getting these studies done. And so they bring in the kind of people who will not gum up the work or run the thing off the rails because of personal intellectual style. So I mean that's one of the guiding principles for how these things get set up and operate. Because the process is too complicated to accommodate people who aren't team players.

c) NCADAC Working Groups

Article 4 of the bylaws addressed NCADAC committees, including sub-committees, which were considered formal standing bodies under the full NCADAC and thus subject to FACA rules, and ad hoc committees, which were temporary but still had to bring their work before the full NCADAC. Importantly, ad hoc committees were not subject to FACA rules. The working groups created by the NCADAC were considered ad hoc committees. From an operational perspective, this meant that any conference calls, meetings, or draft reports or chapters written by the working group members did not have to be provided to the public. However, members of the public were permitted to request such information under FOIA.

At the April 2011 meeting, NCADAC members were asked to complete a form indicating the topics to which they would be interested in contributing, and in what capacity. Even at that early stage it was clear to members that the topics were really working groups: the form asked members to note how they would like to contribute, listing options such as being a leader of a working group or a chapter author, among others.

Given the size of the NCADAC, and to ensure that the committee delivered the NCA in a timely fashion, 15 working groups were formed (Table 6.2) according to the topics that had been outlined during the 2010 strategic planning efforts. Each group had one or two leaders, drawn from the non-ex-officio members of the NCADAC. There was also "staff support" for each working group that was also drawn from the NCADAC membership but could include the ex-officio

members. Then, in addition, there were "other members" who were not NCADAC committee members but staff of government agencies or USGCRP.

Table 6.2. NCADAC Working Groups

Working Group		No. of Leaders	No. of NCADAC Members	No. of Additional Staff	Government Agencies and Other Institutions Represented by Additional Staff
WG 1	Outline, NCA Strategy, and Federal Agency Activities	2	20	0	N/A
WG 2	Engagement strategy and requests for information	1	13	0	N/A
WG 3	Scenarios and regional summaries	1	21	14	DOE, NOAA, NCAR, UCSD, NASA, USACE, Census, UofA, NPS
WG 4	Peer review and data management/portal	1	8	1	
WG 5	Request for Information	2	7	0	N/A
WG 6	Information Quality Assurance	2	8	6	USGCRP, OMB, NOAA
WG 7	Engagement, Communication, and Evaluation	2	12	1	USGCRP
WG 8	Regional Coordination	2	15	0	N/A
WG 9	Sectoral Coordination	2	17	18	USGS, USACE, DOE, DOT, USDA, USFS, NIH, NOAA, NASA
WG 10	Science of Climate Change	2	2	14	NOAA, U of SC, LLNL, NCAR, LBNL, Texas Tech U., Purdue
WG 11	Agenda for Climate Change Science	2	3	0	N/A
WG 12	Adaptation and Mitigation	3	16	5	University of Michigan, PNNL, DOE, Chevron, ORNL
WG 13	Indicators development and evaluation	3	7	12	Information unavailable
WG 14	International	1	14	2	USGCRP, DOS
WG 15	Sustained Process	2	5	0	Information unavailable

As the NCA was developed, USGCRP staff kept careful track of the progress made by each working group. At nearly every meeting, a status update was provided to the NCADAC which included whether each working group had its work approved, proposed, or terminated. Each working group developed a proposal for its scope which was then 'submitted' for approval. The

approval process involved three steps: approval by the Chairs, then approval by the Executive Secretariat, and then approval by the entire NCADAC. The date of each phase of approval was recorded. Once the work had been approved by the entire NCADAC, the working group was considered "terminated". The careful tracking of the working groups' existence was important for the NCADAC because the working groups were ad hoc committees not subject to FACA: it was critical to document that the groups existed only on a temporary basis to justify and demonstrate in a transparent manner adherence to FACA rules and the bylaws.

iii. Convening the NCADAC

The NCADAC met 16 times between April 2011 and May 2014. Seven of these meetings were in person meetings and the others were held by conference call. All of the in-person meetings were held in the Washington, DC area except for one, which was held in Boulder, Colorado. The committee met four times in 2011, five times in 2012, six times in 2013, and twice in 2014.

Attendance at the meetings – both those held in person and by conference call – was high because there had to be a quorum of members present for the meeting to be held. Initially, the proposal for a quorum meant that at least 33 of the 44 voting-eligible[21] NCADAC members had to be in attendance for the meeting to actually happen, although it was decided that a quorum would be reached if 50 percent plus one voting NCADAC member were in attendance (i.e., 23 of the 44 voting-eligible members). Participation by phone was permitted for inclusion in the quorum but email or proxy participation was not permitted.

a) Setting NCADAC Meeting Agendas

Ultimately, the topics discussed at each meeting were determined by the Chair, Vice Chairs, and the Executive Secretariat. However, there did not seem to be a lot of latitude in terms of what

[21] The 16 ex-officio members of the NCADAC were not allowed to vote.

issues were discussed given that the committee was held to a very tight schedule for drafting the NCA. Thus, at the conclusion of a meeting, it was clear that the issues that would be discussed at the next meeting would be those requiring follow-up from the previous meeting. Further, given that there was a sub-group of members serving as the committee's leaders, discussion of issues by other members during meetings was rather limited. Agenda items were presented as either "informational" or "decisional". Time was allotted for discussion with both types of agenda items, but at the meetings this investigator attended as an observer, there was very little discussion among the committee members.

b) Managing NCADAC Meeting Discussions

It took over a year for the NCADAC to make a final decision about how meeting discussions would be managed. As noted above, the bylaws presented at the first NCADAC meeting held in April 2011 included a section noting that decisions would be made by consensus. This issue was raised again at the June 2012 NCADAC meeting, during which a proposal was made to have all committee decisions made by consensus and if for some reason it was not possible to reach consensus, a vote would be taken of the NCADAC members present, assuming a quorum was reached. At the next NCADAC meeting, held in August 2012, the proposal for NCADAC decision-making had changed: voting was no longer included because it was considered inconsistent with the pursuit of consensus, although the proposal to decide issues by consensus remained.

Respondents indicated that opting for a consensus-based decision making process is not typical for federal advisory committees, and had not been used in previous national climate assessments. One respondent noted there are advantages and disadvantages to moving forward with any approach:

Well I mean so if you have a non-consensus based decision-making process you

> might be able to move much more quickly on certain issues. But if that's the case then the question becomes so is it a dictatorial sort of thing? The chair determines what you do. Then in that case with 60 members, the NCADAC or a federal advisory committee is essentially a show. It's just a farce. You don't need that. If you do something that is majority based, sort of democratic if you will, and you just go with what the majority wants, you may end up with a somewhat less efficient but moving forward kind of process but you may lose a lot of people's trust in the process or belief in the outcome if you just sort of drag them along and whatever. So potentially there's quite a fall off of participation or of people feeling like well 'I wasn't heard'.

Respondents also indicated that making decisions by consensus was not always easy:

> This is a hierarchical organization. The decision making is all the way to the top. It's not, we are consensus-based officially. I think we're learning how to do that. I think it's not something we have grown in people's blood how to do that. It's not an easy process. And so what decisions ultimately get made at the very top and things are very heavily influenced by [the Chair].

If there had been discussion, debate, or disagreement about issues, those seemed to have occurred in advance of the meeting itself. Moreover, the timeframe for both informational and decisional items was often very brief: meeting agendas were quite full and there was not much time for discussion. One interviewee noted that:

> I felt like the dialogue, the conversation was somewhat…I felt like sometimes it was a little bit stiff. But the formal dialogue process – you need to be recognized, and you know it maybe that's a good thing but I sometimes worry that it or you had very strict limits. You're only allowed to talk about this for 15 minutes. I wonder to what extent that having a kind of very formal process changes the dynamic and the types of results that come out of it.

It is possible that discussion was limited because committee members were content with the top-down nature of decision-making or perhaps members did not feel it was worth their time to raise issues if they had concerns, given that they knew the Executive Secretariat had such influence over the process. However, there were two examples given by several participants of when the

consensus-based process delayed the release of draft versions of the report and was tedious for all involved. In one instance, one individual was concerned about a draft being released that was not of adequate quality. The requirement that decisions be made by consensus meant that USGCRP staff had to engage to assist in resolving the dispute about the draft. One respondent described the process in the following way:

> It just took a long time and I think to the credit largely of the staff who worked with this person and then being the go-between to the relevant authors who were affected or the comments were directed…whose text it was directed towards, that was just a tedious process and it took a lot of individual meetings. It took a lot of email exchanges, it took a lot of working it out. And in my view actually the most constructive process in this regard was to come up with alternative wording so that the reviewer could say, 'yes I can live with that, no I can't'. So it wasn't just 'no this doesn't work' but it was to come up with alternatives so we could move forward. And it ultimately ended up delaying the report by a few months but I think like I said ultimately probably to a better end.

The second instance of the consensus-based process causing delays happened when the NCADAC was deciding whether to keep comments received during the 90 day public comment period anonymous.

> People who are particularly experienced in IPCC where you see the name of the commenter, they basically felt it helps them a lot in helping to get a better feeling for where is this person coming from, and that helps them give a response, you know, and make the appropriate or not appropriate adjustment. And some other ones of us felt that's precisely the problem. Knowing who someone is should not color how you respond. You should take the thing at the face value and take it seriously and professionally, and politely respond no matter who it is who said it, whether it comes from a kindergartner or a climate skeptic or your grandmother or your dearest colleague in your field. It shouldn't matter. And so in the end that is what we agreed upon: that the reviewer identity will only be made available along with the comment and our responses at the very end.

Overall, it seemed respondents – even those who initially preferred to handle comments in the same way as the IPCC – agreed that treating comments anonymously enhanced the credibility

and legitimacy of the peer review process.

2. Research Question 2: To What Extent Does the Theoretical Disconnect Between the Literature on the Health Policy Process and the Literature on Evidence-Based Policy Have Empirical Support?

As discussed in Chapters 1 and 2, the traditional model of the policy process assumes that policymaking is inherently linear, with policymakers engaged at each stage as rational actors. The push for policy to be more evidence-based or even evidence-informed relies heavily on these assumptions. Critics suggest these assumptions are flawed and argue that any call for policy to be evidence-based ignores the reality of the policy process, including that it is inherently irrational and political. This case study provides an opportunity to assess whether this disconnect has any bearing in practice. Overall, the evidence suggests that at times, the disconnect does bear out in practice, but at other times, it does not. There is support for a number of the different theories of the policy process as well as different models of the research-policy relationship.

The inherent assumption of the step-wise or cyclical models of the policy process is that policymaking occurs in a series of stages and that policymakers are capable of making rational decisions at each stage. With respect to the use of research findings or evidence, an implication of these models is that a problem is defined, and research is conducted which then informs the policy solution to that problem. Findings from the in-depth interviews suggest that there is support for these assertions, although in an attenuated fashion. Research was not commissioned by USGCRP expressly for the NCADAC to use as an input into the NCA, so in that sense, the ability to attribute policy change to research findings is difficult.

In terms of models of the research-policy relationship, the example of the NCADAC and the NCA provides support for some models and not for others. There is moderate support for the problem solving model, which suggests that research findings help solve policy problems by

applying empirical evidence directly to a specific policy issue, which is then resolved because the gap in knowledge is filled (Weiss, 1979). To date, the numerous policy issues in the climate change arena have not been resolved even though two major assessments – the 2014 NCA and the 5th IPCC report – were released close together and have similar findings. However, the intention of these reports was to fill a gap in knowledge about the state of climate change in both the US and globally. Presumably, if the recommendations contained in the reports were acted upon by policymakers, then we would observe improvements in the problems caused by global warming, albeit over a lengthy period of time.

In contrast, there is strong support for the linkage and exchange model, which suggests that when the interface among researchers, policymakers, research funders and knowledge purveyors – all of whom are stakeholders involved with the NCADAC – is strong, research will be used (Lomas, 2000). However, in the case of the NCADAC and the 2014 NCA, respondents generally agreed that the interface among relevant stakeholders was not as strong as it could be, but that with a stronger interaction, national climate assessments could be far more useful for policymakers.

> In other words it's interactive. It has to be interactive. The report is almost an artifact of the interaction. It's in the interaction that people will get smart and have their thinking shaped. Then it'll be 'oohhh'. You know. 'We need to do this here in Seattle'. You know? People in the mayor's office, a light bulb will go off if we spend enough time talking with people at the University of Washington who know about this stuff. So, it's that, I think. It's not the report. But I'm not sure that a FACA is really set up to quite engage in that kind of sustained dialogue. It has to come to grips with management. Not keep management at arms-length. If you're going to do decision support you have to think like management and management has to think a little bit more like scientists.

One way this interface occurs is when policymakers ask researchers for advice on pressing policy problems and researchers aim to provide solutions. Given that a national climate assessment is mandated by law to be issued every four years, it is not readily apparent how policymakers would

request advice on particular issues related to climate change. Although, the strategic planning process that began in 2010 sought the input of officials around the country at various levels of government and the 2014 NCA content was developed from these inputs. Thus, perhaps with continued engagement through the sustained assessment process emphasized by the NCADAC, this interface could be strengthened. One respondent provided support for this by stating the following:

> You need somehow an ongoing process in which the relevant scientific, engineering, technical, and economic expertise is brought together in an ongoing interaction with people who have management responsibilities in various areas, whether it's transportation infrastructure, water infrastructure, local government, or coastal zone management. And they need to learn how to talk to each other. So that the decision makers can get – they don't have to become scientists but they have to learn enough to figure out what they can potentially get from the experts and the experts have to be able to put themselves in the shoes of management...But it needs to be interactive. It can't just be delivering a report. The production of the reports periodically, if done properly, should be done in the context of establishing that interaction…The report itself can't do that but the process that can be initiated in the production of…specific papers, specific workshops, specific consultative relationships.

The general utilization theory model posits that there must be a change in social context which leads to a change in policy issues for policymakers and researchers to interact (Nutley, 2007). It could be argued that the change in the Administration and its new approach to using data to inform policy was a change in social context that allowed certain policy issues to be brought to the fore, which were then discussed by the NCADAC and included in the NCA. Further, the NCADAC "adapted, recreated, [and] transformed" the science behind climate change into information that was more easily digestible for policymakers (Nutley, 2007, p.100). However, as discussed in the next section, some respondents were skeptical of the extent to which the Obama Administration is truly comfortable with climate change science.

The two communities' model, which is based on the premise that policymakers rarely use research because of fundamental differences between how researchers and policymakers operate,

has strong support. Perhaps because of the variety of levels of government (i.e., federal, state, local) involved in policies related to climate change, and more specifically, that could take action as a result of the findings of the NCA, there are more opportunities for policymakers to use research – or not – relative to a policy issue that was focused on only one level of government (e.g., the state level). Respondents recognized that challenges in using research exist on both the "supply" (i.e., scientist/researcher) side and the "demand" side (i.e., policymaker/manager):

> The problem is not just that the advice is irrelevant because it doesn't go far enough, it's that the receiving end doesn't know what to with the good advice they get sometimes. It's a double-edged problem.

Further, respondents discussed the need for researchers to provide policymakers with information that could be used to support their decision-making efforts. Until assessments like the NCA re-orient their approach toward this concept decision support, respondents felt there would be minimal utility of such massive efforts:

> It was intellectually fascinating but it's not decision support. There's something missing. It's written by academics. They don't understand the world of federal management budget and program. They don't understand the world of infrastructure engineers. They don't understand the world of mayor's offices. It's not decision support.

In contrast, there is little support for the enlightenment model, which suggests that policy is not changed due to the findings of a specific study but rather because general ideas rooted in research almost unconsciously enter the policy sphere, and the knowledge-driven model, which suggests that basic research provides an opportunity for applied research to assess whether the initial findings are relevant for practical application (Weiss, 1979).

Findings from this case study support the assumption proposed in Chapter 2: the linkage and exchange model does appear to be relevant to this study given its specific acknowledgement that

a strong interface between policymakers and researchers is needed for research use to occur, and that this interface can be strengthened through a sustained assessment process and a re-framing of how the NCA is presented.

3. Research Question 3: How do FACs Facilitate and Impede the Use of Evidence by Policymakers?

Respondents indicated that the NCADAC facilitates the use of evidence in part because the members help to distill the data and science behind climate change for policymakers and other decision-makers. One respondent focused specifically on how advisory committees benefit the agencies which establish them:

> I think because they're experts in a particular field what they do for the Agency is go through the publications – not data specifically – but more…because they're scientists they're familiar with the data, they're familiar with the publications, they're maybe familiar with the implications of those publications and that information might have, and they try and look at it holistically, they try and filter it sort of through the whole…any controversies that might exist and try to arrive at some recommendations.

Others recognized the unique composition of the NCADAC, in terms of having representatives from a variety of sectors, as being helpful:

> [The NCADAC] help[s] bring the best science as well as the types of questions that might be asked especially when you have an advisory board that includes people from industry and the private sector. People who might be making decisions from utilities or whatever it might be, they can help say what those questions are. And really help to explain what science might be needed to answer those questions. And so the advisory committee can help set the space that a scientific report might inform.

Another respondent noted that NCADAC members can be "ambassadors of the work of their committee and the work of the program and the federal agencies…back to their communities."

As discussed in more depth below, another unique element of the NCADAC is the extensive

stakeholder engagement strategy it used throughout the development of the 2014 NCA. One respondent noted that:

> By having this much broader network, this grass roots component to the assessment, is the thing that will generate insight into what is going on really in each of the regions and sectors by having by design and by intention two-step communication between say us and say the planning association or the American Society for Civil Engineers or the…public health folks. Their constituencies will hear it from their mother organization. They already believe. So it's not then coming from us directly, like who the hell are we, but a bunch of planners around the country, but it'll come from the APA. So, by design we're trying to build a process and a network of partners who can take this much further. So it has a chance to be influential both symbolically, to create political pressure, but also in concrete ways with all of the information that has gone into the assessment to actually help shape policy documents at lower levels of government or in the private sector or whatever.

Another respondent noted that from a process perspective, "you have multiple instances of review and transparency…so that there [are] multiple opportunities to bring the attention of the advisory committee when the authors meet, whatever, that there is other information out there."

In terms of impeding the use of evidence, respondents noted that the selection of members can have a substantial effect on the quality and utility of the advice provided. "I mean often people just go for the big names not the people who have on the ground experience or really understand decision making." Similarly, another respondent noted that "there are a lot of standing scientific advisory boards where I don't think the advisors know very much about what they're advising on. They're smart, they're experts, but they actually don't know how the agencies functions. And so their advice isn't very useful." Finally, respondents noted the role of the agency in how useful the advisory committee is, indicating that "resources are not always fully used because agencies control what they do and don't tell you by what information you share, how you share it, how you frame it."

B. Aim 2: Contribution of Contextual Factors to Adoption of 2014 NCA Recommendations

Participants identified three different contexts that were considered important contributors to whether the recommendations contained in the 2014 NCA would be adopted. Within the government, respondents identified the White House, and more specifically, President Obama, as key influencers on the lifespan of the 2014 NCA recommendations. One respondent acknowledged that part of the success is "the right people being in leadership, alignment with the objectives of the Administration, you know there are a lot of things that play into this. The timing of the release of the document[22] relative to the President's election wasn't really able to be anticipated." Another respondent saw the timing of the release of the draft NCA for public comment as more calculated:

> They decided to release [the draft NCA for public comment] after the election which in my view is just as much a political decision as putting it out before. The difference is that the one is more likely to catalyze a discussion about climate change at a critical point in our political process and the other one was intended to make sure that that didn't happen. And that's exactly what happened. Nobody talked about climate change. It's partly because these guys chose, I believe for political reasons, to defer the report until after the election.

It is unclear exactly why the decision was made to release the draft report after the election. In the context of discussing the role of the political climate on the potential uptake of the 2014 NCA, other respondents mentioned the President's level of comfort with discussing climate change, institutional barriers, and the need to control the message coming out of the assessment to ensure it aligns with the Administration's position.

One respondent indicated that although "Obama is clearly totally uncomfortable talking about climate change… at least [he's] not suppressing it." In addition, respondents indicated that:

> The people on the policy side have agendas running... they don't want an assessment

[22] The respondent is referring to the release of the draft NCA for a 90-day public comment in January 2013.

> to say things that are fundamentally cross-wise with Administration policy. They're hoping for something from the committee that will give a boost, to what they're trying to do, essentially. Not just intellectual help but [a] programmatic, political boost of some kind.

The need for this "boost" may come from the fact that, as one respondent indicated, "the government doesn't seem to be able to do what everybody would intellectually acknowledge what the government should be doing. Because institutionally it's just too hard." The institutional environment in this case also refers to Congress, which is technically the recipient of any national climate assessments under the GCRA. However, respondents were not optimistic that the 2014 NCA would be well-received:

> If you consider [who] is our primary audience and who we are supposed to advise, we are advising a federal government, or I should say a Congress who could not care less about climate change. Or some portions could care less. And it is incredibly difficult to imagine, for me anyway, that we will see climate legislation coming out of that particular report or following our release of the report anytime soon.

Several respondents discussed the importance of climate change for the average American citizen. While the American public is not formally a recipient of the 2014 NCA, nearly all respondents indicated their interest in contributing to the NCA so that it would not only reach but also be meaningful for citizens living in urban and rural areas alike across the United States.

There's a real demand now all around the country for what the hell is going on with the climate. "What does it mean for me, how am I going to run my business if power is going to get interrupted every six months or every year or if the railroad gets washed out by a flood" or whatever.

These findings suggest that the two contextual factors that have the most influence over whether the recommendations contained in the 2014 NCA are adopted are the political environments in the executive and legislative branches and demand by average American citizens for information about climate change and solutions to problems occurring as a result of it.

C. Aim 3: Stakeholder Engagement with the NCADAC

When this study was initially conceived, the third aim was developed based on the investigator's assumption that there was a vibrant civil society community actively lobbying and advocating for certain policies in the climate change arena and that these groups would be actively engaging in efforts to influence the proceedings and outcomes of the NCADAC. In addition, in the absence of knowledge about how the advisory committees functioned and the dynamics between the committees and their establishing agencies, it was assumed that advisory committee members themselves served almost as lobbyists, in addition to science advisors, in their capacity as committee members.

However, after conducting the first few interviews for this case study and attending NCADAC meetings as an observer, it became clear that there was little civil society engagement with the NCADAC through formal channels mandated under FACA legislation, that civil society engagement with the NCADAC was highly structured and organized, that the committee members took their role as science advisors quite seriously, and largely set personal agendas aside. Thus, the research questions originally defined for the third aim quickly seemed less relevant than originally anticipated. Instead, it became clear that there was a far more nuanced dynamic occurring between civil society and the NCADAC involving primarily informal mechanisms of communication. Further, the informal communication that was occurring was influenced heavily by already-existing and long-standing personal relationships. Finally, it was apparent that the mechanism built into FACA for engagement with the public – the mandatory public comment period held at FACA committee meetings – was ineffective. Chapter 7 will address these issues across the two case studies.

With support from USGCRP staff, the NCADAC developed and implemented a stakeholder engagement strategy that was a profound departure from previous assessments.

Importantly, this engagement strategy was not required by FACA but rather was an initiative initially proposed by USGCRP. The rationale for this effort was based on the view that the NCA was more than just a report, but rather was a process that was laying the groundwork to sustain the NCA effort over time so that future assessments could be conducted more easily and without such a massive investment in human and financial resources. In the words of one respondent:

> There has been a design to this engagement strategy from the beginning and part of it has been trying to pull in from the whole country the on-the-ground knowledge to be synthesized with the central scientific findings of the US Government. And it's just a different vision from I think how…everybody's always thought stakeholders are important. Stakeholders should help frame the question. We need to know what stakeholders want to know. We need to know what's important to them, we need to know what's relevant. Most scientists say that. And they think the way you do that is to have a meeting with them, and they tell you what they want, and you go off and do whatever the hell you were going to do anyway. And that's stakeholder engagement.

The stakeholder engagement effort was referred to as NCAnet (National Climate Assessment Network). The concept behind the effort was to have a "network of networks" by engaging partner organizations which would assist USGCRP and the NCADAC in disseminating the 2014 NCA and ultimately, stay involved to sustain the assessment process. A FR notice announced the creation of NCAnet and invited organizations to submit expressions of interest. Organizations could participate at four different levels of engagement and level of effort. In decreasing order of engagement, these levels were sustained process partners, contributing partners, communication partners, and federal partners.

Respondents described several benefits to the NCAnet, including that it was helpful because it allowed people who were not NCADAC members to engage with the process in an official way. In addition, respondents perceived that participating in NCAnet provided access to information that they may not otherwise receive: "people really need to know or they want to know so I think

…that's part of what's driving people to NCAnet." Finally, others indicated that there is a mutually beneficial effect of interactions between the NCADAC members and non-scientists in that it "causes you know the dissemination of knowledge to be much broader."

Other respondents had different views. One respondent noted that the communications process with stakeholders was so controlled that it inhibited civil society and NCAnet members from being as helpful as they could otherwise be:

> So I tried to get people from very early on engaged in the NCADAC process which turned out to be very, very difficult, more difficult than I thought, because they were really not into that…for all the lip service that they give to public engagement and so on, they really don't, they want it to be on their terms. Just like with this report, you know, they want it to come out when they want it to be out and they don't want it to be out before then if they're legally required to have it out before then.

Others felt that the communications process through NCAnet was disorganized and as above, lacking in information:

> But what's plagued us with the NCAnet was a lack of information, like we don't know what's going on and they don't know what's going on either because the process is so kind of disjointed. So we've constantly felt like we were being blindsided, you know, this report comes out all of a sudden.

Aside from the unique effort to engage stakeholders through NCAnet, there were the required FR notices and public comment periods at NCADAC meetings. The key finding from this research related to stakeholder engagement with the NCADAC through these formal channels mandated by FACA is the lack thereof. Respondents in all categories of interviewees expressed surprise at how little interaction there was between civil society – especially NGOs and advocacy groups working on climate change – and the NCADAC. This seems to be due in part to the fact that the NCADAC meetings were not widely publicized. While FACA requires that the meetings are announced in the FR, respondents indicated that no one ever checks the FR. Even if there was

awareness about the occurrence of an SAB meeting, respondents indicated that they felt that attending the meetings were not worth their time. The only opportunity to comment on NCADAC proceedings is during the FACA-mandated public comment period that is only 10 minutes long and scheduled at the end of each day. However, neither of these opportunities for engagement was viewed as being very useful or productive. One respondent indicated that:

> Very few people read Federal Register notices. So, the affected parties almost never know about these actual meetings. Secondly, the public comment part of it in my experience has mostly not been useful and I don't think it's taken very seriously. I think it does provide access to information for people who have lobbyists and more, you know, are sort of in the know and happen to live in Washington but there are lots of affected parties who could engage more usefully.

VII. Findings from Document Review: Issues and Recommendations in the 2014 NCA

A. NCA 2014 Development Process

As described above, the GCRA mandates that every four years, a National Climate Assessment be issued to the President and Congress that:

> integrates, evaluates, and interprets the findings of the USGCRP; analyzes the effects of global change on the natural environment, agriculture, energy production and use, land and water resources, transportation, human health and welfare, human social systems, and biological diversity; and analyzes current trends in global change, both human-induced and natural, and projects major trends for the subsequent 25 to 100 years (U. S. G. C. R. Program, 2014).

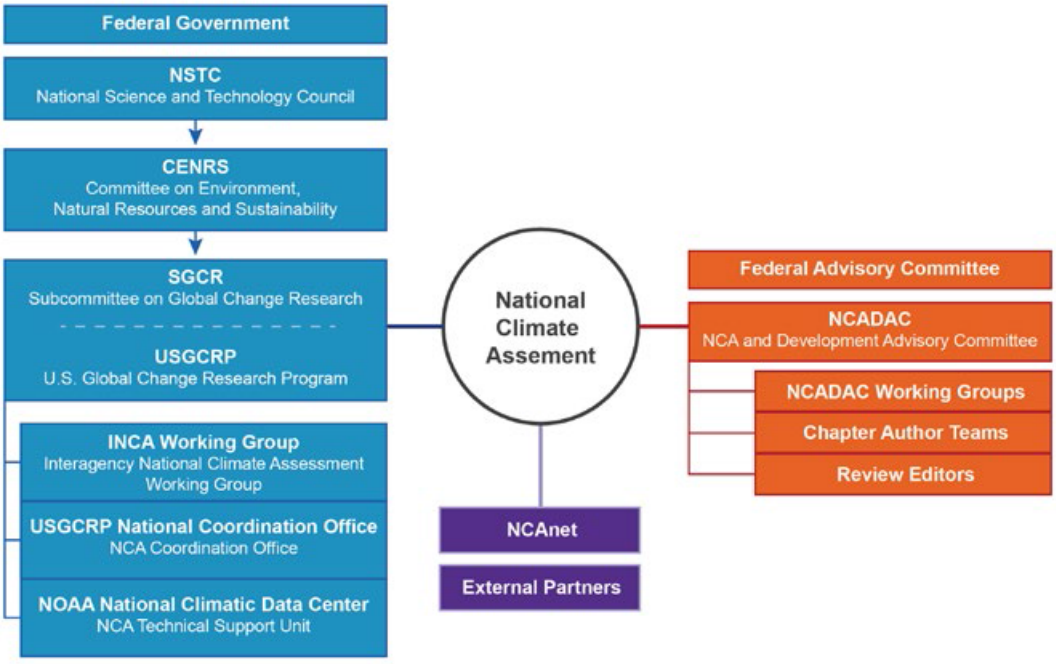
The overarching goal of the NCA process was to enhance the ability of the United States to anticipate, mitigate, and adapt to changes in the global environment, with the recognition that these changes are increasingly due to human activity.

This case study focuses on the NCADAC and its role in the policy process as well as in ensuring that its major objective – developing the NCA – was achieved. NCADAC's meetings,

working groups, and organizational structure have been discussed at length above. An additional role of the NCADAC in drafting the NCA was to select two to three convening lead authors, approximately six lead authors for each chapter, as well as contributing authors based on criteria that included expertise, experience, geography, and ensuring a variety of perspectives. Authors represented the public and private sectors, non-governmental organizations, and universities and served on a volunteer basis. To be clear, NCADAC members served as chapter authors in a variety of capacities, but the majority of the 240 NCA authors were not NCADAC members.

In collaboration with the NCADAC, there were several other critical entities which played a role in the process of developing the 2014 NCA (Figure 6.4). The organizational structure of USGCRP is explained by Figure 6.1. Thus, the following discussion focuses on the portion of Figure 6.4 which is below the USGCRP box. The Interagency NCA Working Group (INCA), comprised of representatives of 13 government agencies, plus additional agencies that supported the NCA activities, coordinated, developed, and implemented interagency activities for the NCA. The NCA Coordination Office was a part of the USGCRP National Coordination Office in Washington, D.C. With support and funding from an interagency agreement with the University Corporation for Atmospheric Research (UCAR), a team of UCAR staff and federal detailees with expertise in planning, writing, and coordinating collaborative climate and environmental science and policy activities provided support for the development of the NCA report and sustained assessment. The NOAA-funded NCA Technical Support Unit (TSU) provided climate science research, data management, web design, graphic design, technical and scientific writing and editing, publication production, and meeting support. NCAnet, discussed above, consisted of more than 100 partner organizations that worked with the NCA Coordination Office, NCADAC, report authors, and USGCRP agencies to engage producers and users of assessment information.

Figure 6.4. Organization of NCA Components



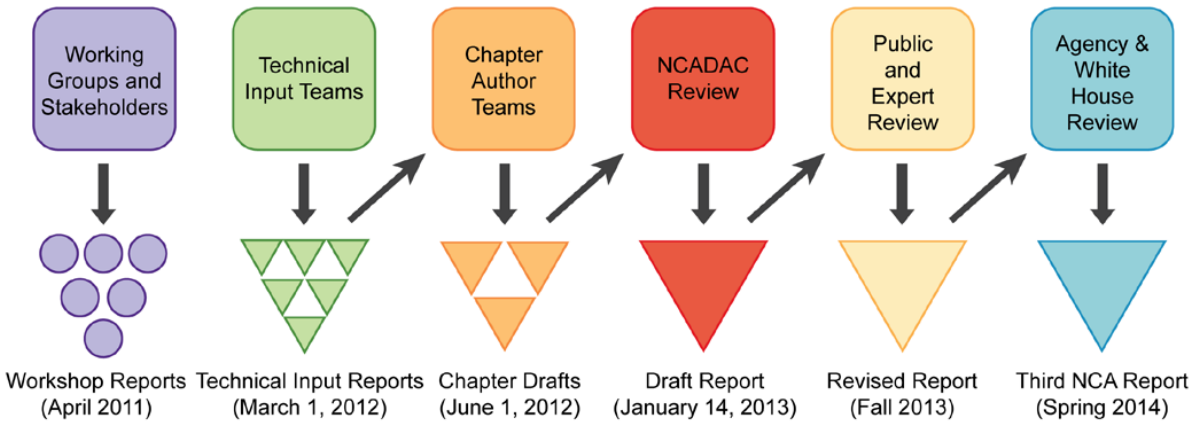
The engagement strategy developed by the NCADAC and the NCA Coordination Office outlined several processes for participation, outreach, communication, and education to help make the NCA process and products accessible and useful to a wide variety of audiences (Figure 6.5). As part of the assessment process, a series of 14 process workshops were held across the country to provide updates on the NCA process, solicit broad input from subject matter experts, and collect feedback on the approach, topics, and methodologies under consideration. These workshops were separate from those conducted during the strategic planning period in 2010.

In addition, in July 2011, NOAA issued a FR notice requesting "expressions of interest from the public in providing technical inputs and/or offering assessment capacity on topics related to National Climate Assessment (NCA) regional, sectoral, and cross-cutting topics" (Commerce, 2011).

This request resulted in the submission of more than 500 technical input documents authored by more than 800 individuals from academia, industry, and government, including 25 technical inputs sponsored by USGCRP agencies. Further, the TSU climate science team developed nine peer-reviewed regional climate scenario documents (one for each of the eight regions and one for the contiguous United States), which provided a scientific consensus view of historical climate trends and projections.

Beginning in December 2011, the chapter author teams met multiple times by phone, web, and in person to produce and refine drafts of their chapters. These meetings were not subject to FACA and thus were not announced in the FR and were not open to the public. The NCADAC reviewed the draft NCA and then released it in draft form on January 13, 2013 for public comment. Concurrently, the NCA underwent an independent expert review by the NRC. The public review period closed on April 12, 2013 at which point 4,161 comments from 644 government, non-profit, and commercial sector employees, educators, students, and the general public had been received. Chapter author teams and the NCADAC revised the draft NCA and prepared written responses to each comment received. External reviewers evaluated the adequacy of the responses to the comments on each chapter.

Figure 6.5. 2014 NCA Report Process



As the result of a NCADAC consensus decision, the entire review process was "blind": NCADAC members and authors did not know the identity of commenters when responding to each comment. The NRC provided a second review of the report which was considered in developing a final draft for submission to federal agencies in Fall 2013. Any adjustments to the NCADAC's Fall 2013 draft as a result of the government review process were made with the chapter authors' approval, and the NCADAC approved the Third NCA Report in Spring 2014.

1. NCA 2014 AND HUMAN HEALTH

The chapter of the NCA 2014 that addressed human health was drafted by a total of 16 authors. The two convening lead authors were affiliated with the CDC and the National Resources Defense Council and the Mailman School of Public Health at Columbia University (one of the authors had a joint appointment at the latter two institutions). The remaining authors were affiliated with institutions ranging from other government agencies (e.g., USDA) to universities to private companies (Luber, 2014).

The chapter has four key messages, which can be summarized broadly by the following (Luber, 2014):

1. Climate change affects human health and well-being in a variety of ways.
2. The risk for health effects are not uniform across the US population: some groups, such as the elderly, children, the sick, the poor, and some communities of color are more vulnerable.
3. Public health preparedness and prevention efforts can be effective to protect people from the impacts of climate change.
4. The response to climate change must be multi-sectoral. This type of response has societal benefits beyond improving human health.

At first glance, these messages seem comprehensive. But upon a deeper reading, there are some missed opportunities to reflect more broadly on the impact of climate change on human health,

particularly with respect to the first message. The chapter focuses on several key causes of human health problems related to climate change, namely decreased air quality due to air pollution, allergens, and wildfires, (warm) temperature extremes, precipitation extremes leading to heavy rainfall, flooding, and drought, and diseases that are vector-, food-, and water-borne. The chapter also notes that climate change can compromise food security and mental health.

What the chapter fails to note is the mediating role of the economic or financial impact of climate events and human health. As was observed with Hurricane Katrina, extreme weather events (especially wildfires, drought, and flooding), can destroy not only the houses that lie in the path of the storm but also crops, farms, and other sources of income for households and communities. Depending on the income level and assets of those who have been affected, such destruction can force households to make a choice between using scarce resources to re-build the physical infrastructure that was destroyed or to pay for needed healthcare, among other things.

In the development economics and global health financing literature, there is evidence that suggests health "shocks", such as a sudden illness, push households without full medical insurance coverage into poverty or deeper into poverty because of the large medical expenditures incurred and that the borrowing and/or selling assets is a common way for households to "cope" with such events (Amponsah, 2015). An economic shock such as home loss or crop loss due to an extreme weather event among uninsured or under-insured Americans could have a similar effect on their medical expenditures: the large out-of-pocket expenses incurred to repair or rebuild could leave households with little, if any, disposable income to pay for medical care. Importantly, the lack of insurance for Americans could refer to both a lack of homeowner's or renter's insurance as well as a lack of medical insurance.

While the chapter acknowledges that the poor are at higher risk for health problems following climate events than the non-poor in its discussion of the second key message, the issue is

defined as problematic because of the combined effect of limited resources and a large number of pre-existing health conditions. Although the effect of floods, wildfires, or hurricanes on human health via constrained resources may be attenuated, the human health chapter of the NCA 2014 could have acknowledged the possibility that such a pattern could occur, at a minimum.

The chapter stops short of making explicit recommendations for actions that can be taken to prevent and prepare for climate change as a way to protect human health in its discussion of the third message, but it does provide the example of the numerous beneficial health effects of reducing carbon pollution. Immediate effects, such as improved air quality, and long-term effects, such as a reduction in obesity rates (noted as resulting from increased used of more active transport methods such as biking and walking), are mentioned as benefits to reducing carbon pollution. Interestingly, one of the two primary components of President Obama's Climate Action plan is the EPA's Clean Power Plan, which proposes new pollution standards for power plants which will "protect the health of our children", according to the White House (The White House, 2014). Although this plan was announced just weeks after the release of the 2014 NCA, there is no indication from publicly-available information that the plan was formed in response to the NCA. Indeed, the Clean Power Plan was an initiative that had been in progress long before the NCA was released (EPA, 2014). It is possible that the NCA, as it was being drafted, informed the Clean Power Plan, but it is not possible to attribute the Plan to the messages contained in the NCA.

VIII. Conclusion

The political context of how previous NCAs were treated under the Clinton and Bush Administrations – namely the legal challenges which alleged that one or more of the laws governing how federal advisory committees are supposed to operate and/or how committee reports are to be reviewed, approved, and released was violated – is a critical difference between the historical

background of the NCADAC and the PEPFAR SAB. This history seems to have had an impact on nearly every aspect of the NCADAC's operations as an advisory committee, including how the committee was structured, how meetings were convened and managed, how decisions were made about managing the writing, editing, and revisions of the NCA, and how stakeholders were engaged. Essentially, the NCADAC and USGCRP staff were committed to ensuring that all decisions and actions taken were transparent and well-documented to mitigate the likelihood of a possible legal challenge once the NCA was released.

Although the motivating factor for taking these measures to ensure transparency ultimately was fear of another lawsuit, the default byproducts were beneficial for any individual interested in tracking the operational and substantive decisions taken by the NCADAC regarding how it would function and also how the NCA would be developed. More specifically, there is a user-friendly and comprehensive record available online of all NCADAC meetings, including agendas, meeting minutes, and copies of the documents that were discussed by the committee. In addition, the emphasis on maintaining transparency through the public comment period of the NCA resulted in a record of what comments were received and how they were addressed, as noted above. Similarly, the online version of the final 2014 NCA has hyperlinks to all of the original sources of data used for charts, figures, and data presented in the text, referred to as "traceable accounts".

The NCADAC and the NCA 2014 benefited from an investment in the strategic planning efforts undertaken in 2010 as well as in substantial staff support throughout the NCADAC's existence, both of which seem to have been critical inputs to the NCADAC's successful delivery of the 2014 NCA. The strategic planning process conducted during 2010 allowed USGCRP to present the NCADAC at their first meeting in April 2011 with a draft outline of the NCA as well as a draft plan for the working groups needed to divide the writing and communications tasks among committee members. While the NCADAC finalized the content of the NCA, the committee was

able to start substantive operations immediately by reacting to the draft outline rather than spending months coming to consensus about what content the NCA should include. The staff support provided to the NCADAC facilitated the smooth implementation, management, and administration of NCADAC processes and meetings.

NCADAC together with USGCRP developed an extensive strategy to engage with concerned stakeholders by creating NCAnet, but challenges remained for meaningful interaction and exchange with the NCADAC itself. The public comment period was under-utilized and the stipulations of FACA law regarding when reports should be made public proved frustrating to government and NGO staff alike.

While the NCADAC was created for the primary purpose of drafting the NCA, which is an objective that is quite different than the PEPFAR SAB, there are a number of similarities between the two committees, which are discussed in the next chapter.

CHAPTER 7 : CROSS-CASE ANALYSIS

I. Introduction

Chapters 5 and 6 provided a detailed analysis of the themes within each case study. This chapter presents an analysis of the major themes across the two case studies. This approach is typical for research with a multiple-case study design (Creswell, 2007; Yin, 2009). As noted in Chapter 4, the goal for multiple case study design research is literal replication (producing similar results across case studies) and theoretical replication (producing different results but for predictable reasons) (Yin, 2009).

The risk in aggregating results across multiple cases is oversimplification and misinterpretation of the findings and loss of the uniqueness and complexity of each individual case (Khan & VanWynsberghe, 2008a; Miles & Huberman, 1994). In addition, there is the potential that the contextual richness of each individual case will be lost, although the literature acknowledges that some loss of contextual detail in a cross-case comparison is permissible and consistent with the goals of a cross-case analysis, namely to identify themes across cases (Ayres, Kavanaugh, & Knafl, 2003). Cross case analyses have been referred to as "essentially a 'decontextualization and recontextualization' of cases" (Tesch, 1990). Thus, the approach to analyzing data across the PEPFAR and NCADAC case studies deserves careful consideration.

The literature suggests there are two approaches to a cross-case analysis (Miles & Huberman, 1994). A variable-oriented approach focuses on the variables across cases rather than on the case itself. For example, a variable-oriented approach is akin to reading a table of quantitative data vertically, by column, so that the relationship between one independent variable is assessed relative to the outcome of interest. In contrast, a case-oriented approach would read a table of quantitative data by row and would also consider all of the background information about the individual study

subject (Miles & Huberman, 1994). In addition, the number of cases for comparison in a variable-oriented approach is high, and the cases should be similar to each other to foster generalizations. Case-oriented approaches allow for fewer cases for comparison and permit the comparison of cases that are seemingly very different (Khan & VanWynsberghe, 2008b). This chapter employs a case-oriented approach and more specifically, uses replication logic as noted in Chapter 4, which is consistent with Yin.

II. Cross-Case Findings

Just as Chapters 5 and 6 followed a similar organizational structure to facilitate comparison in this chapter, the cross-case findings presented here are organized according to the same general structure. First, background characteristics that are critical to the two cases are compared and contrasted, including the difference between the two cases in the amount of experience government agency staff had with implementing a FACA committee, the politically-charged nature of both climate change and HIV/AIDS science and the perspective of those issues in the Bush and Obama Administrations, and finally, key features of the charters and member selection for each committee. Following the comparison of major background characteristics, findings across the two case studies are presented by aim and research question. Conclusions and a discussion of the transferability of the cross-case findings to other FACs are provided at the end of the chapter.

A. Comparison of Key Background Characteristics of the PEPFAR SAB and the NCADAC

1. Influence of Prior Experience Implementing FACA Committees

One major difference between the PEPFAR SAB and the NCADAC was that the PEPFAR SAB was the first FACA committee established by OGAC. In contrast, while the NCADAC as described in Chapter 6 was newly constituted in 2010 to draft the 2014 NCA, there had been three

(or four, depending on how they are counted) previous FACA committees charged with developing a national climate assessment. Moreover, many of the individuals involved with the NCADAC had been involved in some capacity with each NCA since the GCRA was passed, although some switched employers (e.g., moving from government to a research institution or government to civil society). The experiences these individuals had provided a wealth of institutional memory about the potential challenges the NCADAC and the 2014 NCA could face.

The awareness of and concern for legal challenges once the NCA was released seemed to permeate nearly every element of the NCADAC's operational decisions. Transparency of committee proceedings and compliance with FACA were considered to be of utmost importance. In and of themselves, emphasizing transparency and ensuring the committee was compliant with the law are important and should be a part of every FACA committee's priorities. The critical point with the NCADAC is that it took special measures to mitigate the possibility of a future legal challenge.

For OGAC, establishing a FACA committee was a novel endeavor for all involved. Once Ambassador Goosby decided he wanted a group of science advisors external to the government, OGAC staff had to rely on several different Bureaus at the State Department to guide them through the process of implementing the SAB. This should not be considered unusual: it is reasonable to expect that any agency that establishes a FACA committee for the first time would need a substantial amount of assistance throughout the process. However, the lack of experience of OGAC staff and PEPFAR SAB members with FACA committees had several interesting implications for how the SAB was implemented, managed, and convened. These issues are discussed in depth below in Section i.a under the first research question. Thus, the operational elements of the PEPFAR SAB like the NCADAC, were heavily influenced by the lack of and wealth of prior experience, respectively, that its stakeholders had with establishing a FACA committee.

The discrepancy between the two committees in terms of the amount of institutional

memory of NCADAC stakeholders, on the one hand, and the relative lack thereof among the PEPFAR SAB stakeholders, on the other, is remarkable not only because of how divergent the two case studies are in this area, but also because in spite of this difference, there are a number of important similarities across the two cases.

2. The Political Context of HIV/AIDS and Climate Change Science

Each case study briefly discussed some of the key issues and questions in the scientific arena for HIV/AIDS prevention, care, and treatment and climate change, respectively. While the subject matter addressed by each advisory committee could not be more different, there are some interesting commonalities between how the science addressed by the NCADAC and the PEPFAR SAB have been politically charged issues.

Both global warming and HIV/AIDS, along with many other science-based issues, were met with substantial skepticism during the Bush Administration. While the complexity of the Bush Administration's treatment of science falls outside the scope of this research, the overarching political context of how the issues under the purview of the PEPFAR SAB and the NCADAC provides relevant background information for both case studies, as previously discussed in Chapters 5 and 6. There were – and still are – factions that question the causes of global warming. This skepticism was at the root of the legal challenges to previous national climate assessments. As discussed in Chapter 6, the primary aim of the legal challenges was to discredit the assessments by questioning the validity of the science on which they were based. The measures taken by the NCADAC to ensure transparency during the process of drafting the NCA and incorporating comments from the public review period were implemented to provide legitimacy and credibility to the NCA. While the cause of HIV/AIDS was not questioned by policymakers in the Bush Administration, there was a pattern of allocating resources to prevention programming that was not

aligned with scientific consensus, as discussed in Chapter 5.

The transition to the Obama Administration signaled a new perspective on the role of science in public policy on many issues, HIV/AIDS and climate change included. Respondents in both case studies noted the importance of the broad policy context and the value placed on evidence-based policy during the Obama Administration for providing a window of opportunity for the NCADAC to develop a national climate assessment that would likely be met with a much more favorable reaction from the White House than in years past and for the PEPFAR SAB to be established.

3. Characteristics of the PEPFAR SAB and NCADAC Charters and Membership

There are no major discrepancies in the categories of information included in the PEPFAR SAB and NCADAC's charters: the type of information required in each document is set by FACA law. The major differences between the two documents are manifest in the objectives and duties of each committee. As discussed in Chapter 5, the objective of the PEPFAR SAB was to provide advice "concerning scientific, implementation, and policy issues related to the global response to HIV/AIDS". This objective is broad and while some additional information is provided about what scientific, implementation, or policy issues OGAC wanted advice on, even that is rather vague. For example, the charter indicates that the SAB is to "advise on global evaluation and research issues", but does not specify which issues.

The NCADAC charter is much more specific about what the committee's objectives and duties were. As discussed in Chapter 6, the objective of the NCADAC was three-fold: to synthesize and summarize the science on climate change in the United States; provide recommendations for how NOAA and partner agencies could sustain the national assessment process so that developing the national climate assessment results from a continuous synthesis of information rather than a

major endeavor every four years; and finally, develop the NCA. The charter includes five different and specific points about the scope of the NCA.

While a reader can glean much more information about the objectives and duties of the NCADAC by reading its charter relative to the charter for the PEPFAR SAB, this departure is a natural function of the fact that the NCADAC was established essentially to comply with the GCRA, whereas the PEPFAR SAB was the first of its kind and was established because Ambassador Goosby wanted broad scientific and implementation advice from experts external to the government. More specifically, it was clear from the nascent stages of each advisory committee what the overall purpose of the committee would be, and the NCADAC simply had a much more specific purpose because it was required to by law and was informed by previous committees' efforts, whereas OGAC most likely wanted to keep the scope of the SAB broad to maximize flexibility.

An additional point of divergence between the charters is the estimated annual operating cost and staff support for each committee. The NCADAC charter provides an annual operating cost that is greater than the PEPFAR SAB by a factor of 10: the NCADAC indicates it will require $1 million annually to operate, whereas the PEPFAR SAB estimates it will require $100,000 annually. In terms of staff support, the NCADAC charter requests 2.5 years FTE on an annual basis; the PEPFAR SAB charter requests 0.5 years FTE annually. Given the scope of the NCADAC's mandate, namely to draft the NCA, this discrepancy is understandable.

The outcome of the member selection process was quite similar across the two committees. Both committees were large, and were larger than originally envisioned. The plurality of members on each committee was affiliated with universities. The NCADAC had more than twice the ex officio members that the PEPFAR SAB had, but this is due to the fact that the USGCRP is a program that consists of the research arms of 13 different federal agencies. There are several organizational

affiliations that are important to have representation from for the NCADAC but not the PEPFAR SAB, such as state-level government. Similarly, it was important for the PEPFAR SAB to have representation from the UN and global health partnerships, for example, although this would not have been a logical choice for the NCADAC.

Table 7.1. Summary of PEPFAR SAB and NCADAC Members' Organizational Affiliation

Organizational Affiliation	Number of PEPFAR SAB Members *of which* (not US based)	Number of NCADAC Members *of which* (not US based)
University	17 (4)	22
US Government (ex officio)	5	16
Private Sector Company	1	7
Consulting Firm	0	6
State-Level Government (e.g., public utilities)	0	5
Research Institution (not affiliated with a university)	15 (6)	2 (1)
Foundation	3	1
UN Organization/Global Health Partnership	4 (3)	0
NGO	3	1
Think Tank	2	0
TOTAL	**50**	**60**

Perhaps most importantly, and if ex officio members are excluded, what is clear from Table 6.3 is that researchers based at either a university or other research institution (e.g., the NIH) constitute the majority of members on both committees.

III. Comparison of Findings Related to Study Aims and Research Questions

A. Aim 1: The Role of Federal Advisory Committees in the Policy Process

1. RESEARCH QUESTION 1: WHAT ARE THE MECHANISMS AND PROCESSES BY WHICH SABS FUNCTION, INCLUDING HOW THEY ARE STRUCTURED, IMPLEMENTED, CONVENED, AND OPERATE?

i. Implementing a FACA Committee

a) Navigating FACA Rules

Understanding and interpreting FACA rules proved a difficult task for both USGCRP and NOAA staff, who had considerable experience with FACA committees, as well as State Department staff, who had little experience with such committees.

Although the NCADAC stakeholders had a wealth of experience implementing other FACA committees and producing previous NCAs, the task of establishing the NCADAC stymied even those with that institutional memory. One respondent noted that:

> I mean part of it was it was fairly early in the Administration and I don't think everybody understood how to do these things. I pretty much had to figure it out myself. I spent a lot of time talking to GAO about this…we talked to them a lot trying to get input about how these things are done.

In spite of this initial confusion, USGCRP appeared to have a very solid understanding of the rules and regulations stipulated by FACA and related laws by the time of the NCADAC's first meeting in April 2011. Again, this likely stems from the experience of USGCRP staff and leadership with previous FACA committees and national assessments and more specifically, a concern about future legal challenges. As discussed in Chapter 6, the importance of complying with FACA and other rules was emphasized at the April 2011 NCADAC meeting, during which there were three sessions devoted to briefing NCADAC members on previous assessments, FACA law and the NCADAC charter, and ethics rules for special government employees.

As described in Chapter 5, OGAC staff also had difficulty navigating the complexities of establishing a FACA committee. This task was made even more difficult because the trainings on FACA committees were not required. Respondents indicated that while there was a lot of information provided about FACA committees (independent of the training) "sift[ing] through the legal language to figure out how it applies to our situation is sometimes challenging." In addition, the training was open only to direct hires, but the person with the primary responsibility for the SAB's

day-to-day management was not a direct hire and thus was not permitted to attend the training. Further, only one staff member attended a training session two years after the first SAB meeting.

Even with all of the guidance OGAC staff received when establishing the PEPFAR SAB, it was not until early 2013 that staff realized (after attending a FACA training) that conference calls held with the entire SAB – meetings that were interim to the annual, in-person meetings – were required by FACA to be open to the public. If all-committee calls were held after this realization, which occurred in early 2013, they were not announced in the FR or on PEPFAR's website and were not open to the public.

The original intent of the FACA legislation was to ensure that there was greater transparency in how government agencies were using advisory committees. Subsequent case law has helped to clarify the original legislation. In spite of the spirit of the law and efforts to provide greater assistance to agencies by clearing up some of the ambiguous language in the legislation, findings from both case studies indicate that there remain substantial hurdles to smooth implementation of a FACA committee. Politics aside, navigating a government agency's various departments or bureaus to obtain consistent and accurate information about the FACA committee implementation process seems difficult at best. Further, the courts have ruled that agencies are to be left to interpret the FACA law how they see fit, so additional clarification to the legislation itself or through case law does not appear to be an option. At a minimum, it may behoove agencies to open trainings on FACA committees more widely.

b) FAC Member Selection

It was clear from both case studies that the processes of developing an initial pool of potential advisory committee members and then selecting a final list of individuals to appoint to the committee were highly political. With issues as high-profile as climate change and global

HIV/AIDS, and given the history of the national climate assessments and the fact that the PEPFAR SAB was the first of its kind for OGAC, it is not surprising that politics played a substantial role in the member selection process.

However, the member selection process for both committees was also highly personal. The relationships between government agency staff and advisory committee Chair(s)/ members had a substantial influence over not only which individuals were included in the initial pool from which potential committee members were drawn but also, which individual(s) were ultimately appointed as Chair or Co-Chairs and to the committee as members. As discussed in Chapters 5 and 6, one negative implication of government agency staff's ability to exercise their personal preferences for who sat on the committee – both based on area of research expertise and personality – was that the committee could have been perceived to be or actually been biased and/or unbalanced which, in turn, could result in a reluctance of committee members to challenge government agency views or positions and/or provide advice and recommendations which are not truly independent.

If the exertion of personal preferences for member selection on FACA committees is problematic, it was not readily apparent from the two cases included in this research. More broadly, and as noted in Chapter 5, some level of bias may be inevitable given the relatively small number of individuals with niche expertise in the scientific or implementation matters under the purview of FACs. The importance of selecting members who are trusted by the establishing agency and can collaborate effectively as a committee to carry out the work outlined in their charter can further narrow the pool of potential committee members.

Ultimately, the role of pre-existing relationships and the power of their influence over myriad advisory committee characteristics points to the potential value of analyzing the social network among the three categories of respondents. While it is apparent from these two case studies that concerned stakeholders in all three categories of respondents are linked professionally, it was

not clear at the initiation of the research that this was the case. Without researching these connections in more depth, it is not clear ex ante how connected the stakeholders are both within each stakeholder group and across groups, how long-standing the connections are, and what is the origin of the connection as well as to what extent and how the connections have changed over time. For example, it could be the case that a connection between two individuals (A and B) was initiated because they were colleagues at the same organization, but then individual A left to work for the agency that funded the organization, and individual B is now serving as a member of the advisory committee to the agency that employs individual A. Without a social network analysis, the dynamics and intricacies of how FAC stakeholders are connected are not readily apparent.

c) FAC Membership Bias and Balance

The NCADAC and the PEPFAR SAB both struggled with concerns about potential bias of committee members and lack of balance of perspectives, but for different reasons. As discussed in depth in Chapter 6 and again briefly above, the member selection process for the NCADAC was highly politicized. The White House and NOAA leadership rejected the initial composition of the committee because it felt the NCADAC was not as balanced as it could be; this concern was the impetus for releasing the FR notice to request additional nominations. The effort to ensure that the NCADAC membership was balanced in its perspectives and not biased was likely motivated by the importance of the NCADAC being perceived as legitimate by a variety of stakeholders and to stave off concerns about future legal challenges.

Concerns about bias on the PEPFAR SAB were related to the primary function of PEPFAR, namely as a funder of HIV/AIDS prevention, care, and treatment programs. As discussed in Chapter 5, respondents noted that many of the PEPFAR SAB members received large amounts of PEPFAR funding and yet they were providing advice to PEPFAR. Further, there was some concern

that these individuals were not as candid as they would otherwise be if they were not receiving PEPFAR funds. However, views about the independence of the committee members were mixed, with other respondents noting that those who received a lot of funding "just say what they want". Ultimately, this issue of appointing advisory committee members who are also recipients of funding from the agency to which they are providing advice boils down to concerns about conflict of interest. All nominees to FACA committees go through an extensive clearance and vetting process. Key elements of the vetting process include in-depth financial disclosure through the Office of Government Ethics Form 450 which is a standard financial disclosure form for the Executive Branch. Nominees provide information on assets and income sources, liabilities, positions held outside the government, agreements or arrangements (e.g., for continued participation in a previous employer's retirement plan), and gifts and travel reimbursements. With the exception of the outside positions and gifts/travel reimbursement categories, the FAC nominees must report all information for himself, his spouse, as well as any dependent children.

The tension between appointing advisory committee members who are both experts in a specific content area (e.g., ocean acidification, HIV infection among people who inject drugs) *and* have an understanding of the policy, politics, and implementation of government programs but do not have conflicts of interest may be impossible to resolve. A committee consisting of only content experts may not be useful to a government agency if its members do not understand how the agency functions and implements its policies. Similarly, a committee consisting only of policy and implementation experts may not provide the agency with advice informed by a deep understanding of the science underlying the issues the committee was established to address. Ultimately, the optimal level of conflict of interest may not be zero. However, it is critical to remember that the primary function of any FACA committee is to provide guidance and advice to the federal government, *not* to make policy decisions. It remains at the discretion of the establishing agency

whether the advice of the committee is taken into account. The establishing agency can disregard the advice of the committee if the agency feels the committee is too conflicted.

ii. Managing a FACA Committee

a) FAC Staff Support

The discrepancy between the support provided by USGCRP staff and OGAC staff to the NCADAC and PEPFAR SAB, respectively, could not be more stark. The National Climate Assessment – and by extension, the NCADAC – had twelve USGCRP staff supporting it. While three of these individuals were student assistants, the other staff members were either doctoral-level climate scientists or had established expertise in climate science. This staff supported nearly every function of the NCA, including coordinating all of the chapter authors (of which there were 240), ensuring consistency across the NCA report itself, and coordinating the implementation of the stakeholder engagement strategy, among other things. With an endeavor as massive as the 2014 NCA, it is difficult to imagine how the assessment would have been completed without the level of staff support provided to the NCADAC.

In contrast, the PEPFAR SAB was supported on a day-to-day basis by one individual at .5 FTE who was not a direct hire. Other, more senior OGAC staff also had some responsibility for the substantive and administrative components of the SAB, although it is not clear what percentage of their time was devoted to the SAB (although it was certainly less than 50 percent). It seemed that the lack of staff support from OGAC had negative implications for the SAB. As an example, respondents indicated that it was often the case that SAB meeting agendas were distributed to the committee within only a few days of the meeting itself, which left the committee members little time to prepare. OGAC struggled with the lack of staff support as well: "The first year was a huge struggle because it was just another of the many jobs we try to balance and with time there were

more people who could devote more time to it."

Although the question of whether the NCADAC and the PEPFAR SAB were a "success" falls outside the scope of this research, it does seem that a committee's operating efficiency is improved when it receives adequate staff support. Further, from the agency's perspective, staffing a committee appropriately may actually enable the committee to be more useful to the agency.

b) FAC Organizational Structure

The concept of an organizational structure applies primarily to the NCADAC, which had a Chair, two Vice-Chairs, and an Executive Secretariat. As noted in Chapter 6, these positions were identified in the NCADAC bylaws. The PEPFAR SAB had a Chair identified in the FACA database, but many respondents were unclear who the Chair was. Their surprise at hearing who was "officially" Chair suggests that the sample of respondents included in this study were somehow unaware of whom the Chair was or that several individuals from OGAC were the "face" of the agency during SAB meetings and it was unclear who was actually chairing. This researcher's observations of several PEPFAR SAB meetings support the latter conclusion.

Findings from the two case studies suggest that the leadership and management style of the Chair can be an important factor in how efficiently committee meetings are run. In addition, whether the committee Chair is affiliated with the establishing agency on a contractual basis may affect perceptions of the independence of the committee's recommendations.

c) FAC Ad-Hoc Working Groups

As a result of both the number of members and the scope of the objectives of the NCADAC and the PEPFAR SAB, ad hoc working groups were established so that each committee could actually accomplish the objectives set out in their charters. Respondents from both cases indicated that accomplishing tasks as a group of 50 or 60 was simply not feasible. For both

committees the working groups were focused on substantive (not administrative) issues, although the NCADAC did have two working groups devoted to process issues (communications/stakeholder engagement and the peer review process for the draft NCA).

Participation on the working groups was voluntary, although some respondents in the PEPFAR SAB case study indicated that Ambassador Goosby may have suggested some individuals participate on certain working groups, depending on the topic.

One interesting departure between the two committees is that the NCADAC members were asked to select the working group(s) on which they wanted to participate at the first meeting. Prior to that meeting, USGCRP had already developed a draft outline for the 2014 NCA, and the working group list matched that outline. The draft outline was informed by the year-long planning efforts and events held during 2010. While the proposed outline was subject to change pending discussion and approval by the NCADAC, in fact, the draft version bore substantial similarity to the version approved by the NCADAC. In contrast, the PEPFAR SAB created its working groups in a much more ad hoc manner. Further, they were created in response to Ambassador Goosby's request as well as the committee's own requests.

iii. Convening a FACA Committee

a) Setting FAC Meeting Agendas

The NCADAC's specific objective to draft the NCA meant that there was very little latitude in terms of what topics were included on meeting agendas: from meeting to meeting, agendas included progress updates on the NCA. Naturally, the scope of these updates changed as the NCA was being written. At the initial meetings, the NCADAC moved quickly to approve the outline for the NCA and set the working groups that would actually carry out the tasks. As the assessment was being written, the working groups would provide updates on their progress. The timeframe for

delivering the assessment was discussed as needed. From attending the meetings as an observer, it appeared that the Executive Secretariat did a substantial amount of work outside of the full committee meetings: issues were usually presented to the committee for information or for decision, but there was very little discussion that followed and meetings often ended early.

In contrast, the agendas for the PEPFAR SAB meetings were not governed by the need to deliver a major assessment of the scientific issues under the SAB's purview. As discussed in Chapter 5, the agenda items were set both by SAB members as well as by Ambassador Goosby. Frequently, there was insufficient time for discussion due to there being too many agenda items for the time allotted, members of the SAB were actively engaged in discussion and debate, and the Chair often did not curb discussion to adhere to the agenda. As a result, the agenda had to be re-arranged, and respondents felt that the advisory board was not being used as effectively as it could otherwise be.

Findings from both case studies suggest that the pre-existing relationships between government agency staff and civil society were influential on the issues discussed by the advisory committee. A similar pattern was observed of those relationships between the advisory committee Chairs/members and civil society. While some of the influence exerted by civil society came through formal channels, such as the public comment period held at the end of each advisory committee meeting, much of it seemed to occur informally, namely by email, phone, or conversations between specific members of civil society and government staff or committee members. Findings suggest that this pattern of communication was primarily initiated by the members of civil society. The ability of these individuals to reach out directly to government staff and/or committee Chair(s)/members was predicated on long-standing mutual trust and respect built through professional relationships.

2. Research Question 2: To What Extent Does the Theoretical Disconnect Between the Literature on the Health Policy Process and the Literature on Evidence-Based Policy Have Empirical Support?

As described in depth in Chapter 2, traditional models of the policymaking process – independent of whether research is involved – describe the policy process as a sequence of steps or a cycle including agenda setting, formulation, implementation, and evaluation (Buse et al., 2005). Underlying these traditional models is the assumption that policymaking is a linear process and by extension, that policymakers make rational decisions at each stage. In turn, this assumption implies that there would be a direct relationship between evidence and policy decisions at each stage and moreover, that "research precedes the policy solution to a pre-defined problem" (Buse et al., 2005, p.160). Critics argue that the traditional model of policymaking ignores its reality: that policymaking is inherently complex.

Other models of the policy process attempted to address some of the shortcomings of the traditional model. Lindblom argued that small, incremental changes in policy are not only all that is feasible, but also are advantageous over major shifts because incrementalism reduces the complexity of the process as well as the number of policy options that need to be considered. Cohen's garbage can model suggests that it may not be possible to make decisions pro-actively, since problems and solutions emerge from the garbage can when new opportunities arise (Nutley, 2007). Kingdon's multiple streams model focuses primarily on agenda setting and suggests that issues will rise to the policy agenda when problems with feasible solutions come to the attention of policymakers during a time of a favorable political environment. Both the garbage can and multiple streams model "suggest that research…may enter policy through diverse and indirect routes and from a variety of different sources" (Nutley, 2007, p.97).

As described in Chapters 2 and 3, this research draws upon the traditional model of

policymaking, in spite of its flaws. Not only does "the rational, linear model of the relation between research and policy still tends to inform the day-to-day working assumptions of many researchers and policymakers"(Buse et al., 2005, p.160), research can still play a role at each stage of the process. At the agenda setting stage, research can "help clarify the nature of issues of concern, and to push such issues onto the policy agenda"(Nutley, 2007, p.93). During the implementation phase, research can help define policy alternatives and can help address implementation problems, through process evaluations, for example. During the evaluation stage, research can make a "substantial contribution,"(Nutley, 2007, p.93) since evaluation involves research by definition (Buse et al., 2005, p.160).

Separate from models describing the policy process are models describing the relationship between research and policymaking. These models are discussed in depth in Chapter 2 and applied to the findings of each case study in Chapters 5 and 6. They are reviewed again briefly here as part of the synthesis across the two case studies. Caplan's two communities model suggests that researchers and policymakers exist in two completely separate cultures and that policymakers rarely use research (Caplan, 1979b). This model is not refuted by this research but it is not entirely supported by the findings either. Support for the two communities model is found in the fact that establishing an advisory committee is an explicit acknowledgement that a government agency needs and/or wants assistance using research. Respondents in the PEPFAR SAB case noted that this was a motivation for establishing the SAB and that while the government had some expertise, there was a need for additional experts outside of government. The NCA could not have been drafted without a diverse committee of experts. As noted in Chapter 6, one of the respondents indicated that because the government did not have staff with the appropriate scientific knowledge there was really no other option than establishing a FACA committee to ensure that the NCA was drafted, given that the advice of external experts was needed.

The evidence that does not entirely refute the model is the informal communication that occurred in both case studies. However, this communication occurred between respondents in the NGO community and government agency staff, not between researchers and agency staff.

The issue of selecting members to sit on the advisory committee is particularly relevant to the two communities model: if a committee is comprised of individuals who do not understand the policymaking process or the realities of agency-level implementation, the concept of researchers and policymakers existing in two separate cultures is only amplified. Thus, while there could be concerns about conflict of interest, selecting committee members who are both content experts and are well-versed in policy and program implementation is critical.

Perhaps, then, the isolation between the researcher and policymaker communities is driven by the policymakers: many of the SAB members who were researchers, at least in the PEPFAR case, had a blend of research and implementation expertise, whereas the government agency staff had expertise in the implementation arena. The blend of expertise held by many PEPFAR SAB members may be more of an exception than a rule among FACs given that PEPFAR is a program which provides funding for the implementation of HIV/AIDS prevention, care, and treatment programs which are often evaluated by the implementers who often are trained as researchers. Other government agencies may also provide funding to the organizations with which their FAC members are affiliated, but the funding may be for research in less applied settings.

Wingens' general utilization theory model suggests that research use occurs when there is interaction between the systems in which policymakers and researchers exist. This interaction happens when a change in social context occurs that in turn prompts a change in policy issues. However, for research to be used, it must be "adapted, recreated, and transformed"(Nutley, 2007, p.100). The background for each case study highlighted the treatment of both the scientific consensus on HIV/AIDS prevention, care, and treatment and climate change during the Bush

Administration and how there was a marked change in the perspective on these issues as well as in the role for research in public policy when President Obama took office (Haskins, 2011; Orszag, 2009). This change in social context seemed to prompt a change in which policy issues were considered feasible to address and each advisory committee adapted and transformed (but did not re-create) the relevant science in the process of delivering the NCA and the recommendations from the PEPFAR SAB. It is unclear what exactly is meant by "use" in this context, and as such, it is difficult to ascertain the extent to which the general utilization theory model is supported by this research aside from OGAC's adoption of the SAB's recommendations about treatment as prevention.

Lomas' linkage and exchange model conceptualizes research and policy as processes, not products, which suggest that there are numerous opportunities for there to be mutual influence between research and policy (Lomas, 2000). The political and institutional contexts are critical to the linkage and exchange model, which argues that decisions are more likely to be shaped by these contexts than they are to be rational and determined by research. Findings from both case studies suggest that the political and institutional contexts were, in fact, important influences on which issues were considered by the NCADAC and the PEPFAR SAB for discussion. OGAC's adoption of the SAB's recommendations on treatment as prevention provides an example of a decision being *based* on research, but it is unlikely that the political and institutional environment within OGAC and the US government more broadly played no role.

Weiss's enlightenment model views the influence of research on policy as a phenomenon that occurs gradually as the concepts and perspectives generated by a body of research diffuse through various subtle and indirect pathways (Weiss, 1979). The relevance of the enlightenment model to this research is somewhat suspect; establishing a FACA committee is not subtle nor is it indirect. However, if one assumes that there could have been a gradual diffusion of research on

climate change and research on HIV/AIDS prevention, care, and treatment to the members of the PEPFAR SAB and the NCADAC, respectively, as well as to the government agency staff managing the committees, then the enlightenment model seems more applicable.

Weiss also proposed the knowledge-driven model which assumes that knowledge will be used by policymakers simply because it exists. However, she argues that this model is more relevant for basic research and if scientific findings "affect government decisions…it is not likely to be through the sequence of events posited in this model" (Weiss, 1979, p.427). Indeed, as indicated by the findings from both case studies, it was clear that policymakers were not using the knowledge generated by research, or at least were not using it to the extent that they could have, which was one of the motivating factors for establishing the PEPFAR SAB and to some extent, the NCADAC (although establishing the NCADAC may have been driven more by a need for a group of experts to draft the NCA).

Finally, the problem solving model, also put forward by Weiss, suggests that policymakers search for already-existing research once they are faced with a decision or commission specific research when a knowledge gap is identified (Weiss, 1979). In either pathway to research use, empirical evidence is applied directly to a specific policy issue, which is then resolved because the gap in knowledge is filled. There is some support for this model within the PEPFAR SAB case study. Respondents indicated that part of the reason why the SAB was established was to legitimize increasing the investment in ART because at the time, skeptics across the U.S. government were questioning the cost-effectiveness of anti-retroviral therapy and arguing that funding should be directed away from treatment and towards prevention. The results of the HPTN 052 trial had not been released, but a number of observational studies had already indicated that ART can be effective in reducing the risk of transmission of HIV among sero-discordant couples (Bunnell et al., 2006; Del Romero et al., 2010; Donnell et al., 2010; Reynolds et al., 2011). Thus, the problem was the conflict

between stakeholders within USG about how funding should be allocated. It may have been the case that Ambassador Goosby had a policy goal in mind, namely to increase PEPFAR's allocation to ART, and created the SAB to have his goal validated by a group of independent experts external to the government.

Overall, it seems that the findings from each case study suggest that there is not a conclusive answer to the question of whether there is empirical support for the disconnect in the policy process and evidence-based policy literature. Examples exist in each case study that support some models but not others, or support one element of a model but refute its other characteristics. This is not surprising given this study's scope: with only two case studies it is certainly not possible to extrapolate to all FACs about the extent to which their processes and interactions with policymakers support or refute various models and theories proposed in the literature. The primary objective of each FAC as outlined in the charter, and especially whether it is to provide broad advice, like the PEPFAR SAB, or is to deliver a specific product, like the NCADAC, may influence the extent to which it is even feasible to observe if and how policymakers react to and integrate the advice and recommendations from FACs into policy. More specific to this study, the fact that the 2014 NCA was delivered to the President and Congress obfuscates efforts to attribute or even trace policy action back to the NCA's findings. In contrast, the PEPFAR SAB provided very specific recommendations in response to a very specific request from Ambassador Goosby regarding what PEPFAR guidance should be in light of the findings from HPTN 052. It may be the case that for this second research question, the differences between the two selected cases are just too substantial to synthesize findings into a meaningful conclusion.

3. Research Question 3: How do FACs Facilitate and Impede the Use of Evidence by Policymakers?

Across both case studies, respondents provided similar suggestions for how advisory

committees could facilitate the use of evidence by policymakers. Respondents indicated that committee members can serve as translators of scientific information who understand the implications of that information for policy and can then make recommendations which may help to resolve controversies or ideological debates. The perceived legitimacy of the advisory committee was also noted as an important factor in facilitating the use of evidence. More specifically, respondents noted that having respected academics from an array of disciplines as committee members is critical. For the NCADAC in particular, the NCANet was noted as an important component that would help the NCA recommendations translate to lower levels of government or into the private sector.

The concept of a committee impeding the use of evidence was more easily grasped by respondents from the NCADAC case than the PEPFAR case. Many respondents in the PEPFAR case study took it as a given that any policy on HIV/AIDS prevention, care, and treatment would be based on the best science available. Those who did offer suggestions for how an advisory committee could impede the use of evidence had responses similar to respondents from the NCADAC case study: flawed member selection, namely appointing "big names" who do not have content expertise or a good understanding of how the government implements its programs, was viewed as a major way for advisory committees to impede the use of evidence. In addition, respondents across both cases indicated that the establishing agency has a responsibility or a duty to the committee to be clear about its expectations and share information in a candid way so that the committee could be as effective as possible.

B. Aim 2: Contribution of Contextual Factors to Adoption of Committee Recommendations

With the caveat that the only observed adoption of advisory committee recommendations during the study period was OGAC's adoption of the SAB's recommendations on treatment as prevention, respondents in both case studies noted the importance of the favorable views of the

White House on evidence-based policy in terms of potentially adopting any advisory committee's recommendations. Respondents indicated that having "the right people in leadership" is critical and that "it starts with the President".

There is a fundamental difference, however, between the two case studies in terms of what government entity receives each committee's recommendations. The NCADAC delivered the 2014 NCA to Congress, as required by the GCRA. The PEPFAR SAB delivered its recommendations to OGAC under Ambassador Goosby. Thus, even though there was a favorable political climate emanating from the White House, NCADAC stakeholders were not optimistic that Congress would act on the recommendations put forward in the NCA. Indeed, much of the action taken on climate change during the Obama Administration has been through Executive Orders.

The issue of what entity receives an advisory committee's recommendations seems to play an important role in the potential feasibility of adopting those recommendations. Relying on a Congress with a Republican majority to take legislative action on climate change is not likely to be fruitful. In contrast, if a committee delivers its recommendations to the leadership of an agency, it is possible that the agency would have more latitude in adopting the committee's recommendations.

In addition, the number of agencies that may be affected by an advisory committee's recommendations may also play a role in how feasible it is to fully adopt and implement committee advice. The NCADAC had 16 ex officio members, mainly because the USGCRP serves as a coordinating body for 13 agencies involved in climate change. In contrast, there were six ex officio members on the PEPFAR SAB. PEPFAR funding is funneled primarily through USAID and CDC, whereas the recommendations contained in the 2014 NCA affect 13 agencies at a minimum.

C. Aim 3: Stakeholder Engagement with FACA Committees

As discussed in Chapters 5 and 6, the key finding from this research related to stakeholder

engagement with the PEPFAR SAB and the NCADAC is that there was little civil society engagement with either committee, that civil society engagement with the NCADAC was highly structured and organized via the NCAnet, and that there was a far more nuanced dynamic occurring between NGOs and the advisory committee members and government agency staff involving informal "offline" (i.e., not using the official public comment period) mechanisms of communication. Further, the informal communication that was occurring was influenced heavily by already-existing and long-standing personal relationships. Finally, it was apparent that the mechanism built into FACA for engagement with the public – the mandatory public comment period held at FACA committee meetings – was ineffective.

Across both case studies, respondents in all categories of interviewees expressed surprise at how little interaction there was between civil society – especially NGOs and advocacy groups working on global HIV/AIDS or climate change – and the PEPFAR SAB or NCADAC, respectively. Respondents indicated that because the committee meetings were not widely publicized there was little knowledge in the climate change and HIV/AIDS advocacy communities that meetings were occurring. While FACA requires that the meetings are announced in the FR, respondents indicated that no one ever checks the FR. Further, while meeting announcements were added to the PEPFAR SAB website they were not announced on the main PEPFAR website nor were they sent out via listservs to the HIV/AIDS NGO community in Washington, DC. Thus, it was often the case that individuals were unaware that SAB meetings were occurring. The NCADAC had its own website as well and meeting announcements were placed there, along with meeting agendas and any documents that could be made publicly available. But, like the PEPFAR SAB, an individual interested in attending a NCADAC meeting would have to take the time to check the website periodically to be informed of meetings (assuming they were not checking the FR on a weekly basis).

Although both committees took an additional step beyond merely posting meeting notices in the FR, as is required by FACA law, by creating websites for the committees, it seems clear that taking additional measures to release information about committee meetings would help to inform civil society when meetings were occurring, at a minimum. This could be done by announcing committee meetings on major listservs that are used for communication among civil society groups. To the extent that meeting agendas were available in advance of the meetings, it would be helpful to include such documents in meeting announcements so that members of the public could determine whether it was worth their while to attend the meeting and/or prepare public comment.

IV. Conclusions

Although the findings from case studies cannot be generalized in a probabilistic sense, they may still be relevant to other contexts. The findings from the PEPFAR SAB and NCADAC case studies, as well as from this cross-case analysis, may be comparable to other studies of FACs. Comparability in this context refers "the degree to which the parts of a study are sufficiently well described and defined that other researchers can use the results of the study as a basis for comparison" (Khan & VanWynsberghe, 2008b). Related concepts of "naturalistic generalizability" or "transferability" refer to the extent to which "working hypotheses" generated from case study research are appropriate for understanding other cases, which in turn is a function of how similar the potential cases are to the original case (Gomm, Hammersley, & Foster, 2000). Yin rejects defining generalizability as analogous to probabilistic generalizability and as described in Chapter 4, refers to analytic generalizability. He notes that analytic generalizability is not automatic, but can be achieved through replicating findings in multiple cases (replication logic). Yin notes that conducting nine to 12 cases could provide "substantial support" for the initial study proposition (Yin, 2009, p. 55).

The literature suggests that the extent to which a case may be generalizable to other contexts may depend on the heterogeneity of the "population" of potential cases. If the assumption can be made that the population is comprised of nearly identical units, then the likelihood that a single case or a small number of cases could be broadly transferable or generalizable to other contexts is high. However, if there is a great degree of diversity across the pool of potential cases in areas that are consequential for the research, then transferability is more limited. Selecting cases strategically, based on the information – even if limited – that is known about the population of cases, can improve transferability (Flyvbjerg, 2006; Gomm et al., 2000).

The findings from the NCADAC and PEPFAR SAB cases could be transferable or generalizable to other FACs within limited parameters, namely FACs established by agencies with a common function. However, the difference between the two committees' primary objectives should be taken into consideration when generalizing the findings of this research. More specifically, the findings from the NCADAC case study are likely to be more generalizable to other FACs with very focused objectives which include drafting a major assessment synthesizing the state of the science in a particular area. Similarly, the findings from the PEPFAR SAB case study are likely to be more generalizable to FACs established to provide broad advice and guidance to an agency on a range of issues that fall under the purview of that agency.

While additional segregation of the pool or population of potential cases (i.e., other FACs) by primary objective may enhance the analytic generalizability of this study's research, there are conclusions which are applicable to FACs with any objective. These conclusions and recommendations based on them are addressed in the next chapter.

CHAPTER 8: DISCUSSION

I. Policy Implications and Recommendations

Based on the findings of the two individual case studies and the cross-case analysis, there are 9 preliminary implications and recommendations for policy. The following suggestions are offered with the hope that government agencies, advisory committee members, and civil society will take them into consideration when future committees are established.

A. Implications and Recommendations for Government Agencies

- *Government agency leadership and staff should consider and define ex ante a detailed scope of work for the FAC and clearly communicate expectations for the committee about successfully meeting the agency's expectations.*

This recommendation is offered with the understanding that issues may arise ad hoc which the establishing agency may need the committee to address. However, apart from unexpected matters requiring the committee's attention, the host agency has a responsibility to be clear and transparent with the advisory committee Chair(s) and members regarding the specific issues on which it would like the committee to provide advice; what, if any, products (i.e., reports) are expected from the committee; and under what timeframe the agency expects the committee to deliver. If any of these expectations change during the committee's tenure, the establishing agency has a duty to inform the committee. Whether the charter needs to be amended to reflect these changes would be left to the discretion of the agency in consultation with the DFO, CMO, and legal advisors. This type of iterative process of updating and managing expectations would help to ensure that the establishing agency obtains from the committee what it expects, that the committee delivers on said expectations, and ideally, would mitigate the likelihood that the establishing agency would perceive that the FAC had 'failed' because it did not deliver.

While broad objectives are outlined in every FACA committee's charter, there should be

additional guidance on what issues or scientific questions the agency expects the committee to provide advice that are developed well in advance of the first committee meeting and then distributed with sufficient time for committee members to review the guidance and formulate responses. The committee should be permitted to discuss and debate the guidance provided as well as to suggest that additional issues be added to the overall scope of the committee's agenda and/or that some of the original issues proposed by the agency be eliminated.

- *Government agency leadership should ensure that adequate staff time and resources are dedicated to effectively implement, manage, and administer its advisory committees.*

As noted in Chapter 7, a major difference between the PEPFAR SAB and the NCADAC was the staff support provided to each committee. As noted in Chapter 5, respondents in the PEPFAR case thought that the SAB could have been more useful to OGAC if more staff or more staff time had been dedicated to overseeing the SAB's operations and that the SAB could have been more efficient in completing its tasks with additional OGAC staff support. Although government agencies are nearly always operating in a resource-constrained environment, it is clear that without sufficient staff resources, establishing an advisory board can become an unfunded mandate, which compromises the potential effectiveness of the board.

Serious consideration should be given to re-balancing employees' responsibilities when an advisory committee is in the nascent phases of implementation to maximize the committee's effectiveness. A staff dedicated to managing the advisory committee not only can provide administrative support to the committee (e.g., setting up and effectively managing committee meetings and conference calls, receiving and responding to committee members' questions, assisting with the production and distribution of documents for committee meetings) thereby helping the committee itself to conduct its work in a more efficient manner, but can also help to ensure that agency leadership allocates sufficient time to thoughtfully considering on which issue(s) he/she

wants the committee to provide advice and recommendations. The need for substantial staff support seems to be particularly acute with large advisory committees.

Based on the findings from this research, the specific amount of staff time or the ratio of staff to committee members that would be optimal for a committee's effectiveness likely varies considerably by the expected outcomes of the committee. FACs like the NCADAC, which are tasked with delivering a major report or assessment of the state of the science on a certain issue, are likely to need a substantial amount of staff support at a variety of levels, from administrative to highly technical. FACs providing advice on recommendations on broad issues primarily in response to the requests of agency leadership may need less staff support on a standing basis, but should have access to additional support as needed. For example, when a FAC working group is tasked with delivering its report to the full committee, it may need both administrative and technical assistance. Thus, the model for a FAC like the PEPFAR SAB may involve not only having more staff/more staff time devoted to the committee on a standing basis, since 0.5 FTE on an annual basis was not sufficient, but also the flexibility to pull staff into FAC support on an ad hoc basis.

- *Training of FACA committees should be open to staff directly involved with the administration of agency committees, including non-direct hires.*

Given the restrictions on government agency hiring, it is often the case that individuals are hired through contractors, rather than directly by the agency itself. However, as discussed in Chapter 5, non-direct hires are prohibited from attending trainings on FACA committees. To the extent that this is a government-wide rule, and not just a rule of the State Department, consideration should be given to opening the FACA trainings to all agency employees hired under any mechanism who are spending at least 50 percent of their time administering a FACA committee. While agencies may perceive direct hires to be an investment in the future of the agency, and thus the more appropriate choice for training eligibility, the reality of US government agency staffing is that staff are often

hired through contracting mechanisms. Prohibiting them from enrolling in trainings that are directly relevant – if not critical – to their job duties compromises the effectiveness of the staff with respect to their duties related to supporting the FAC and potentially, the effectiveness of the FAC.

- *To ensure that advisory committees are perceived and actually do provide independent advice, the Chair(s) of the committee should be an individual who is not an employee or consultant of the establishing agency.*

In addition to difference in staff support received by the PEPFAR SAB and the NCADAC, another major departure point between the two committees was the affiliation of the chair. The chair of the PEPFAR SAB was technically a consultant to OGAC as well as a professor at UC Berkeley. In contrast, the chair of the NCADAC had no contractual affiliation with the DOC, NOAA, or USGCRP at the time he served as chair. If a primary goal of implementing a committee under FACA is to obtain advice and guidance from individuals who are independent of the establishing agency, then committee chairs should not be employees in any form of the establishing agency. This is not to say that the independence of the advice from committees with government employees or consultants who serve as chairs is always compromised. Rather, this recommendation is provided with the acknowledgement that even the perception that a committee's advice is not fully independent can compromise the legitimacy of the committee.

When selecting a chair, the agency should consider an individual's prior experience chairing FACA or other similar advisory committees, leadership style, ability to manage robust debates and discussions, and ability to keep the committee on task while maintaining a good rapport with committee members. These management skills should be considered in balance with scientific expertise: a chair with no experience in the scientific matters under the purview of the FAC but with a wealth of FAC management expertise would not be a logical choice. In reality, the option is not likely to be dichotomous, but an agency may have to weigh one skill set over another in selecting a chair. The appropriate choice would likely depend on the expertise and skills of other FAC members

as well as their personalities, the desired outcomes of the FAC, and the perceived or proven ability of the proposed chair to navigate agency politics in a facile manner.

- *Agencies should create and manage websites for their advisory committees that serve as "electronic homes" where all committee meeting announcements, agendas, presentations, reports, and minutes, are housed.*

Taking measures to ensure that all committee materials are posted in a timely manner on a website devoted specifically to the FAC helps to ensure that the activities and proceedings of FACA committees are fully transparent. In addition, maintaining up-to-date websites could strengthen engagement with civil society: with meeting materials posted online, the public has the opportunity to review the content and provide feedback through formal or informal channels. In addition, agencies should consider posting meeting announcements through listservs which are actively read by civil society groups, especially listservs maintained by NGOs on certain issues relevant to the topics addressed by the advisory committee. As noted in Chapters 5 and 6, respondents indicated that public attendance at committee meetings may have been low because meeting announcements were publicized in the FR, which few people read. By going a step beyond what FACA law requires and publicizing the meeting announcements more widely, agencies could engage more productively and frequently with civil society.

B. Implications and Recommendations for Advisory Committee Members

- *If not directed by the establishing agency, committee members should determine a process for decision-making.*

A primary impetus for drafting the FACA legislation in the early 1970s was to ensure that advisory committee proceedings and decisions were more transparent so that the American public and Congress could hold agencies accountable for their actions. Although meeting minutes are required by law, the extent to which the FAC or establishing agency complies with this is unclear. The PEPFAR SAB website contains no documents identified specifically as meeting minutes. Two

of the four meetings held during the committee's tenure have "executive summary" documents that are apparently intended to serve as meeting minutes, but neither of these documents reflect the tenor of the discussions held during the meetings.

Further, findings from the PEPFAR case study indicate that it was not always clear how the SAB arrived at its recommendations. In contrast to the NCADAC, which implemented and documented a comprehensive process to guide how the committee would make decisions (i.e., by consensus), the PEPFAR SAB did not have such measures. While debate among PEPFAR SAB members about a variety of topics was robust, in the absence of a specific set of procedures outlining how the board made final decisions about what recommendations and advice to present to OGAC, there seems to be room for additional transparency. Further, if a committee chooses not to make decisions by consensus and there are dissenting opinions from the majority, having a pre-determined decision-making process in place would permit these dissenting opinions to be noted in the meeting minutes.

C. Implications and Recommendations for Civil Society

- *Civil society should encourage government agencies to increase efforts to raise awareness about committee meetings.*

A common theme in both case studies was the lack of awareness among civil society groups about committee meetings. Surprisingly, both the PEPFAR SAB and the NCADAC had websites which announced the date, time, and location of upcoming meetings. While maintaining such websites provides an opportunity for the public to stay informed of committee proceedings, it requires proactive effort by civil society to visit the website (or check the FR). In the spirit of FACA, it seems appropriate for the agency to make an additional effort to provide notice of committee meetings to key NGOs or other organizations so that such information can be released via blogs, listservs, or other electronic media. Civil society groups are uniquely positioned to request this of

agencies, given that these organizations manage the listservs through which FACA committee information would be announced.

Aside from the potential to glean useful perspectives from members of civil society, more productive engagement could facilitate civil society buy-in to FAC decisions and processes. However, more frequent engagement by civil society – at least through the formal public comment period mandated by FACA – is not guaranteed to provide useful inputs to the FAC. Given how short the public comment period is (usually 10-15 minutes) and that the DFO can request that any attendees from the general public submit their comments in advance of the meeting, concerns about civil society groups being disruptive or otherwise distracting seem unlikely to be realized.

- *Civil society groups should engage more actively in committee proceedings.*

A surprising finding in both case studies was the low level of attendance and engagement by civil society at committee meetings. Respondents indicated that there were myriad factors which contributed to this, including that the meetings were not well-publicized, were not a good use of time, did not permit any engagement with committee members, and that there were other channels (e.g., conferences) through which civil society could access committee members. While all of this may be true, it seems possible that there is a negative feedback loop that could be at the root of the lack of engagement: irregular attendance at committee meetings and/or a poor experience with the public comment period could discourage civil society groups from attending future meetings. However, civil society groups could be helpful to the establishing agency and the advisory committee, by disseminating information about the committee's proceedings via blog posts, for example, and by reaching out to non-Washington, DC-based audiences that may have a vested interest in a committee's discussions but may not otherwise be able to attend the meetings in person. This may be especially true for FACs such as the PEPFAR SAB, which is designed to provide

HIV/AIDS prevention, care, and treatment services to individuals in other countries. Essentially, more regular and active engagement on the part of civil society may in turn make such engagement more fruitful.

D. Implications and Recommendations for Revisions to the FACA Legislation

- *FACA committee working groups should continue to not be subject to the rules and regulations of the FACA legislation.*

More specifically, should revisions to the FACA legislation be proposed, any meetings, discussions, or conference calls among working group members should not be required to be open to the public. Although arguments have been made that FACA committees are lacking in transparency because of the allowance for working groups to conduct their business away from the "sunshine" of the public, the results from the two cases included in this research suggest that there is limited interest among the public in the overall advisory committee's operations, let alone what is occurring at the working group level. Further, the logistical challenges of ensuring that all working group activities are open to the public and the delays in delivering on tasks that would likely ensue should the requirements be changed outweighs calls to open all committee operations to the public. Finally, there are measures to prevent working groups from having undue influence on the advice and recommendations received by the agencies: FACA requires that all working group reports, advice, and recommendations have to be approved by the advisory committee as a whole, and then presented by the committee (not the working group) to the host agency.

II. Strengths and Limitations

This study is the first empirical assessment of advisory committees focused on health issues established by government agencies at the federal level in the United States. The existing literature on FACA committees has not looked specifically and only at advisory committees for health. Given

that U.S. government agencies which include public health in their purview consistently and systematically establish federal advisory committees to provide recommendations regarding how research and evidence can be integrated into policy, gaining a better understanding of how FACA committees operate makes a valuable contribution to the understanding of how research and evidence are integrated into the health policy process.

The case studies included in this research allowed for a novel and 'real-time' examination of two high-profile advisory boards addressing issues that are high priorities in the public policy arena. PEPFAR is the largest program to combat a single disease by any nation. Climate change is a major policy priority for the Obama Administration. In the context of ever-increasing healthcare costs in the United States and concerns that funds allocated to international development could be better spent on domestic issues, ensuring that health policy is based on sound evidence is increasingly important. This may be especially true for policies determining what programs receive government funding and the volume of funding allocated. This research makes a novel contribution to the understanding of how advisory committees, which provide one mechanism for evidence to be integrated into public policies – function in the policy process.

Despite these strengths, there are limitations to the study. The policy implications and recommendations outlined above are based on findings from only two case studies. However, the concern about limited theoretical generalizability is mitigated to some extent because replication logic was used in the Stage 1 screening process: "if two or more cases are shown to support the same theory, replication may be claimed" (Yin, 2009, p.38). The transferability of the findings to other advisory committees should ultimately be tested through additional research, but the similarities in the findings across the two cases suggest there is relevancy for other FACA committees.

Secondly, the interview data may suffer from selection bias because the respondents self-

selected into the study: not all invited participants responded and some declined. Thus, the data obtained from the in-depth interviews may not be representative of the respondents' interview category (i.e., committee members, NGO/advocacy staff, and government officials). In particular, committee members who were relatively uninvolved in meeting discussions or did not attend committee meetings were not included in the pool of respondents because they were not recommended through the snowball sampling process. Those who did participate recommended the investigator avoid such individuals because it was assumed they would not have provided rich data. Further, there may have been a missed opportunity to obtain additional and rich data because a few of the participants who did not respond to multiple requests for an interview or declined to participate were recommended by a large number of other participants.

Finally, the gap between data collection and analysis is a departure from the grounded theory method and may have compromised theoretical sampling. Recall bias may have affected which topics were ultimately raised because the investigator was relying on her memory of topics raised in previous interviews and her interview notes – rather than coded interview data – to guide which topics were raised during interviews. However, all interviews were transcribed by the investigator which enabled her to remain close to the data.

III. Future Research

There are several areas for future research which are suggested by the two case studies. First, additional advisory committees established by agencies should be studied to assess whether the findings of the two case studies included herein are supported in different contexts. While the two advisory committees included in this study were intentionally selected to have many common characteristics, they differed on one key parameter, namely their objective to their host agency. Thus, it would be a contribution to the literature to analyze additional committees that are agency-

established for the purpose of providing broad scientific guidance and advice, as the PEPFAR SAB did, as well as committees that are established for the purpose of producing a report assessing the state of the science in a particular area, as the NCADAC did. Research that included a larger number of case studies would also provide more data about how agency-established FACs function and play a role in the policy process.

Further, advisory committees established by other authority – statutory authority/Congress, authorized by law, and Presidential – should be studied and compared to those established by agencies to better understand how institutional factors affect an advisory committee's role in the policy process. In addition, including FACs established by other types of authority would allow for a more robust comparison of how effective FACs are as a mechanism to facilitate the use of research and evidence by federal policymakers.

Related to future research that would study additional advisory committees by applying the same selection criteria used in this study as well as slightly varied criteria is research that expands the timeframe or boundary for each of the case studies. Extending the timeframe of the case studies so that the research is more longitudinal in nature would facilitate an assessment of the impact of the committees' recommendations on policy or program. While the PEPFAR SAB's recommendations on treatment as prevention were adopted almost immediately by OGAC, it may be the case that this is the exception to the rule. While attributing policy or program change to a committee's recommendations would likely be difficult given the number of other sources of advice which an agency is receiving, conducting a follow-up study several months or even years following the release of a committee's recommendations or report could be useful. Such a study could provide information about any lasting effects of a committee, including whether a committee's recommendations were adopted and why or why not.

In combination with additional case study research on FACs, it would be useful to

understand the overall landscape of FACs for health so that individual case studies could be placed within a larger context. Such research could draw on some of the findings from this study and utilize the FACA database to extract and analyze various basic characteristics of committees, such as the organizational affiliation of the committee chair (i.e., government staff or external organization) as well as the committee members, the number of committee members, the estimated budget and FTE requested, among other variables. This approach would involve substantial time and effort because the data on each variable exist on individual webpages within a specific FAC's record in the database, so the data on each page would have to be downloaded and then compiled with the rest of the data on that committee, which in turn then would have to be compiled with the other committees of interest.

In addition, committee charters could be analyzed to assess the scope of the committee objectives to better understand whether committees such as the NCADAC which had a primary purpose of developing the NCA are rare. While the response rate may be low, a survey could be developed and sent to the DFO and chairs for each health FAC that addressed questions which could not be answered from the data available in the FACA database but may not need to be answered through an in-depth interview, which is time consuming for both the respondent and the researcher. Alternatively, the survey could be administered as a part of the in-depth interview. This would potentially increase the response rate. The survey could address issues such as how the committee arrives at decisions (i.e., by consensus or other method) and whether there are working groups and if so, how many, since a current issue for FACA is whether the law should be amended to require FAC working groups to be subject to the same rules as the overall FAC. To facilitate responses, the survey questions would likely need to be multiple choice and include few, if any, questions with open-ended responses.

Additional research is also necessary to analyze the social networks that exist among advisory

committee stakeholders. Findings from both case studies indicate that the pre-existing professional relationships among the three categories of respondents can have a substantial influence on a variety of advisory committee characteristics, including the composition of the committee and what issues the committee discusses. There are three combinations of relationships that are of particular interest among the triad of respondent categories: government agency staff-advisory committee Chair(s)/members; government agency staff-civil society; and advisory committee Chair(s)/members-civil society.

While it might be understandable and even desirable for government agency staff to select committee members who are 'known entities' and thus already linked in some capacity to the agency and/or to each other, it is not clear ex ante just how connected these stakeholders are. A social network analysis would facilitate understanding of questions related to how dense (i.e., connected) the different stakeholders are to each other within and across stakeholder groups, as well as the power dynamics of individuals within the network (i.e., how central certain individuals are within the network). To the extent that the density of a social network analysis – or at least the density of the government agency staff and advisory committee members' portion of the network – serves as an indicator of how like-minded a group is in their thinking, such an analysis could also provide data on the homogeneity or diversity of a committee's perspectives.

IV. Conclusions

There are numerous mechanisms and opportunities, both formal and informal, for research and evidence to play a role in the policy process at all of its stages. This research sought to describe how one of the more formal mechanisms – advisory committees under the purview of FACA – are implemented, function, and managed. To date, there is a gap in the literature on even this most basic of descriptions. In keeping with the understanding that policymaking does not occur in a vacuum,

this study also sought to understand what and how contextual factors in the policy environment at the agency level and in the overall US government influenced the uptake of recommendations provided by FACs. Similarly, the role of key stakeholders – especially NGOs – was assessed to better understand whether and how these groups attempt to influence FAC proceedings and/or outcomes.

The two case studies conducted for this research provide a number of novel insights into the questions outlined above. While it is neither possible nor appropriate to claim that the findings from this research are applicable to all FACs, the findings do suggest that in spite of the heterogeneity that exists across FACs, there are important common elements that point to opportunities for future research as well as policy action, as outlined above. Although FACA has been clarified through additional legislation and case law since it was passed in 1972, these efforts are clearly not sufficient. Without definitive guidance on FACA rules, agencies have a wide berth with which the law can be interpreted. In turn, this affects how FACs are implemented, including who is appointed as chair, how transparent meeting proceedings are, and the information made available to the public. The member selection process is highly political and inevitably results in a FAC that is not without conflicts of interest. However, a FAC with no conflicts of interest may be a FAC with little utility to the establishing agency, as FACs need members with both implementation and scientific expertise. The political context – namely the perspective of the President and Congress about the role of evidence in policy – influences not only whether the recommendations from a FAC are used but more fundamentally, whether a FAC would be established at all.

Although the implementation and administration of FACs is challenging, and while the agencies which establish them are not bound to act on the recommendations they provide, federal advisory committees under FACA can provide a valuable opportunity for the US government to obtain sound advice from an independent and objective body of experts. While it may be difficult to

for the executive branch to obtain advice from a group of external experts through a mechanism other than a FACA committee, the benefits of establishing a FAC may outweigh the costs. FACA committees can provide credibility and legitimacy to an agency's decisions and can help to resolve inter-agency or inter-governmental disputes about the appropriate (i.e., evidence-informed) path for policy action. Further, the original intention behind drafting FACA has carried through over the past 40 years: the influence of external advisors on the executive branch is kept in check, the process of providing advice to the government is relatively transparent except in rare cases when national security might be compromised by having meetings open to the public, and the individuals who comprise FACs are ostensibly balanced in their perspectives, among other factors. While there is potential for a FAC to serve merely as a rubber stamp for an agency's decisions, this research suggests that agencies and FAC members alike take the role of the FAC very seriously and view FACA committees as a valuable mechanism which can facilitate policy and programs being informed by the best science available.

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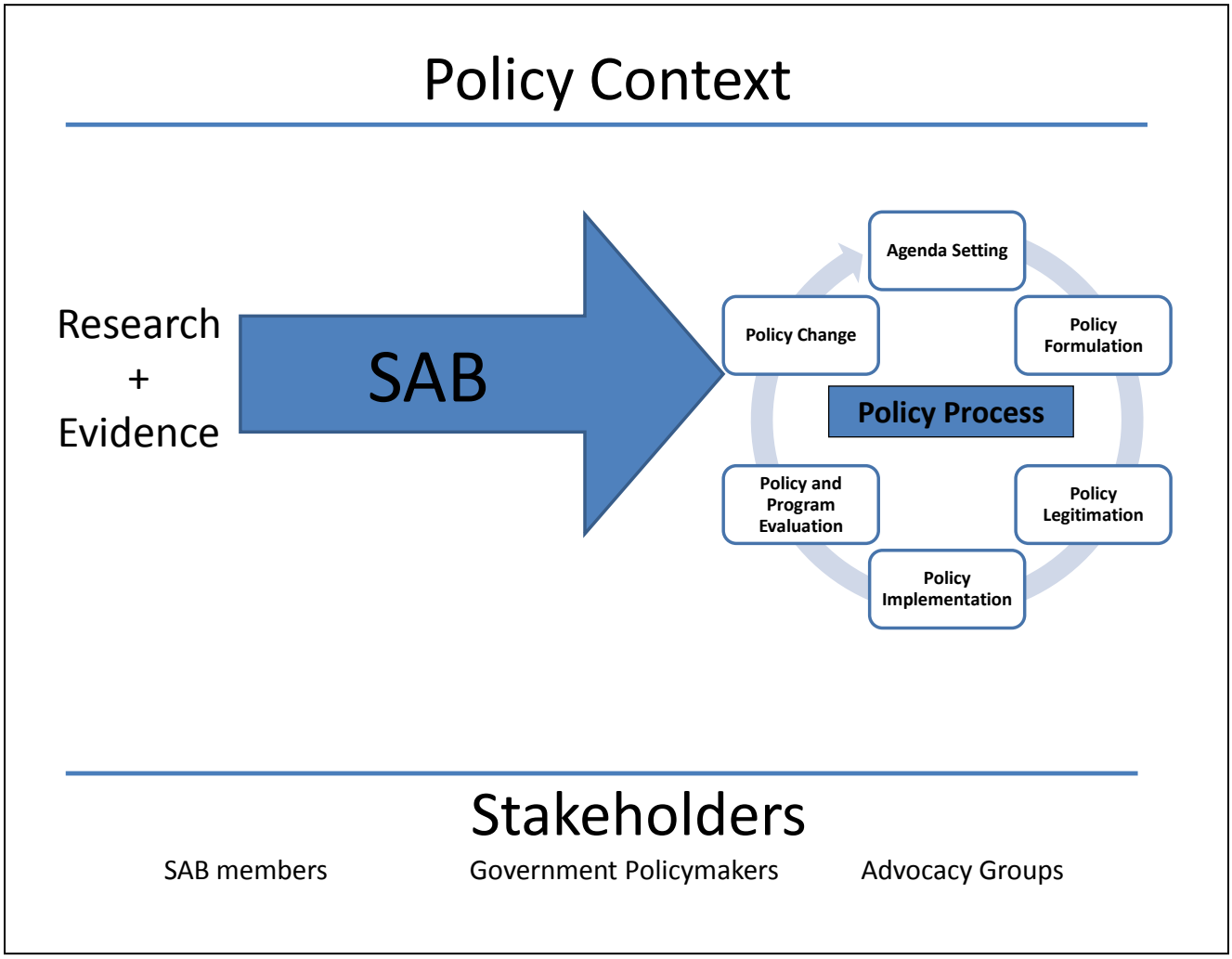
APPENDICES

Appendix A: Initial Conceptual Framework



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Appendix B. IRB Notice

FWA #00000287

Institutional Review Board Office

615 N. Wolfe Street / Suite E1100
Baltimore, Maryland 21205
Office Phone: (410) 955-3193
Toll Free: 1-888-262-3242
Fax Number: (410) 502-0584
E-mail Address: irboffice@jhsph.edu
Website: www.jhsph.edu/irb

INITIAL APPLICATION APPROVAL NOTICE

Date: June 21, 2012

To: Stephen Teret, JD, MPH
(Lisa Fleisher)
Department of Health Policy and Management

From: Luke Mullany, PhD, MHS
Alternate Chair, IRB-X

Re: **Study Title**: "The Role of Science Advisory Boards in US Federal Health Policy"
IRB No: 00004477

The **JHSPH IRB-X** voted to approve the above referenced application at its meeting on **June 21, 2012**. **The Board made the following determinations:**

Expedited ☐ **Convened** ☒ DHHS 46.110 ☐ DHHS ☒ FDA 56.110 ☐ FDA ☐ Category: 6 & 7 **GWAS** ☐	**Consent/Parental Permission Required From:** Adult Participant ☒ LAR ☐ One Parent ☐ Two Parents ☐ Legal Guardian ☐ (Foster Care Children)	**Form of Consent/Permission:** Written Consent ☒ Waiver of Signature ☐ (Oral Script) Waiver of Informed Consent ☐ HIPAA Authorization ☐ HIPAA Waiver ☐	**Study Site(s):** U.S. ☒ International ☐ **List Country(ies):**
Vulnerable Populations: **Children** ☐ **Foster Care Children** ☐ **DHHS** **FDA** 46.404 ☐ 50.51 ☐ 46.405 ☐ 50.52 ☐ 46.406 ☐ 50.53 ☐	**Assent Required From:** No children (waived) ☐ Children aged: _____ ☐ **Form of Assent:** Written ☐ Oral ☐ Assent Statement in Parent Permission ☐	**Pregnant Women/Fetuses** 46.204 ☐ **Neonates** ☐ 46.205 **Prisoners** 46.305 ☐ 46.306 ☐ **Epidemiological Research** ☐	**Sample Size:** (screened plus enrolled) 48 **Secondary Data Analysis:** (# specimens/participants)

Approval of the research is for the period of **June 21, 2012** to **June 20, 2013**. A Progress Report for continuing review must be submitted to the IRB Office no later than six weeks prior to the approval lapse date of **June 20, 2013.**

This approval is inclusive of the following documentation:

Research Plan (Version #1, 6-18-12)

In-Depth Interview (Version #1, 6-21-12)

Recruitment Email (Version #1, 6-15-12)

In-Depth Interview Guide (Version #1, 6-5-12)

As principal investigator of the research, you are responsible for fulfilling the following requirements of approval:

1) The co-investigators listed on the application should be kept informed of the status of the research.
2) Submit an Amendment Request Form for any changes in research. These changes in research are required to be reviewed and approved prior to the activation of the changes, with the following exceptions:
    a) changes made to eliminate an apparent immediate hazard to the research participant may be instituted immediately and the JHSPH IRB should be informed of such changes promptly; and
    b) changes to IRB Approved questionnaires, interview or focus group guides, other data collection or recruitment materials – limited to rewording to clarify meaning, correcting grammatical or typographical errors, or removing items that will not be used in the research.
3) Unanticipated problems involving risk of harm to participants or others that are related to the study procedures must be reported to the JHSPH IRB within 10 days of the time that the PI learns of such problems. A Problem Event Report Form must be submitted to the IRB immediately.
4) Only consent forms with a valid JHSPH IRB approval stamp or logo, with the correct IRB Approved version number and approval date may be presented to participants. All consent forms signed by subjects enrolled in the study should be retained on file. The Office of Graduate Education and Research conducts periodic compliance monitoring of study records, and consent documentation is part of such monitoring.
5) Federal regulations require review of approved research not less than once a year, unless a shorter period is determined by the IRB. **Therefore, a Progress Report for continuing review must be submitted to the IRB Office no later than six weeks prior to the approval lapse date. This will allow sufficient time for review of the application to be completed prior to the approval lapse date.** Failure to submit a Progress Report prior to the approval lapse date will result in termination of the study, at which point new participants may not be enrolled and currently enrolled participants must discontinue participation in the study. All ongoing research activities must stop immediately, including data analysis.
6) If your research involves international travel, please don't forget to register with the International Travel Registry https://apps4.jhsph.edu/ITR/Default.aspx so that the School may locate you in the event of an emergency.

LM/sro

Appendix C. Informed Consent Document

Approval Date: June 21, 2012
Approved Consent Version No.: 1
PI Name: Stephen Teret
IRB No. 00004477

JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

INFORMED CONSENT DOCUMENT

In-Depth Interview

Study Title: The Role of Science Advisory Boards in US Federal Health Policy
Principal Investigator: Professor Stephen P. Teret
IRB No.: IRB00004477
PI Version Date: June 5, 2012

What you should know about this study

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- You are a volunteer. You can choose not to take part and if you join, you may quit at any time. There will be no penalty if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.

Purpose of research project

You are invited to take part in a research project. This research is being done to understand how health policymakers use research and evidence when they make decisions.

The specific purpose of this interview is to understand how science advisory boards play a role in health policy.

Why you are being asked to participate

You are being asked to participate in this study because of your experience with science advisory boards and the issues they address. Approximately 48 people will take part in this study.

Procedures

Ms. Lisa Fleisher is asking expert informants who have experience with science advisory boards if they would like to participate in an interview.

This is a project asking only about your professional opinions, activities, and experiences, not your personal behaviors or beliefs. You do not have to answer any questions with which you feel uncomfortable.

- With your permission, Ms. Fleisher will record the interview with a digital recorder. We expect that the interview will take no more than 60 minutes of your time.
- In the interview, you will be asked questions about how science advisory boards function and their role in health policy.
- You will also be asked about the impact of science advisory boards and about how different groups can facilitate the uptake of recommendations put forth by science advisory boards.
- At the end of the interview, you will also be asked to recommend other potential participants, either members of advisory boards, researchers, government agency staff, or advocacy group staff who you think I should also interview as part of this project.

Risks/discomforts

Being part of this project is not likely to create any significant risk for you. Ms. Fleisher will be asking you questions about science advisory boards and their role in health policy. It is possible that you may not be comfortable with one or more of the questions. You do not have to answer any questions you would prefer not to answer.

There is a risk that someone may find out that you are participating in this project. We will do everything we can to prevent that from happening. Your contact information will be stored separately from any notes, recordings, or transcripts resulting from this interview. Ms. Fleisher will not include any identifying information, such as your name or job title, in any notes or transcripts from the interview. You will not be named in any reports that are written on the basis of this dissertation, nor will there be any description of you that would allow someone to identify you. Your contact information, as well as the digital recording and transcript of the interview, will be stored on a password-protected computer. Only Ms. Fleisher will have access to this information, and she will not be allowed to share it with anyone else.

Benefits

There is no direct benefit to you from participating in this project. However, we hope the findings from this project will be useful to you and your organization.

Protecting data confidentiality

All research projects carry some risk that information about you may become known to people outside of a study.

Although we anticipate that there will be minimal risk to you as a result of your participation in this interview, you will not be identified on the interview audio recordings. Your participation in the interview will be kept confidential. Your contact information is stored in a password-protected file separately from any notes, recordings, or transcripts from the interviews. Audio files will be destroyed using the "erase" button on the audio recorder immediately following transfer to Ms. Fleisher's password-protected laptop. Data will be stored on a password protected laptop and backed up on a secure password protected online cloud drive (SpiderOak.com). Raw data will not be shared. Only Ms. Fleisher will have access to the data from this study, and she will not share it with anyone else. Participants will not be named or otherwise identified in any reports that are written on the basis of this dissertation.

Protecting subject privacy during data collection

Interviews will be done in the privacy of the respondents' own offices or a private meeting space, should the participant share an office.

Who do I call if I have questions or problems?

You do not have to agree to be in this project, and you may change your mind at any time.

- Call the faculty advisor, **Stephen Teret**, at (410) 955-3995 if you have questions or complaints about being in this project.

- Call or contact the Johns Hopkins Bloomberg School of Public Health IRB Office if you have questions about your rights as a study participant. Contact the IRB if you feel you have not been treated fairly or if you have other concerns. The IRB contact information is:

Address:	Johns Hopkins Bloomberg School of Public Health 615 N. Wolfe Street, Suite E1100 Baltimore, MD 21205
Telephone:	(410) 955-3193
Toll Free:	1 (888) 262-3242
Fax:	(410) 502-0584
E-mail:	irboffice@jhsph.edu

What does your signature on this consent form mean?

Your signature on this form means:

- You have been informed about this study's purpose, procedures, possible benefits and risks.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this study.

Interview Participant (Print)	Interview Participant (Signature)	Date
Lisa Fleisher (Print)	Lisa Fleisher (Signature)	Date

Appendix D. Amended Informed Consent Document

Approval Date: July 31, 2014
Approved Consent Version No.: 2
PI Name: Stephen Teret
IRB No. 00004477

JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

INFORMED CONSENT DOCUMENT

In-Depth Interview

Study Title: The Role of Science Advisory Boards in US Federal Health Policy
Principal Investigator: Professor Stephen P. Teret
IRB No.: IRB00004477
PI Version Date: July 30, 2014

What you should know about this study

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- You are a volunteer. You can choose not to take part and if you join, you may quit at any time. There will be no penalty if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.

Purpose of research project

You are invited to take part in a research project. This research is being done to understand how health policymakers use research and evidence when they make decisions.

The specific purpose of this interview is to understand how science advisory boards play a role in health policy.

Why you are being asked to participate

You are being asked to participate in this study because of your experience with science advisory boards and the issues they address. Approximately 48 people will take part in this study.

Procedures

Ms. Lisa Fleisher is asking expert informants who have experience with science advisory boards if they would like to participate in an interview.

This is a project asking only about your professional opinions, activities, and experiences, not your personal behaviors or beliefs. You do not have to answer any questions with which you feel uncomfortable.

- With your permission, Ms. Fleisher will record the interview with a digital recorder. We expect that the interview will take no more than 60 minutes of your time.
- In the interview, you will be asked questions about how science advisory boards function and their role in health policy.
- You will also be asked about the impact of science advisory boards and about how different groups can facilitate the uptake of recommendations put forth by science advisory boards.
- At the end of the interview, you will also be asked to recommend other potential participants, either members of advisory boards, researchers, government agency staff, or advocacy group staff who you think I should also interview as part of this project.

Risks/discomforts

Being part of this project is not likely to create any significant risk for you. Ms. Fleisher will be asking you questions about science advisory boards and their role in health policy. It is possible that you may not be comfortable with one or more of the questions. You do not have to answer any questions you would prefer not to answer.

There is a risk that someone may find out that you are participating in this project. We will do everything we can to prevent that from happening. Your contact information will be stored separately from any notes, recordings, or transcripts resulting from this interview. Ms. Fleisher will not include any identifying information, such as your name or job title, in any notes or transcripts from the interview. You will not be named in any reports that are written on the basis of this dissertation, nor will there be any description of you that would allow someone to identify you. Your contact information, as well as the digital recording and transcript of the interview, will be stored on a password-protected computer. Only Ms. Fleisher will have access to this information, and she will not be allowed to share it with anyone else.

Benefits

There is no direct benefit to you from participating in this project. However, we hope the findings from this project will be useful to you and your organization.

Protecting data confidentiality

All research projects carry some risk that information about you may become known to people outside of a study.

Although we anticipate that there will be minimal risk to you as a result of your participation in this interview, you will not be identified on the interview audio recordings. Your participation in the interview will be kept confidential. Your contact information is stored in a password-protected file separately from any notes, recordings, or transcripts from the interviews. Audio files will be destroyed using the "erase" button on the audio recorder immediately following transfer to Ms. Fleisher's password-protected laptop. Data will be stored on a password protected laptop and backed up on a secure password protected online cloud drive (SpiderOak.com). Raw data will not be shared. Only Ms. Fleisher will have access to the data from this study, and she will not share it with anyone else. Participants will not be named or otherwise identified in any reports that are written on the basis of this dissertation.

Protecting subject privacy during data collection

Interviews will be done in the privacy of the respondents' own offices or a private meeting space, should the participant share an office.

Who do I call if I have questions or problems?

You do not have to agree to be in this project, and you may change your mind at any time.

- Call the faculty advisor, **Stephen Teret**, at (410) 955-3995 if you have questions or complaints about being in this project.

- Call or contact the Johns Hopkins Bloomberg School of Public Health IRB Office if you have questions about your rights as a study participant. Contact the IRB if you feel you have not been treated fairly or if you have other concerns. The IRB contact information is:

  Address: Johns Hopkins Bloomberg School of Public Health
  615 N. Wolfe Street, Suite E1100
  Baltimore, MD 21205
  Telephone: (410) 955-3193
  Toll Free: 1 (888) 262-3242
  Fax: (410) 502-0584
  E-mail: irboffice@jhsph.edu

What does your signature on this consent form mean?

Your signature on this form means:

- You have been informed about this study's purpose, procedures, possible benefits and risks.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this study.
- You certify that you are at least 18 years of age, and are participating in the project, with authorization, in your official capacity as an employee of the United States Department of State.

_____	_____	_____
Interview Participant (Print)	Interview Participant (Signature)	Date
_____	_____	_____
Lisa Fleisher (Print)	Lisa Fleisher (Signature)	Date

Appendix E. FACA Committee Categories and Topics

Category		Topic (* included as public health)
Agriculture	1.	Agriculture
	2.	Forestry
	3.	Plant Biology
	4.	Rural Development
Animals	5.	Animal Sciences and Husbandry
	6.	Fish and Wildlife
	7.	Veterinary Medicine
Applied Science	8.	Applied Sciences
	9.	Engineering
	10.	Mathematics
	11.	Statistics
Arts	12.	Arts and Humanities
Aviation	13.	Air Traffic
	14.	Airline Sciences
	15.	Aviation
Basic Science	16.	Basic Sciences
	17.	Biology
	18.	Chemistry
	19.	Materials Research
	20.	Microbiology
	21.	Physics
Business	22.	Business and Domestic Commerce
	23.	Business and Domestic Commerce
	24.	Industry
	25.	Management Science
	26.	Manufacturing
	27.	Patents and Trademarks
	28.	Small Business
Civil Rights	29.	Children
	30.	Civil Rights
	31.	Disabled
	32.	Equal Opportunity
	33.	Minorities
	34.	Native Americans
	35.	Women
Communications	36.	Broadcasting and Communications
	37.	Radio
Computer Technology	38.	Applications
	39.	Computers
	40.	Information Technology
	41.	Internet
	42.	Semiconductors
	43.	Systems Engineering
	44.	Technology
Data	45.	Data Integrity
	46.	Data Quality
	47.	Privacy
Education	48.	Education

Category	Topic (* included as public health)
	49. Schools and Academic Institutions
	50. Sports
	51. Training
Eligibility	52. Eligibility Programs
	53. Social Services
	54. Welfare
Emergency	55. Disaster Assistance
	56. Earthquake, Flood, and Fire Hazards and Administration
	57. Emergency Preparedness and Management
Energy	58. Energy
	59. Fuel
	60. Fuel Transportation
	61. Mining and Minerals
	62. Natural Resources
	63. Nuclear Power
	64. Pipelines
Environment	65. Earth Sciences
	66. Environmental Issues
	67. Oceans and Atmospheric Sciences
	68. Waste Disposal
Federal Employment	69. Compensation
	70. Federal Employees and Personnel
	71. Public Services
Finance	72. Banking
	73. Credit
	74. Finance
	75. Investment
	76. Securities
	77. Tax
Food and Drugs	78. Biotechnology
	79. Food and Drugs (*)
	80. Medical Devices
Government	81. Federal Government
	82. Internal Federal Government
	83. State Government
	84. Tribal Government
Health	85. Aging (*)
	86. Biodefense (*)
	87. Health Care (*)
	88. Hospitals (*)
	89. Medical Education (*)
	90. Medical Practitioners (*)
	91. Nutrition (*)
	92. Nutrition for Women, Infants and Children (*)
	93. Physical Fitness (*)
	94. Public Health (*)
	95. Radiation Protection (*)
	96. Safety (*)
	97. Sports (*)

Category	Topic (* included as public health)
	98. Treatment (*)
Honorary Award	99. Honorary Award
Housing and Urban	100. Housing and Urban Development
	101. International Programs, Studies, and Diplomacy
International	102. International Economic Policy
	103. International Law
	104. International Organizations
Justice	105. Criminology
	106. Drug Abuse Policy and Enforcement
	107. Justice
	108. Juvenile Justice
	109. Law Enforcement
	110. Prevention
	111. Research and Statistics
Labor	112. Employment
	113. Job Training
	114. Labor
	115. Occupational Safety and Health (*)
	116. Wages
	117. Workforce and Occupations
Land	118. Conservation and Preservation
	119. Grazing Areas
	120. Land Management and Use
	121. National Parks, Sites, Trails, Recreational Areas Monuments
Legislation	122. Administrative Procedure
	123. Jurisprudence
	124. Legislation
	125. Regulations
	126. Regulatory Negotiation
	127. Rulemaking
Medicine	128. Diseases (*)
	129. Health and Health Research (*)
	130. Illnesses (*)
	131. Medicine and Dentistry (*)
	132. Radioactive Materials
National Defense	133. National Security and Defense
	134. Overseas Security Issues
Rehabilitation	135. Rehabilitation and Disability
Research	136. Basic Research
	137. Research and Development
	138. Research and Statistics
Retirement	139. Employee Welfare
	140. Pensions
	141. Retirement
	142. Social Security
Science and Technology	143. Innovation
	144. Science and Technology
Social Sciences	145. History
	146. Risk Communication

Category		Topic (* included as public health)
	147.	Social Sciences
Space	148.	Space and Aeronautics
Tax	149.	E-payments
	150.	Information Reporting
	151.	Administration
	152.	Compliance
	153.	E-file
	154.	Electronic Services
Trade	155.	Competitiveness
	156.	Exports and Imports
	157.	International Commerce and Investment
	158.	Trade and Trade Policy
Transportation	159.	Boating and Navigation
	160.	Highways
	161.	Mass Transit
	162.	Railroads
	163.	Surface and Vehicular Transportation
Veterans	164.	Benchmark and Clinical Trials Research Studies
	165.	Veterans and Veterans' Medical Care
Water	166.	Harbors
	167.	Rivers
	168.	Water Use
	169.	Waterways

Appendix F. Results from Phase 1 Screening (ordered chronologically by fiscal year)

FY	Agency	Committee Name	Topic	Function
1993	EPA	Clean Air Act Advisory Committee	env	National Policy Issue Advisory Board
1993	USDA	National Advisory Committee on Microbiological Criteria for Foods	safety	Scientific Technical Program Advisory Board
1993	HHS	Board of Scientific Counselors National Institute for Occupational Safety and Health	safety	Scientific Technical Program Advisory Board
1993	DOE	Environmental Restoration and Waste Management Advisory Committee	env	National Policy Issue Advisory Board
1996	EPA	Pesticide Program Dialogue Committee	env	National Policy Issue Advisory Board
2003	HHS	CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment		Other
2003	USDA	Advisory Committee on Biotechnology and 21st Century Agriculture	env	Other
2004	HHS	National Science Advisory Board for Biosecurity	safety	Scientific Technical Program Advisory Board
2005	DOD	Veterans' Advisory Board on Dose Reconstruction	hc	Scientific Technical Program Advisory Board
2006	DOT	National Emergency Medical Services Advisory Council	osh	Other
2008	HHS	Board of Scientific Counselors National Center for Injury Prevention and Control	safety	Other
2008	HHS	Board of Scientific Counselors Coordinating Office for Terrorism Preparedness and Emergency Response	ph	Scientific Technical Program Advisory Board
2011	DOS	The President's Emergency Plan for Aids Relief	ph	Other
2011	DOC	National Climate Assessment and Development Advisory Committee	env	Other

Appendix G. List of SABs Excluded under Phase 2 Screening with Rationale for Exclusion

FY	Agency	Committee Name	Topic	Function	Exclude/ Include	Rationale
1993	EPA	Clean Air Act Advisory Committee	env	National Policy Issue Advisory Board	exclude	- Advises on the implementation and enforcement of a specific piece of legislation (compromises literal replication) - Potential time boundary problems because the committee has existed for 22 years
1993	HHS	Board of Scientific Counselors National Institute for Occupational Safety and Health	safety	Scientific Technical Program Advisory Board	exclude	- Focuses entirely on research – extent to which committee recommendations affect broader public health policy is unclear
1993	DOE	Environmental Restoration and Waste Management Advisory Committee	env	National Policy Issue Advisory Board	exclude	- Focuses on nuclear waste cleanup. Active projects in 14 states in the U.S.
1996	EPA	Pesticide Program Dialogue Committee	env	National Policy Issue Advisory Board	exclude	- Reports to the EPA Administrator through the Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention; - Provides guidance specifically to the pesticide program (i.e., not the entire EPA)
2003	HHS	CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment		Other	exclude	- Topic areas addressed by this SAB have overlap with PEPFAR SAB. Since theoretical replication is a key component of Phase 2 case study selection, it is important to have variation across the case studies, including in the substantive topics addressed by each.

FY	Agency	Committee Name	Topic	Function	Exclude/ Include	Rationale
2003	USDA	Advisory Committee on Biotechnology and 21st Century Agriculture	env	Other	exclude	- Current focus of SAB (to develop practical recommendations for strengthening coexistence among different agricultural production methods) is tangentially related to public health.
2004	HHS	National Science Advisory Board for Biosecurity	safety	Scientific Technical Program Advisory Board	exclude	- Focus of SAB is very narrow - Unclear whether SAB would be a viable case study given secret/classified nature of SAB topic and frequency of closed meetings
2005	DOD	Veterans' Advisory Board on Dose Reconstruction	hc	Scientific Technical Program Advisory Board	exclude	- Topical focus of SAB is very narrow (i.e., provide "review and oversight of the Radiation Dose Reconstruction program and make such recommendations on modifications in the mission, procedures and administration of the Radiation Dose Reconstruction Program.") - Focus on veterans as a population is also narrow.
2008	HHS	Board of Scientific Counselors National Center for Injury Prevention and Control	safety	Other	exclude	- Spoke with David Grossman as key informant re: scope and objectives of SAB. - He clarified that the major activity of the BSC is to serve NIH as a secondary advisory council and to make recommendations for grant funding.
2008	HHS	Board of Scientific Counselors Coordinating Office for Terrorism Preparedness and Emergency Response	ph	Scientific Technical Program Advisory Board	exclude	- Provides advice about operations and administration of programs rather than technical guidance on implementation of public health programs or research

Appendix H. Final Interview Protocol

Introduction

1. Can you please describe for me what have been your interactions with science advisory boards under FACA?

2. What has been your experience to date with the PEPFAR [NCADAC] advisory board [committee]?

Role of SABs in Evidence-Based Policy

I would like to ask you some questions about how science advisory boards function and their role in the policy process.

1. What was the rationale for establishing the PEPFAR SAB?

   PROBE: What is your sense of why the PEPFAR SAB was established when it was? [NOTE: This question is only relevant to the PEPFAR case because the NCADAC has existed in various forms for several years.]

2. Could you describe the process involved with your appointment to the SAB?

3. What is your sense of how the decision-making process went for appointing the Chair?

4. What is your sense of how the PEPFAR SAB [NCADAC] is balanced in terms of the areas of expertise, organizational affiliation, etc. of the other board [committee] members?

5. To what extent do you think the size of the SAB [NCADAC] had an effect on its proceedings, efficiency, etc.?

6. How do you think science advisory boards facilitate the use of evidence by policymakers?

7. How do you think science advisory boards impede the use of evidence by policymakers?

Factors Contributing to Adoption of SAB Recommendations

I would like to ask you some questions about the impact of science advisory boards.

1. Could you please describe your sense of the role of the agency in the board's [committee's] work?

2. How would you characterize a successful science advisory board?

   PROBE: If an advisory board is considered 'successful', what does that mean?

3. How would you characterize a failed science advisory board?

   PROBE: If an advisory board is considered a 'failure', what does that mean?

4. What factors do you think contribute to policymaker's use of the recommendations from science advisory boards?

5. If policymakers do not use the recommendations from a science advisory board, what factors do you think contribute to this?

Stakeholder Strategies

I would like to ask you some questions about the strategies different stakeholders use to help to facilitate the uptake of recommendations put forth by science advisory boards.

1. To what extent do you think the public comment period is effective?

2. What are other mechanisms for external stakeholders – especially advocacy groups, civil society, or NGOs – to engage with the SAB [NCADAC]?

3. How do you think advocacy groups/government officials/SAB members could be more effective in ensuring that SAB recommendations are used by policymakers? [Note: adjust per type of respondent.]

   PROBE: What other strategies could advocacy groups/government officials/SAB members use to facilitate the uptake of SAB recommendations?

4. Who else would you recommend I speak with about this issue?

5. Is there anything else you would like to tell me?

Appendix I. Curriculum Vita

LISA K. FLEISHER

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EDUCATION

Johns Hopkins Bloomberg School of Public Health, Baltimore, MD
PhD Candidate, Health Policy and Management (expected 2015)
Dissertation: The Role of Science Advisory Boards in U.S. Federal Health Policy

Johns Hopkins Bloomberg School of Public Health, Baltimore, MD
MPH, 2005

Stanford University, Stanford, CA
BA, Human Biology, 2001
Minor: Spanish

Universidad de Salamanca, Spain
Visiting Student, Spring 2000

PROFESSIONAL EXPERIENCE

The World Bank, Washington, DC **August 2012–present**
Short-Term Consultant, Health, Nutrition and Population Unit (HNP), Human Development Network

- Co-author of a case study on verification of results-based financing for health in Afghanistan.
- Co-author of a cross-case analysis of six country cases (Afghanistan, Argentina, Burundi, Panama, Rwanda, United Kingdom) of verification of results-based financing for health programs.
- Drafted and edited content of nine e-learning modules for results-based financing in health online course. Assisted with course design and implementation.
- Co-managed the Health and the Economy work program. Co-authored two HNP Discussion papers on trends in health financing and the political economy of government health spending.

May–September 2012
Short-Term Consultant, East Asia and Pacific Health, Nutrition and Population Unit

- Analyzed health outcome, macro-economic, and health financing data for assessment of macro-fiscal implications of attaining universal health coverage in Vietnam.
- Drafted policy note assessing macro-fiscal context of universal coverage in Vietnam.

The United States Agency for International Development, Washington, DC **2011–2012**
Technical Advisor, Global Health Initiative

- Provided technical guidance on the development and implementation of two Evidence Summits on 'Community and Formal Health Systems Support for Enhanced Community Health Worker Performance' and 'Increasing Use of Maternal Health Services through Financial Incentives'.
- Designed and administered survey on USAID Mission support for performance-based incentives (PBI). Analyzed survey results and briefed Global Health Bureau and front office staff on key findings.
- Drafted workplan for PBI Interest Group and Executive Summary of existing USAID guidance documents on PBI design, implementation, and evaluation.

The World Bank, Washington, DC **Summer 2010**
Short-Term Consultant, Health, Nutrition, and Population Unit, Human Development Network
- Wrote working paper on aid effectiveness and achievement of the health MDGs. Worked with the Health Results Innovation Trust Fund, International Health Partnership and Related Initiatives, and Health Systems Funding Platform teams to consider possible impacts of improved aid effectiveness on health outcomes.

ONE, Washington, DC **2009**
Senior Policy Associate, Global Policy Team
- Managed health portfolio for policy team. Developed ONE's position on major events such as the G8 Summit (health component), launch of President Obama's Global Health Initiative, GFATM Replenishment meeting, and U.S. budget proposals for global health.
- Advised senior leadership on strategic directions for health advocacy efforts, especially innovative financing mechanisms and replenishment of global health funds. Served as ONE's focal point for collaboration with the global health advocacy community.
- Drafted ONE's positions on developments in HIV/AIDS, malaria, vaccines, health systems, maternal and child health, and innovative financing.
- Advised U.S. Government Relations team on health-related lobbying activities. Reviewed and edited draft legislation.
- Wrote health and aid effectiveness sections of ONE's 2009 DATA Report, tracking progress of G8 donor commitments for development in Africa. Drafted briefs for ONE principals, health and aid effectiveness content for website, and blog postings on key health issues.
- Supervised research assistant and intern. Served as liaison to ONE's field team staff and volunteers.

Abt Associates, Bethesda, MD **2007–2008**
Senior Analyst, Health Systems 20/20 Project
- Co-managed technical assistance to Kenya Ministry of Health for National Health Accounts (NHA) estimation. Analyzed financial flow data; advised on use of findings for policy; and co-led data analysis and report writing workshops. Briefed USAID/Kenya mission staff on project progress and findings.
- Co-managed design and implementation of health system assessment in Nigeria. Served as technical lead for health financing module. Led focus group discussions with state government officials to collect state-level data; analyzed data; and co-authored report on findings.
- Developed case study for facilitating use of reproductive health NHA data to inform resource allocation decisions by Rwanda's Ministry of Health. Advised on revision of Liberia NHA survey instrument.
- Assisted with design and implementation of PEPFAR-funded evaluation of transition program for men released from drug rehabilitation facilities in Vietnam.
- Contributed to successful bids for $300 million DFID-funded Partnership for Transforming Health Systems (PATHS2) project in Nigeria and $10 million Health Policy Initiative (HPI) project in Vietnam.

The World Bank, Washington, DC **2005–2007**
Junior Professional Associate, Health, Nutrition, and Population (HNP) Unit
- Assisted with management and priority setting of Health Systems and Financing Policy team. Edited Health Financing Revisited: A Practitioner's Guide and co-authored other publications on global health aid architecture. Analyzed health financing and morbidity and mortality data to perform cross-country comparisons of health systems.

- Core member of team which developed the World Bank Strategy on Health, Nutrition, and Population Results. Wrote introduction on impact of investment in health on economic growth and annex on trends in global aid architecture. Coordinated inputs from regional staff on Strategy implementation plans.
- Assisted with development of Sub-Saharan Africa-focused World Bank/WHO initiative to coordinate agendas of global health donors; wrote and edited briefs and presentations for HNP Unit and World Bank senior management; assisted the Acting Director of HNP with special assignments.

The Center for Law and the Public's Health, Georgetown and Johns Hopkins Universities, Baltimore, MD **2004–2005**

Research Assistant

- Assisted with CDC-funded project to develop voluntary and legal interventions for health departments to use to reduce transmission of STIs and HIV among individuals who patronize commercial sex venues.

FHI360, Arlington, VA **2003–2004**

Associate Program Officer, YOUTHNET Program

- Coordinated among USAID/Washington, YouthNet staff, and country-level colleagues to design, implement, monitor, and evaluate reproductive health and HIV/AIDS projects for youth in Sub-Saharan Africa and Latin America.

AcademyHealth, Washington, DC **2001–2003**

Research Assistant, Changes in Health Care Financing and Organization (HCFO) Initiative

Supported HCFO Initiative grant-making activities.

PUBLICATIONS

Peer-Reviewed Articles

- Ajay Tandon, **Lisa Fleisher**, Rong Li, Wei Aun Yap. 2014. "Reprioritizing government spending on health: pushing an elephant up the stairs?" *World Health Organization South-East Asia Journal of Public Health* Special Issue on Universal Health Coverage 3 (3-4): 206-213.
- Trujillo, Antonio, Amanda Glassman, **Lisa K. Fleisher**, Divya Nair, and Denizhan Duran. 2014. "Applying Behavioral Economics to Health Systems of Low- and Middle-Income Countries: What are Policy Makers' and Practitioners' Views?" *Health Policy and Planning* doi: 10.1093/heapol/czu052
- Amanda Glassman, Denizhan Duran, **Lisa Fleisher,** et al. 2013. **"**Impact of conditional cash transfers on maternal and newborn health" *Journal of Health Population and Nutrition* 31(4 Suppl 2):48-66.
- Trujillo, Antonio and **Lisa K. Fleisher**. 2013. "Beyond Income, Access, and Knowledge: Factors Explaining the Education Gradient in Prevention Among Older Adults With Diabetes and Hypertension in Latin America*", Journal of Aging and Health* Volume 25 Issue 8.
- Schieber, George, Pablo Gottret, **Lisa Fleisher**, and Adam Leive. 2007. "Financing Global Health: Mission Unaccomplished", *Health Affairs*, 26, no. 4: 921-34

Additional Publications

- Tandon, Ajay, **Lisa Fleisher**, Rong Li, and Wei-Yun Yap. January 2014. *Reprioritizing Government Spending on Health: Pushing an Elephant Up the Stairs?* HNP Discussion Paper: The World Bank, Washington, DC.
- **Fleisher, Lisa,** Adam Leive, and George Schieber. November 2013. *Taking Stock of Fiscal Health: Trends in Global, Regional, and Country Level Health Financing.* HNP Discussion Paper: The World Bank, Washington, DC.

- Hatt, Laurel E. and **Lisa K. Fleisher**. January 2009. *Toward Solving Health Financing Challenges in Africa – A Way Forward*. Bethesda, MD: Health Systems 20/20, Abt Associates Inc.
- Kombe, Gilbert; **Lisa Fleisher**; Eddie Kariisa; Aneesa Arur, Parsa Sanjana (Abt Associates Inc. Health Systems 20/20); Ligia Paina (USAID); Lola Dare, Ahmed Abubakar, Shekwoduza Baba, Eno Ubok-Udom, Sam Unom. April 2009. *Nigeria Health System Assessment 2008.* Abt Associates Inc.
- **Fleisher, Lisa**, Pablo Gottret, Adam Leive, George J. Schieber, Ajay Tandon, and Hugh Waters. 2008. "Assessing Good Practice in Health Financing Reform" in George Schieber, Pablo Gottret, and Hugh Waters, eds., Good Practices in Health Financing: Lessons from Reforms in Low- and Middle-Income Countries. World Bank: Washington, DC.
- Atim, Chris, **Lisa K. Fleisher**, Laurel Hatt, Stephen Musau, and Aneesa Arur. Forthcoming. "Health Financing in Africa Today: Challenges and Opportunities". Washington, DC: Africa's Health in 2010, Academy for Educational Development, and Bethesda, MD: Health Systems 20/20 Project, Abt Associates, Inc.
- Dodd, Rebecca, George Schieber, Andrew Cassels, **Lisa Fleisher**, and Pablo Gottret. 2007. "Aid Effectiveness and Health," *Making Health Systems Work: Working Paper No. 9*, WHO/HSS/healthsystems/2007.2. Department for Health Policy, Development and Services; Health Systems and Services. WHO: Geneva.
- Schieber, George, **Lisa Fleisher**, and Pablo Gottret. 2006. "Getting Real on Health Financing", *Finance and Development*. Vol. 43, No. 4. International Monetary Fund: Washington, DC. December.
- **Fleisher, Lisa K**. 2003. "Access and Use of Health Care Vary by Medicaid Managed Care Program", AcademyHealth, Vol. 6, Issue 3, June.
- Austin, Bonnie J. and **Lisa K**. **Fleisher**. 2003. "Financing End-of-Life Care: Challenges for an Aging Population", AcademyHealth: Washington, DC. February.

PRESENTATIONS

- Dutta, Arin and **Lisa Fleisher**. 2008. "Planning for Sustainable HIV/AIDS Services Using the HIV/AIDS Program Sustainability Assessment Tool (HAPSAT) Software – A Hands-on Training". Training Workshop, *Global Health Council 36th Annual International Conference on Global Health: Community Health – Delivering, Serving, Engaging, Leading.* May 27. Washington, DC.
- **Fleisher, Lisa K**. 2008. "International Financing of Disease Control Programs". Invited discussant. Johns Hopkins Bloomberg School of Public Health. April 2. Baltimore, MD.
- **Fleisher, Lisa K**. 2007. "Linking NHA and NASA: A Coordinated Approach". Presentation to UNAIDS *National AIDS Spending Assessment (NASA) Workshop for Eastern Europe and Central Asia*. December 3-7. Bucharest, Romania.
- **Fleisher, Lisa K.** 2007. "Global Trends in Aid for Health", Presentation to the University of Michigan Population Leadership Program Fellows. March 15. The World Bank: Washington, DC.
- **Fleisher**, **Lisa K**. 2006. "Global Health Policy Environment", Presentation for Health, Nutrition, and Population *Learning Series for the Novice*. May 10. Washington, DC.

AWARDS AND HONORS

- Recipient, Outstanding Student Service Award, Johns Hopkins Bloomberg School of Public Health Department of Health Policy and Management, 2011
- Recipient, Health Policy and Management Fellowship, Johns Hopkins Bloomberg School of Public Health, 2009 and 2010

TEACHING EXPERIENCE

Teaching Assistant

2012–2013 Making Change through Policy

	MPH Capstone Projects (qualitative methods and global health policy)
2011–2012	MPH Capstone Projects (qualitative methods and global health policy) Health Policy 4: Health Policy Analysis and Synthesis Comparative Health Insurance Health Policy 2: Public Health Policy Formulation Making Change through Policy
2010–2011	Comparative Health Insurance Public Health and the Law Health Policy 2: Public Health Policy Formulation

SERVICE AND LEADERSHIP

- Co-Chair, Health Policy and Management Student Coordinating Committee, 2010–2011

ADDITIONAL INFORMATION

- *Citizenship:* American
- *DOB*: June 8, 1979 (San Diego, California)
- *Languages*: English (native); Spanish (proficient); French (conversational)
- *Technical*: Fluent with Macintosh and PC platforms, MS Office. Proficient with STATA.