Forging Governmental Change
Lessons from Transformations Led by Robert Gates of DOD and Francis Collins of NIH

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IBM Center for
The Business of Government

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Foreword

On behalf of the IBM Center for The Business of Government, we are pleased to present this report, *Forging Governmental Change: Lessons from Transformations Led by Robert Gates of DOD and Francis Collins of NIH,* by W. Henry Lambright, Professor of Public Administration, International Affairs, and Political Science at the Maxwell School of Citizenship and Public Affairs at Syracuse University.

This report continues the IBM Center's long interest in leadership and transformation. In Robert Gates, former secretary of defense, and Francis Collins, director of the National Institutes of Health, Professor Lambright has identified two outstanding government leaders who both led transformation initiatives in their organizations. In the case of Robert Gates, the report focuses on his efforts to transform weapons procurement at DOD. Upon returning to government in 2006 as secretary of defense, Gates concluded that he had an opportunity to rein in the cost of defense weapons procurements and halt the production of unneeded weapons.

In the case of Francis Collins, the report focuses on his efforts to transform NIH by creating a new institute, the National Center for Advancing Translational Sciences, which Collins believed would serve as a catalyst to change the culture of NIH. Collins sought to enhance NIH's capability to translate its knowledge in addressing what the public needs from drugs and treatment.

Professor Lambright found many similarities in the challenges faced by Gates and Collins, as well as their effective responses to these challenges. Lambright concludes that experience and leadership skills really do matter, and that both leaders set clear goals and offered clarity as to means. The report also describes how both overcame opposition to their transformation initiatives.
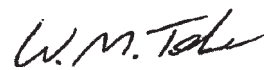
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As noted above, this report builds upon prior research by the IBM Center for The Business of Government on the crucial topics of leadership and transformation. In 2011, the IBM Center published *A Leader's Guide to Transformation: Developing a Playbook for Successful Change Initiatives* by Robert A. F. Reisner.

Forging Governmental Change is the sixth report prepared by Professor Lambright for the IBM Center. In 2002, Professor Lambright chronicled the experience of Francis Collins, then director of the National Human Genome Research Institute, in his report *Managing "Big Science:" A Case Study of the Human Genome Project.* Lambright's research for the IBM Center also includes leadership case studies of three recent administrators of the National Aeronautics and Space Administration: Dan Goldin (2001), Sean O'Keefe (2005), and Michael Griffin (2009).

Coupled with the recent Reisner report on transformation, we trust that this new report will provide insights to all government leaders seeking to transform their organizations through new initiatives and reform.

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Part I: Leading Transformation

How do leaders of very diverse agencies direct ambitious change? How do they achieve significant goals? What strategies do they use to overcome opposition and win allies? How do specific organizational and political contexts affect strategies and outcomes?

These are important and age-old questions. To help answer them, this report examines the roles played by Robert Gates as secretary of defense from 2006–2011 and by Francis Collins, director of the National Institutes of Health (NIH) since 2009. By all accounts, both men have been effective leaders of change. Gates has been called the most influential defense secretary since Robert McNamara in the 1960s. Collins is likely also to rank highly among NIH directors, especially if he remains in office beyond the first term of the Obama administration.

Hence, Gates and Collins, in their respective spheres, represent administrators with a reputation for making a difference. Given the times in which they have served, that is saying a great deal. They are contemporary public executives whose times are characterized by war, recession, congressional gridlock, and widespread public disdain for government. Many administrators have had little choice but to hunker down as maintainers, eschewing change-agent roles. Not these two. Rather, they have seen the times as requiring change, and pressed their organizations to adapt to new realities.

What goals did they accomplish and how did they achieve them? This study examines the key priorities that illustrate their roles as public executives intent on change. For Gates, the focus is weapons reform. For Collins, it is the establishment of a new institute to speed the translation of science into medicine.

Lessons Learned from Robert Gates and Francis Collins

Do leaders of different agencies use similar strategies to achieve transformation goals? How do contexts matter in how those strategies are employed? What lessons can be learned from the experience of Gates and Collins in their leadership actions?

Experience and Skill Matter

Both Gates and Collins came to their leadership positions with great experience. They not only knew the agencies they led well, but also knew the Washington policy community. Their managerial and political skills had been honed in previous positions. Leadership in Washington is not a task for amateurs.

Set Clear Goals at the Outset

Both Gates and Collins set clear goals at the beginning of their tenures. They were bold goals, but limited in number. What remained to be seen was how those broad goals would evolve and be carried out. Both leaders thought in transformative terms from the outset. Gates

wanted to speed the delivery of weapons to the field. He also wanted different kinds of weapons developed to fight the kind of wars he saw ahead, and he wanted to economize in weapons production. Collins was interested in translating NIH research into health cures. He wanted NIH to continue to do basic research, but also engage in additional translational research and development to get this research applied in medicine. In both instances, what these leaders wanted clashed with the status quo they faced in their agencies. DOD was slow-moving and favored Cold War-style weapons. NIH preferred pure research to application, and was wary of close industrial connections. Change was necessary in the view of both Gates and Collins for their agencies to be more relevant to the times.

Have Clarity as to Means

Both leaders had to specify what these goals meant in terms of programs and, in Collins' case, a new institute. What they wanted to achieve had to be implemented in a context of increasingly tight resources. Doing the new required dispensing with the old rather than adding on to the base. It is one matter to forge change in a time of expanding budgets, but quite another when funding is relatively level or even declining. This meant, for both men, following a strategy of reallocation and reorganization.

Get Started as Soon as Possible, and Use the Power of the Office at Your Disposal

Both Gates and Collins hit the ground running. The difference in power at their disposal meant that Gates could go faster and more ruthlessly. The secretary of defense is arguably the most influential secretary in the Cabinet when there is a war going on. In getting existing weapons needed to the troops in the field more quickly, Gates took weapons delivery out of regular channels to fast-track it, changing managers in the process. The context of DOD is hierarchical and the defense secretary can act forcefully.

The NIH director is less powerful. He heads an organization within the U.S. Department of Health and Human Services (HHS) and does not have direct cabinet-level access to the President. Moreover, NIH has a scientific, quasi-academic culture. The director of NIH has at least to appear consensual. Hence, while Collins knew what he wanted to do, to actually undertake the task of reform took longer and was relatively indirect. Collins' tools included the Common Fund (discretionary money) and Scientific Management Review Board (a legitimating body). He could not dictate change. Hence, the context helped determine the styles of leadership in change.

Build Support and Neutralize Opposition

In both cases, there was top-down innovation. However, both Gates and Collins sought buy-in from influential officials inside their agencies and outside. Gates sought support from service secretaries and the Joint Chiefs for his effort to displace certain weapons developments with alternatives. Collins sought support from key institute directors for his establishment of the National Center for Advancing Translational Sciences (NCATS) and abolishment of the National Center for Research Resources (NCRR).

In building support, both leaders needed external help. Gates required the President, Collins needed HHS Secretary Sebelius and the White House. Both had to have congressional support as well and both lobbied for it. For Gates and Collins, reforms were linked to the budget process. The budget process created deadline pressures. Collins felt a sense of urgency about translational research that others in his agency or Congress did not feel. Gates felt an urgency about weapons reform that others in his agency or Congress did not feel. Both therefore had to recruit allies and neutralize opposition. Gates could remove subordinate officials relatively

easily. Collins could not do so. Gates could be more preemptive in strategy than Collins, although Collins pushed his prerogatives to the limit. Indeed, Collins was criticized within and outside NIH for going too fast. Gates neutralized resisters by firing them. Collins neutralized resisters by attrition.

Avoid Landmines

It is notable that Collins made a serious mistake in strategy that he had to overcome later. His interview in the *New York Times* sent alarms to NIH and the political world. It came across that Collins was going to take money from existing entities to grow NCATS. That might or might not have been the case, but it was not good to have a journalist discuss such possibilities in print. Also, it appeared he was moving too far into industrial turf, in moving NIH in an applied direction. Leaders bent on change need to be conscious, especially at the front end of the process, in what they say to the media.

Gates seemed to have the media on his side and he used the media well. He gained from a honeymoon effect in succeeding the much-criticized Donald Rumsfeld, and made the most of it. Moreover, he was fighting the military-industrial complex, and thus was a man on a white horse against a well-known villain. His mistake was hailing the Joint Strike Fighter (JSF) as a reason not to order more F-22s. The JSF was not the model of efficiency he initially said it was.

Collins was up against an analogous biomedical industrial complex. One side of this complex was NIH scientists and academic researchers oriented primarily to basic research, and the other side (industry) was oriented to profit-making product development. These central tendencies led to the Valley of Death between research and medicine. Both sides were relatively complacent and content with the status quo. Collins wanted NCATS to shift researchers and users away from their comfort zone. He had to do that without appearing too threatening.

Stay Focused and Persistent in the Midst of Toxic Politics

The toxic politics between the White House and Congress in the period during which Gates and Collins served made it extremely difficult to do anything new that appeared to raise costs. Hence, the strategy of displacement and budget neutrality was critical to getting acceptance by White House and Congress. Gates wanted more money for defense; Collins wanted more money for NIH. Neither could get exactly what they wanted and future funding prospects looked grim.

During this time period, many agency heads became maintainers rather than change agents in response to the larger political/budgetary context. Gates and Collins did not give up their quest. Leaders have to be confident in what they are doing without coming across as arrogant. Both Gates and Collins were able to walk this thin line relatively well. They were criticized at times, but persevered and ultimately achieved or made progress toward ambitious goals they set when they arrived.

Build Capacity for Implementation

Gates left DOD feeling he had moved it to a good place—certainly a better place than when he arrived. He had to be a war secretary and defense manager. Weapons reform was relevant to both roles. Because the Iraq war eventually went better under Gates than Rumsfeld, Gates could concentrate more over time on weapons reform. His reputation in one sphere helped him in the other. But he knew that long-term changes depended on acceptance by the professionals in DOD. He intervened in the personnel process to promote officers who agreed with his policies. He upgraded the position of the manager of the Joint Strike Fighter and strengthened the

office that ran it. He took other actions to preserve a program (JSF) he regarded as essential but which needed to be better run.

Collins' strategy from the outset was about capacity-building for change. NCATS was a new institute that would carry on after he went. He knew that there had to be an organizational locus for change in the NIH bureaucracy. More than that, NCATS would have to be an advocate for translational research. Translational research required more application and new relationships to succeed. Collins had to work with existing institutes and the biomedical industrial complex. Narrowing the gap between science and health was a long-term challenge. It entailed novel linkages between government and the private sector. The best the leader could do, he realized, was set that change process in motion and create an organizational capacity that would continue to elevate and diffuse this mission over time. Hence, agency contexts matter and require different leadership styles. Change is amenable to similar strategies, but those strategies have to be applied with an eye to context.

The case studies of the two leaders follow.

Part II: Robert Gates and Weapons Reform

Introduction

From the time he arrived at the Department of Defense (DOD), Robert Gates put policy for weapons reform near or at the top of his agenda. He sought to accelerate the movement of existing weapons systems into the war zones of Iraq and Afghanistan. He desired to shift the emphasis in weapons development from the types of weapons created in Cold War-era conflicts to weapons systems for wars like Iraq, which he saw as more typical of the future. And he wanted to save money by cutting overly expensive weapons systems that DOD either did not need, or did not need in the amount being produced. This stance brought him into conflict with the military-industrial complex—the triad of military, industrial, and congressional forces who stand to gain from the existing weapons process.

Background

Sixty-four at the time he took office in 2006, Gates was born in Wichita, Kansas, on September 25, 1943. He graduated from the College of William and Mary with a BA in 1965, Indiana University with an MA in 1966, and Georgetown University with a PhD in Russian and Soviet History in 1974. He began his many years of government service in 1966 when he joined the Central Intelligence Agency (CIA) as an analyst. He spent almost three decades in the intelligence field, specializing in Soviet affairs, and became director of the CIA in 1989, the only entry-level analyst ever to achieve this feat. Along the way, he spent almost a decade working in the National Security Council and in other White House posts. From 1986 to 1989, he was CIA deputy director. He was President George H.W. Bush's CIA director from 1989 to 1993.

After leaving federal service in 1993, Gates worked in the private sector on various corporate boards and wrote his memoirs, *From the Shadows: The Ultimate Insider's Story of Five Presidents and How They Won the Cold War*. From 1999 to 2001, he served as interim dean of the George H. W. Bush School of Government and Public Service at Texas A&M. He became President of Texas A&M in 2002, serving in that position up to his return to Washington in 2006.

Gates evolved a distinct management style as he advanced as an executive. He was an action-intellectual. He collected and used information from multiple sources inside and outside his organization in making decisions. He thought about how to accomplish what he wanted to do systematically. Although conservative, especially in defense matters, he was even more a pragmatist, non-ideological. Regarded as an able manager, he was equally a canny bureaucratic politician. He understood and used power well, but did so mainly behind the scenes. He came across as mild in manner, even shy. But he was fully capable of removing officials who did not measure up to his standards. There was no question that he knew what it took to be in charge and get things done in Washington. His network of contacts was immense. Very much an organization man, he respected institutions. However, he also was change-oriented and saw DOD

as needing change. Appointed as secretary of defense by President George W. Bush, he was retained by President Obama in January 2009.

The Department of Defense

The Department of Defense in the Gates era had more than three million personnel and spent approximately $700 billion annually, counting war costs. Three hundred billion dollars went to salaries and benefits for military and civilian personnel. The remainder, $400 billion, went to weapons and service contracts.[1] The weapons included planes, ships, tanks, guns, armor, missiles, bombs, and all other hardware of modern war. Acquiring these weapons is incredibly complicated, expensive, and vital. It is also extremely controversial.

Defense secretaries typically ask two questions: "How much is enough?" and "For what?" They usually are in combat with the military-industrial complex over total budgets and priorities within them.[2] More often than not, defense secretaries are less than successful in weapons decisions. What defense secretaries can do depends greatly on whether DOD is engaged in a war or not. DOD budgets tend to soar when the country is engaged in conflict and then, in the aftermath, go down. The rise and fall can be extreme. When Gates became secretary, the DOD budget had enjoyed a strong rise extending back to 9/11. DOD was engaged in two wars—and neither was going well. In 2006, the sorry state of the Iraq war had cost Defense Secretary Donald Rumsfeld his job, and President Bush his Republican control of Congress.

Two major roles of a defense secretary are war manager and weapons manager. The two roles intersect. There was no question that Bush hired Gates to first turn around the Iraq war and then the situation in Afghanistan. In his swearing-in remarks, in December, 2006, Gates spoke of the wars and also the need for "defense transformation."[3] In doing so, he was implicitly linking war and weapons management. In exercising these two tasks, he became what the long-serving Senator John McCain called "as influential a secretary of defense as I can ever remember."[4]

The Bush Years (2006–2009): A Quick Start

Gates did not bring any staff with him when he took office. He wanted to signal trust in the existing leadership, civilian and military. However, he indicated he would make changes if he had to do so. He told the generals fighting in Iraq and Afghanistan that they should tell him what they needed, and he would work the Pentagon, Capitol Hill, and the White House to get it. Rumsfeld had informed the troops that "you go to war with the army you have."[5] That was not an acceptable position for Gates. His first weapons priority thus was to get the soldiers fighting in Iraq and Afghanistan the weapons and other equipment they needed. That effort caused him to make a change in the team he inherited.

The Army and Marines had a new armed vehicle, called MRAP, which could provide greater protection to soldiers. But it was moving into the field too slowly. At the same time, the Air

1. Dana Hedgpeth, "Pentagon Looks for $100 Billion in Cost Savings," *washingtonpost.com,* http://www.washingtonpost.com/wp-dyn/content/article/2010/06/28/AR2010062805053.html

2. Jen Dimascio, "Congress Saves," *Aviation Week and Space Technology* (December 19/26, 2011), 62.

3. "Secretary Gates' Swearing-In Remarks," *Defense.gov* (December 18, 2006), http://www.defense.gov/speeches/speech.aspx?speechid=1077

4. Andrea Shalal-Esa, "McCain Sees Defeat of GE-Rolls Engine This Year," *Reuters* (September 20, 2010), http://uk.reuters.com/article/2010/09/20/us-washington-summit-engine-idUKTRE68J3ZQ20100920

5. Thomas E. Ricks, "Rumsfeld Gets Earful From Troops," *The Washington Post* (December 9, 2004), http://www.washingtonpost.com/wp-dyn/articles/A46508-2004Dec8.html

Force had a new fleet of unmanned vehicles, with surveillance and missile-firing capacity, called drones. These could be put to use to help in the campaign, but were bogged down in the Pentagon procurement and delivery system.

Gates took both programs outside regular channels. He added money to build and deploy more MRAPs on a crash basis. He fired the Air Force Chief of Staff, General T. Michael Mosley, for various reasons as noted below, but one was torpidity in weapons deployment. He replaced him with General Norton Schwartz. Schwartz came from the Air Force Transportation Command. He had won favor with Gates by working energetically to transport MRAPs to Iraq.

Gates saw MRAP and drones as part of a larger weapons problem: the top Pentagon officials were wedded to planning for the Cold War rather than the "asymmetrical conflicts" Gates saw as much more likely in the future. In late 2007, he had General David Petraeus, U.S. Commander in Iraq and a leader in counterinsurgency action there, chair that year's army promotion board. Gates wanted colonels promoted to brigadier general who reflected the Petraeus (and Gates) thinking. It was an attention-getting way to send a signal to the Pentagon that he meant change when he said change.[6]

Weapons Development and Production (2006–2008)

Gates's war secretary role took precedence in the Bush years (2006–2009). This meant getting weapons that were available to the troops. But much of DOD's money was in the development and early production stages of new weapons. Gates focused on two of the most visible and expensive ones that got this notice in 2007 and 2008. These were the F-35 Joint Strike Fighter (JSF) and the F-22 Raptor. The first was a huge research and development program, the biggest by far supported by DOD. The second had reached the production phase, and the question was how many F-22s to buy.

The Joint Strike Fighter had been conceived in the early 1990s, as various military services looked ahead to a time when existing tactical fighter planes would have to be replaced. The decision was made to have a common plane with variants to suit requirements of the Air Force, Navy, and Marines. In 2001, shortly after 9/11, DOD chose Lockheed Martin as prime contractor and development commenced. Envisioned as taking 10 years for development, the total program was projected to cost $233 billion, including production.

This amount would buy 2400 planes at $69 million per plane. In 2001, DOD provided a $4 billion contract to Pratt and Whitney for the JSF engine. Gates initially went along with the JSF program he inherited, including the Pratt and Whitney engine. But why, he asked, was DOD paying another $3 billion for an alternative engine developed by General Electric and Rolls-Royce? This decision, made in 2005, seemed to have more to do with the power of the military-industrial complex than any rational technical need.

Gates wanted to kill the Joint Strike Fighter alternate engine, but had to choose his battles. He was more concerned early in his tenure with the F-22 Raptor. The Air Force loved the F-22, and wanted to acquire many more F-22s than Gates thought needed. He noted that initial versions of the F-22 had not been used in Iraq or Afghanistan. Moreover, the Joint Strike Fighter could perform many tasks of the F-22 at less cost per plane. When Air Force Chief of Staff T. Michael Moseley and Air Force Secretary Michael Wynn lobbied for more F-22's than Gates had approved, he forced both to resign. This was in June 2008.[7]

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6. Fred Kaplan, "The Transformer," *Foreign Policy* (September/October 2010), http://www.foreignpolicy.com/articles/2010/08/16/the_transformer?page=full
7. Amy Butler, "Empty Nest," *Aviation Week and Space Technology* (December 19, 2011), 61.

Sending a Message to a Successor (2008)

Gates assumed he had only a limited time left to serve at DOD before a new secretary under a new President took his place. He used rhetoric as a strategy to lay out an agenda for his successor. As the Bush administration moved to its conclusion, Gates spoke on many subjects needing attention. But he highlighted expensive weapons as a particular problem. Again and again, he said DOD must shift from "baroque" Cold War style weapons to less expensive weapons for wars the U.S. would most likely be fighting.[8]

Gates's call for less expensive and more relevant weapons was based not only on his sense of military requirements, but also on the changing political and economic landscape. In 2008, the wars in Iraq and Afghanistan were going better than they had been when Gates came aboard. The country was more worried about economic issues as Wall Street firms went down and the "Great Recession" hit hard. After years of having a blank check, political reality said the Pentagon would have to become far more cost-conscious. The election of a Democrat, Barack Obama, as President in November 2008 seemed to guarantee a fresh look at DOD. Gates was trying to establish a change agenda for his successor. He did not know who that successor would be. But President Obama asked Gates to stay. As Gates later explained, "I punted all these balls to my successor and discovered I was the receiver."[9]

The Obama Years (2009–2011)

Gates wanted to leave Washington, but could not say no to the new President. Certainly not while Americans were still dying in Iraq and Afghanistan. But it was also what was happening domestically with the economy and budget deficit that made him stay. He saw a budget-related train wreck coming down the pike. It would threaten the Defense Department and thus the security of the country. He believed that a strategy of preemptive strike would help DOD. His aim was to "stay in front of the train and not get hit by it."[10]

In agreeing to stay, Gates told the President he would gladly accept political appointees of the President's choice, but he wanted a "veto."[11] He was interested in competence above all. A key Obama appointee that he came to find highly valuable in weapons reform was Ashton Carter. Carter was a veteran defense analyst and former Harvard Kennedy School professor. Carter came aboard DOD in April 2009 as undersecretary for acquisition, technology and logistics. With a PhD in physics, Carter was confident in dealing with the technical intricacies of weapons programs, and had experience in national security positions under President Clinton. By the time Carter took office, Gates had set a course for him to implement.

A Preemptive Strike (2009)

Gates began planning his weapons systems initiatives as soon as he knew he was staying as secretary of defense. He wanted to take bold action in weapons decision-making, going beyond what most previous defense secretaries had done. He enlisted the new President, service secretaries and service chiefs in his effort. He argued that there was a repetitive cycle in defense spending "during hard times or after a war of the United States unilaterally disarming." He did not want to see that happen—that "train wreck."[12] He wanted a stronger, but leaner and more technically appropriate DOD. To get there, over 10 intensive weeks at the

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8.   Kaplan.
9.   Ibid.
10. Robert Gates, Remarks, Ceremony, "2012 Elliott Richardson Prize for Excellence in Public Service Honoring Robert M. Gates," Transcript.
11. Ibid.
12. John Barry and Evan Thomas, "A War Within," *Newsweek* (September 20, 2010), 39.

beginning of 2009, Gates and a carefully selected group of associates, operating in relative secrecy, drew up "a hit list of big ticket weapons to be chopped in favor of programs that were less glamorous, but more useful." He told those with whom he was working to "do what you think right and let me worry about the politics."[13] The exercise was timed so that the proposals would become part of the first defense budget Obama would submit to Congress in April 2009. Gates made everyone involved sign no-leaks agreements.

He "gave the service chiefs and secretaries as much time as they wanted to present their case." He wanted them involved so that they would have ownership of the decisions as well as he, and thus support them after he was gone. He knew many of them had "tenure" and he did not. He did not make any statements indicating decisions about the programs being considered. "So nobody knew where I was going to come out on these things." He wanted to be strategic in going from point A to B, and in the end, in April, at the time of defense budget rollout, announced cutbacks in 33 programs. He listed them at a press conference. He regarded his strategy as "a blitzkrieg on the Hill because everybody's ox was getting gored. And that prevented them from forming alliances." He contrasted this strategy with that of Defense Secretary Dick Cheney, who cut two programs, and was relatively unsuccessful in this regard. Cheney and other predecessors, in his view, "had been too cautious." Even Obama was affected, as one of the cuts was to a new Presidential helicopter. He asked the President "How do you feel about a billion-dollar helicopter?" Obama was "less than enthusiastic" about the need for the White House helicopter.[14]

The list of programs covered was breathtaking. For example, he exchanged "near-term alternatives" for "far-out missile defense schemes." He took money away from the C-17 transport aircraft and gave it to drones development. He extended production of the Navy's DDG-100 destroyers and postponed its CG(X) cruiser. He enlarged the number of ships he deemed "useful for in-shore operations." They were more likely to be used, he believed, than ships armed for "a full-scale sea battle." And he put on his list of programs to be cut the two programs he had targeted in his Bush years for change: the Joint Strike Fighter alternative engine and F-22 Raptor. He knew that there would be strong pushback from the military-industrial complex on these two programs in particular.

Meeting with Obama ahead of the weapons decision announcement,[15] Gates told the President that it was essential to "shake up sacred cows and be seen as taking on fights." It was important, he told the President, that they take on a high-profile system and show a statement of resolve. Gates would make the choice, he said, but Obama had to back him since Congress and industry would fight. Rahm Emanuel, the President's chief of staff, agreed about the need "to show we were willing to expend political capital and to win on something that people thought we could not."[16]

In discussing the F-22 changes in the President's budget, Gates espoused the Joint Strike Fighter as a substitute. He pointed out he was not killing the F-22 plane. He was capping the purchase of additional planes. The F-22 would continue to be used and even modernized. Obama, as planned, fully backed Gates. When Gates submitted his defense budget to Congress, the President added to it a message that he "would"—not "might"—veto the bill if it contained more money for the F-22. This was the only veto threat Obama made in his initial budget.[17]

13.   Robert Gates, "Remarks," Richardson prize.

14.   Ibid.

15.   John Barry and Evan Thomas, "A War Within," *Newsweek* (September 20, 2010), 39; Shalal-Esa, "Gates Sees More Changes to U.S. Weapons in 2011," *Reuters* (April 15, 2009), http://www.reuters.com/article/2009/04/15/us-pentagon-gates-idUS-TRE53E4KG20090415

16.   Christopher Drew, "Victory for Obama over Military Lobby," *New York Times* (October 29, 2009), http://www.nytimes.com/2009/10/29/business/29defense.html

17.   Kaplan.

Using a Dual Role for Influence (2009)

The focus in this profile is Gates as a weapons reformer, not war manager. However, these two roles go together and one can strengthen or weaken the other, and thus the leader in general. So it was with Robert McNamara. His strong role as a weapons reformer was eviscerated by his management of the unpopular Vietnam War. In some ways, the war role destroyed his overall image in history. Gates knew this. Indeed, he had watched Rumsfeld as a near-term example.

Obama kept Gates as defense secretary in large part because his management of the war seemed to be positive and the President wanted continuity. Also, Gates, as a Republican, could help Obama with Congress. No one could say that Gates was soft on defense. Gates was known as more hawk than dove in defense policy. He got along with the Joint Chiefs even as he sought change in the military. His allies included the chairman of the Joint Chiefs, Admiral Michael Mullen. Moreover, once Obama started working with Gates, he gained additional respect for his defense secretary. He found him a trusted and pragmatic advisor as the President sought to shift war policy from Iraq to Afghanistan. The two men met frequently. When Obama made decisions to enhance the war effort in Afghanistan, while decreasing that in Iraq, the decisions bore the hand of Gates.[18]

Esteemed by both parties, Gate's war role and proximity to Obama enhanced his power to wage a domestic thrust on the weapons development front.

Winning the F-22 Battle (2009)

Having picked the F-22 as the high-profile flagship for his reform effort, Gates had to win this battle. Gates personally sought support from key lawmakers. He clashed with, bargained, and cajoled lawmakers from states that would be negatively affected. He gave speeches against additional F-22s. In July, at the Economic Club of Chicago, he complained: "If we can't get this [F-22 decision] right, what on earth can we get right? It is time to draw the line on doing defense business as usual."[19]

The President weighed in as Gates ally at the time of a key vote in Congress on the F-22 in July. Threatening a veto, the President declared: "Our budget is a zero-sum game, and if more money goes to F-22s, it is our troops and citizens who lose."[20] The fight continued throughout the remainder of 2009. At the end of the year, when Congress passed the FY 2010 defense budget bill, F-22 production was capped. Gates had won this critical and symbolic battle. Most of the cutbacks Gates sought in his April 2009 blitzkrieg were approved sooner or later.

Fighting the JSF Alternate Engine (2009)

The most visible case of Gates not getting his way in 2009 was the F-35 Joint Strike Fighter alternate engine. The alternate engine was not singled out by Gates or the White House for the kind of campaign waged against the F-22. However, ending it was a big priority for Gates, and he made clear his intent to go after it again.

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18.   Kaplan.

19.   Elizabeth Bumiller, "Defense Chief Criticized Bid to Add F-22s," *New York Times* (July 17, 2009).

20.   "Remarks by the President on Health Care and the Senate Vote on F-22 Funding," *Whitehouse.gov* (Jul. 21, 2009), http://www.whitehouse.gov/the_press_office/Remarks-by-the-President-on-Health-Care-and-the-Senate-Vote-on-F-22-Funding

In August 2009, Gates toured the Lockheed Martin facility in Fort Worth, Texas, where the JSF was being developed and built. There, he praised the plane and its future significance. At this point, pursuing the JSF was part of the strategy for ending production of the F-22. It was also a way to mollify the services that were losing weapons systems under Gates's efficiency reforms. In fact, the Joint Strike Fighter, with its emphasis on commonality across services, embodied his quest to have more defense at less cost.

But while lauding the JSF, he lashed out at the alternate engine. He charged that this was a time when the Pentagon was "trying to count every dollar and where a dollar from one program takes away from another program that we think is more important." There was simply no need for another engine, he said. He followed up with the threat to recommend a Presidential veto of legislation containing the alternate engine program.[21]

Raising JSF as an Issue (2009)

It was the alternate engine Gates wanted killed—not the plane. He called the JSF "the root of the core of our combat aircraft in the future."[22] He advocated its development and eventual deployment. But while Gates extolled the JSF to external audiences, his inside advisor on weapons, Ashton Carter, was making some unwelcome discoveries.

Carter was working on the FY 2011 weapons budget. Starting in the fall of 2009, Carter noticed the JSF was missing milestones and suffering rising costs. When he spoke to the plane's top DOD managers, he became even more concerned. He had independent advisors take a hard look at the program. He became increasingly persuaded that the program had lost sight of "affordability as a core pillar."[23]

As Carter saw it, JSF had sought to address its technical problems since 2001, when development began, simply by asking for more money. In DOD's post 9/11 environment of sharply increasing budgets, and given the program's paramount significance, JSF program managers got what they wanted. Also, in recognition of JSF's unique multi-service role, DOD had created a Joint Program Office to manage the effort. While that administrative design might have made sense in theory, in practice the Joint Program Office had not been able to give the contractor the oversight required. The program grew rapidly, and the Joint Program Office "did not have our very best people looking at the airplane, and all the information came from the performers of the work."[24] The more Carter looked, the more alarmed he became. He brought the bad news to Gates, news that contradicted the secretary's endorsement of JSF as a positive model of commonality in defense acquisition.

Restructuring JSF (2010)

What was acknowledged internally now became highly visible outside DOD. Once aware of the problem, Gates wasted little time in taking dramatic action. On February 1, 2010, he fired the head of the JSF program, Marine Corps Major General David Heinz. He said he would upgrade the position from two-star to three-star. Calling JSF "the backbone to U.S. air superiority for the next generation," he admitted that the program needed change. In addition to replacing the leadership, he augmented the technical expertise of the Joint Program Office so

21. "Media Availability with the Secretary of Defense Robert Gates at Lockheed Martin Factory," *Defense.gov* (Aug. 31, 2009), http://www.defense.gov/transcripts/transcript.aspx?transcriptid=4469

22. "F-35 Nunn-McCurdy Breach all but Certain: AF Chief," *Defense Tech* (February 16, 2012), http://defensetech.org/2010/02/18/f-35-nunn-mccurdy-breach-all-but-certain-af-chief/

23. "Hearings to Receive Testimony on the F-35 Joint Strike Fighter Program in Review of the Defense Authorization Request for Fiscal Year 2012 and Future Years Defense Program," *U.S. Senate Armed Services Committee* (May 19, 2001),3.

24. Ibid, 17.

that it could better control the contractors. But the prime contractor, Lockheed Martin, was an important corporation, well-connected politically. Gates intended to send a message to industry. The company had missed goals and targets for the past two years. "As a result," announced Gates, "I will withhold $614 million in fees from the prime contractor, since the taxpayers should not have to bear the entire burden of getting the JSF program back on track." He also used the occasion to again blast the alternate engine program as an unnecessary expense, and again warned he would recommend to the President a veto of legislation continuing it.[25]

On February 24, Carter added details to Gates' restructuring decision. DOD would add 13 months to the development and demonstration stage of the plane. Full-scale production would slip to November 2015. While development would cost more, the plane ultimately produced would be better and require fewer retrofits later, Carter said. Money would be saved in the long run, he argued. Savings would also come from purchasing fewer planes in the production stage.[26]

The man Gates chose on March 7 to straighten out the JSF program was Vice Admiral David Venlet. Carter told Venlet to conduct a "no-holds-barred" investigation of where the program stood. "Tell it like it is!"[27] What Venlet found was that the program was going to breach the Nunn-McCurdy Act. Under this legislation, Congress had to be informed when a program ran 15% or more above its original baseline estimate and JSF was going to do that. With a 25% overrun, termination had to be considered under this legislation unless the defense secretary certified to Congress that it had to be retained for purposes of national security. It now appeared that the JSF would possibly have a cost ultimately requiring such a certification.[28] And that meant Congress would inevitably give the JSF far greater oversight than it had.

On March 24, Gates testified on the proposed defense budget for the upcoming year. He emphasized that the proposed budget was "suffused" with "continued reform, fundamentally changing the way the department does business: the priorities we set, the programs we fund, the weapons we buy—and how we buy them." Noting that certain weapons programs would be terminated or altered, he prepared a special report on the JSF. There would be more topside control, he declared. An office independent of the program office would review cost and schedule. There would be additional development and testing of planes. The review of the program by DOD would be "brutally realistic" before he would move it to full production. Of course, Gates pointed out, Congress had to do its part. If it wanted cost control on the JSF, it needed to end the alternate engine program. If it did not, he would "strongly recommend" a Presidential veto.[29]

In March 2010, Gates gave a speech at the Eisenhower Presidential Library on defense spending. He praised Eisenhower for his effort to constrain the appetite of the military-industrial complex and spoke of the "steep institutional and political challenges—many lying outside the five walls of the Pentagon." He mentioned programs he wanted to end where resistance had proved especially strong. Not surprisingly, he highlighted the alternate engine, which "the Air Force, Marine Corps, and Navy do not want." He again said he would "strongly recommend a Presidential veto."[30] A media observer commented that Gates was stepping up

25. "DOD News Briefing with Secretary Gates and Admiral Mullen from the Pentagon," *Defense.gov* (February 1, 2010), http://www.defense.gov/transcripts/transcript.aspx?transcriptid=4823
26. Jeremiah Gentler, "F-35 Joint Strike Fighter (JSF) Program: Background and Issues for Congress," *Congressional Research Service*, (September 23, 2010), 17.
27. Hearings to Receive Testimony on the F-35 Joint Strike Fighter Program, 6.
28. "F-35 Nunn-McCurdy Breach all but Certain: AF Chief," *DefenseTech,* February 18, 2010.
29. Testimony as delivered by Secretary of Defense Robert M. Gates, House Appropriations Committee—Defense (Budget Request). *Defense.gov* (March 24, 2010). http://www.defense.gov/speeches/speech.aspx?speechid=1434
30. "Eisenhower Library (Defense Spending) Remarks as Delivered by Secretary of Defense Robert M. Gates," *Defense.gov* (May, 8, 2010), http://www.defense.gov/speeches/speech.aspx?speechid=1467

his campaign against the alternate engine from the past year. His strident rhetoric resembled his fight against the F-22, a fight he had won.[31]

While the defense budget proposal worked its way through Congress, Gates came up with another initiative to rationalize existing resources—while hoping to preempt further cuts not of his choosing. The strategy was to take $100 billion in savings over five years from overhead and infrastructure and redeploy it to programs that would better help the war fighter in the present and in the future. Gates obtained an agreement from the White House to reprogram such money. Gates worked to get Congress to go along with this initiative. It was not a reduction in DOD funds, he emphasized—it was an efficient redirecting of existing money.

Carter unveiled the new plan on September 14, 2010. It had 23 steps to cut waste in weapons programs. These included a mandate for affordability as a requirement on all weapons programs. The other measures varied and were highly detailed. Many were generic measures to be applied across the board. Some affected the JSF fighter in particular, such as mandating the move to fixed-price contracting. Affordability was always an implicit requirement, but now Gates and Carter were making that stipulation explicit. Defense program managers would now set an affordability cap which could only be lifted with Carter's approval.[32] DOD program managers and contractors would have to live with this constraint. Gates said these initiatives would put money in DOD's teeth instead of the department's tail.[33]

Gates was still coping with wars in Iraq and Afghanistan, but was giving increasing and intentionally conspicuous attention to efficiency measures in the Pentagon. *Newsweek* pointed out how this campaign suited Gates' economy-minded style as a leader and wrote a cover story on his "war within" the defense establishment.[34] Aides commented how "passionate," "revved up" and "stoked" the normally subdued secretary was about this effort. Under Bush he had talked reforms—now under Obama, he was instituting them.[35] It was common knowledge that he wished to leave government, but wanted these management reforms to be well under way before he left. Gates was a true believer in a well-funded DOD. But he insisted that the money be spent efficiently and effectively. Powerful observers were impressed. Senator John McCain found him one of the most influential secretaries of defense in history.[36] Fred Kaplan, writing in *Foreign Policy*, declared that he had "changed the way the Pentagon does business and the military fights wars more than any defense secretary since Robert McNamara."[37]

Maybe so, but he was running up against a strong test with JSF.

A Second JSF Restructuring (2011)

As Gates and his associates worked on the fiscal year 2012 budget in the fall of 2011, it became obvious that the JSF program had still more problems and the initial remedies had not worked sufficiently.

31. Jen DiMascio, "House Committee Passes Defense Bill," *Politico* (May 20, 2010).

32. Andrea Shalal-Esa, "FACTBOX-Pentagon Changes Aim to Boost Productivity," *Reuters* (Sept, 14, 2010), http://www.reuters.com/article/idUSN148499920100914; James Asker, "The Trials of JSF, " *Aviation Week and Space Technology* (September 20/27, 2010), 24.

33. Barry and Thomas, "A War Within," 9.

34. Ibid.

35. Kaplan.

36. Andrea Shalal-Esa, "McCain Sees Defeat of GE-Rolls Engine This Year" *Reuters* (September 20, 2010), http://uk.reuters.com/article/2010/09/20/us-washington-summit-engine-idUKTRE68J3ZQ20100920

37. John Feffer, "Gorbachev of the Pentagon?" *Huffington Post* (September 28, 2010), http://www.huffingtonpost.com/john-feffer/gorbachev-of-the-pentagon_b_742180.html; Kaplan.

Costs continued to rise, and there were additional delays, especially on the Marine version of the plane. At the same time, the political environment was changing dramatically. Congressional elections in November 2010 turned the House over to the Republicans, with an especially conservative group of tea-party Republicans elected. They made deficit reduction their goal and did not give a pass to DOD. The Democrats barely retained control of the Senate. The budget deficit and economy moved even more to the forefront of the Washington political debate, and Obama felt he had to take his own preemptive cuts. These included DOD. The Pentagon might get a raise (above inflation) in the fiscal year 2012, but would have to absorb a $78 billion cut below what had been proposed. The out-years showed significant declines in growth over a five-year projection and an eventual flat budget.

Gates decided to end, or reorient, a number of programs the services wanted. Of particular concern was JSF. With the JSF continuing to rise as the overall budget went down, its size meant it would cannibalize other programs unless Gates took additional action to bring it under far tighter control.

Of the three variants of the JSF, the most problematic was the Marine variant. In some ways, it was slowing down the overall effort because of its complexity and interdependence with other models. Should the Marines version be terminated to save money and protect the Air Force and Navy versions? Gates discussed the possibility and the Marines leadership "made a compelling case" to hold off termination. Carter recommended putting the Marines' plane on "probation" for a year to see if the Marines and Lockheed Martin could resolve the technical issues. Otherwise, termination might indeed have to be the chosen option. Gates decided to give the Marines two years. The fact that he was terminating another program the Marines savored, the Expeditionary Fighting Vehicle, may have played a role in his decision to spare the Marines' JSF plane. But it was also clear that Gates believed JSF was important to the country as well as to the Marines, as he said publicly.

On January 6, 2011, Gates announced the JSF restructuring, the second in a year. The JSF overhaul was part of a broader cost-reduction plan. It separated the Marines' plane from those of the Air Force and Navy. The Marine Corps' Short-Takeoff-and-Vertical-Landing variant (called STOVL), he said, was suffering "significant testing problems. These issues may lead to a redesign of the aircraft's structure and propulsion—changes that could add yet more weight and more costs to an aircraft that has little capacity to absorb more of either."

Even with the decoupling from the Marine Corps, development of the Air Force and Navy JSFs would also slip another nine months beyond the 13-month delay announced under the earlier restructuring. This meant full production would not start until 2016. The STOVL would be ready depending on what happened in its probation period. Overall development costs for the JSF program would rise to a total of $59.4 billion (the original estimate was $38 billion).

Despite these difficult, frustrating issues, Gates defended the JSF program, and said that the Air Force and Navy planes were "actually progressing quite well." He expressed "confidence in the program."[38]

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38.   Amy Butler, "JSF Tests Slip Again, Purchase to be Slashed," *Aviation Week and Space Technology* (January 17, 2011), p. 2; David Ljunggren, "U.S. Defense Sec Says Happy with F-35 Jet Program," *Reuters*, (January 27, 2011), http://www.reuters.com/article/2011/01/27/usa-defense-fighter-idUSN2719002520110127

Showdown on the Alternate JSF Engine (2011)

On February 14, 2011, Gates announced DOD's budget proposal for the next fiscal year. In doing so, he gave greatest emphasis to the need to kill the alternate engine. It had symbolic significance for him. He felt it epitomized some of the worst aspects of weapons acquisition. There had been efforts to kill it going back to Rumsfeld. In hearings on the defense budget, Gates again came back to the alternate engine, and once more, said he would strongly urge Obama to veto any bill funding it. It was a "waste" of $3 billion, he charged.[39] He was a man who tended to guard his feelings, but where the second engine was concerned, his views were intense.

But the contractors, GE and Rolls Royce, saw $100 billion to be made if their engine stayed alive. That was potential great profit from the production contract that would come after development. If they could show their engine was "better" than the Pratt and Whitney engine, they might yet win the big prize. They lobbied hard. Their legislative allies—Democrats and Republicans—all saw jobs at stake. Some of the jobs would be in Ohio, home of John Boehner, the Republican Speaker of the House who supported the alternate engine.

From the outset of his presidency, Obama had agreed with Gates that the second engine was an outsized example of Pentagon waste. He had said so—but had refrained from following Gates's threat of a Presidential veto of defense legislation to enforce that perspective. Whether he would do so this year (2011) was a question, as Gates indicated publicly he would be leaving in a matter of months.

On February 11, 2011, for the first time, a congressional vote went against the second engine (233–198). The vote was in the House on a continuing resolution to keep the government running until the end of the fiscal year (September 30, 2011). The freshmen tea-party Republicans joined with liberal Democrats to kill the engine. Over Gates's term, he had been successful in canceling or cutting production on most of his targeted weapons programs, but had failed each year to end the alternative engine. It may have helped Gates that everyone was aware in Congress and the media that the JSF program as a whole was suffering a huge overrun. The alternate engine had thus come increasingly to the fore as one element of the program that might be sacrificed to the altar of economy.[40]

With the House decision behind and the Senate vote ahead, Gates pushed his influence with Congress to the limit. On March 24, he ordered DOD to halt all spending on the second engine. This was a $1 million-a-day "stop order." Carter declared: "We understand the ultimate outcome will be decided by Congress. We have shown great forbearance to continue to fund something we don't believe is needed." He said the stop order would last 90 days.[41]

GE and Rolls Royce countered that they would use their own funds to continue developing the engine. They condemned "this unilateral action before Congress has completed its work on the fiscal 2011 budget." Complaints continued as the Senate debated. In April 2011, the Senate voted in accord with the House, and the engine was killed. However, the companies vowed to keep working on the project with their own funding and come back the next fiscal year to get it back in the budget.[42]

39. John Bennett, "Gates Urges Congress to Cut Funds For a Second F-35 Engine or 'Waste' $3 Billion," *The Hill* (February 16, 2011), http://thehill.com/homenews/house/144463-gates-urges-congress-to-cut-second-f-35-engine-or-waste-3b

40. Christopher Drew, "House Votes to Cancel F-35 Jet Engine Program." *New York Times* (February 16, 2011), http://www.nytimes.com/2011/02/17/us/politics/17-f-35-engine.html

41. Tony Capaccio, "Pentagon Issues 90-Day Stop-Work Order on GE's F-35 Engine," *Bloomberg* (March 24, 2011), http://www.bloomberg.com/news/2011-03-24/pentagon-issues-90-day-stop-work-order-on-ge-engine.html

42. Michael Bruno, "Game Time," *Aviation Week and Space Technology* (March 28, 2011), 20. "US kills GE/ Rolls Royce Engine for F-35 Fighters," *Reuters* (April 25, 2011), http://www.reuters.com/article/2011/04/25/us-ge-engine-idUSTRE73O56G20110425; Jim Wolf, "Update 2-GE, Rolls Royce Seek to Complete Second F-35 Engine," *Reuters* (May 5, 2011), http://www.reuters.com/article/2011/05/05/ge-rollsroyce-engine-idUSN0529276720110505

Protecting Core Capabilities, Including the JSF (2011)

Gates could be pleased with his long-sought victory in the alternative engine battle. But he saw dark clouds ahead. Money was still pouring into Iraq and especially Afghanistan, Obama's priority. Meanwhile, Libya became an added expense. The U.S. assisted NATO, as it moved to oust Muammar el-Qaddafi. President Obama was looking far more aggressively to cut the long-term federal budget deficit. He had already directed one cut for DOD, and was now discussing with Gates a much larger cut over several years—$400 billion between then and fiscal year 2023.[43] Gates held that the DOD budget was outsized because of the wars, and that the "base" was not part of the problem the U.S. faced in deficit reduction.[44] Instead, he argued, it had to grow and be protected, at least insofar as core capabilities were concerned.

Gates wanted to leave DOD in what he called "a good place."[45] Looking at budget pressures, he declared: "The easiest thing is to say, 'cut defense by X percent,' and I think that would be the most dangerous approach of all."[46] He had tried to do an effective job in better aligning DOD with the "current conflicts" it faced, and those akin to it. He said he had also sought to build up programs for "high-end conflicts." He regarded the JSF as particularly important in this latter respect.

In March, 2011, Gates declared: "Having a robust, large quantity of fifth-generation tactical air fighters is something I view as a core requirement and in this era of increasing budget constraints, my goal is to ensure that core capabilities for all the services are protected. This has meant scaling back or cutting other programs that are not essential, and intervening directly to get the [JSF] program back on track, on budget, and on schedule."[47]

Defense planners were beginning to shift attention from the greater Middle East to the Asian region, where China was rapidly augmenting its military forces with sophisticated weapons. The U.S. had to adjust. The JSF was seen as critical.

Gates's prime agent for getting the JSF program back on track was Carter. On May 19, Carter testified at a special hearing on the JSF held by the Senate Armed Services Committee. The chairman of the committee, Carl Levin (D.–MI), praised Gates for the actions he had taken on JSF, but noted "recent revelations of the new total lifecycle costs for JSF program [that] exceed $1 trillion." Senator McCain (R–Arizona), added that the JSF was originally supposed to cost $233 billion. Each plane was projected to cost $69 million. Now, the senator noted, the program was up to $385 billion and each plane would cost $133 million. Moreover, the JSF was intended to be operational by now, but McCain charged it was still in the development stage.

Carter said of the JSF: "We want it, but it has to be affordable. At the moment, it is not." Carter explained that the $1 trillion figure came because DOD was looking ahead beyond development and procurement to the years when the services put the planes to use. The sustainability stage stretched decades, maybe as much as 50 years, into the future. It would cost a great deal to operate a fleet of planes; costs arising from fuel, maintenance, bases, training, etc. These expenses would be much greater than the development and purchase of the planes.

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43. Julianna Goldman and Tony Capaccio, "Obama Said to Seek $400 Billion Defense Cut Through Fiscal 2023," *Bloomberg* (April 13, 2011), http://www.bloomberg.com/news/2011-04-13/obama-said-to-seek-pentagon-cuts-that-go-beyond-defense-chief-gates-s-plan.html
44. "Remarks by Secretary Gates During Troop Visit at Seymour Johnson Air Force Base, N.C." *Defense.gov* (May 6, 2011), http://www.defense.gov/transcripts/transcript.aspx?transcriptid=4819
45. Goldman and Capaccio.
46. David Alexander, "Tight Budgets Put All U.S. Defense Programs on Table, " *Reuters* (May 18, 2011), http://www.reuters.com/article/2011/05/18/usa-military-budget-idUSN1827341420110518
47. "Remarks by Secretary Gates at the U.S. Air Force Academy," *Defense.gov* (March 4, 2011), http://www.defense.gov/transcripts/transcript.aspx?transcriptid=4779

But DOD, he avowed, was not accepting the $1 trillion figure as inevitable. "So what we are asking," said Carter, "is not what the aircraft will cost, if we keep doing what we are doing, but what it should cost and we call that should-cost analysis. And we are beginning that … It involves scrutinizing every aspect of the bill, every aspect of the cost of the airplane, work by prime contractors, subcontractors, suppliers, direct costs, and indirect costs, and seeing how they can be driven out over time of this program. They have crept in. We need to drive them out."[48]

Obama decided to go forward with a directive to DOD to cut another $400 billion over a period of years. Gates reacted on May 24 by emphasizing that paring this much money from DOD over the next 12 years could not be accomplished by piecemeal trimming or efficiency savings. There would have to be hard choices on the basis of national security. Again, he specifically defended the JSF, saying the Pentagon might have to cut pay, benefits, and the size of the armed forces to reduce costs while it protected core capabilities such as the JSF.[49]

Leaving DOD (2011)

Gates left DOD in late June, 2011. Leon Panetta, previously Obama's CIA director, and former Clinton budget director and chief of staff, was Gates's and Obama's choice to succeed him.

On July 1, Panetta took office. He inherited a DOD that Gates had wanted to be in a "good place" at this time, with stability in its base budget and a new culture in weapons management, one of cost-consciousness. But there was little chance of that stability given the fiscal situation the country faced. As for cultural change, that would take more time and further work. The JSF continued to stand out as the biggest program and biggest target for defense cuts. It would be the test case for weapons acquisition in the leadership transition. Gates had begun a process of transformation at the Pentagon that called for cutting and changing, but keeping in mind "core capabilities." Carter stayed at DOD, promoted to deputy secretary. It was now up to Panetta to determine what to do next about the transformation process Gates had launched.[50]

Conclusions

What lessons for transforming government organizations can be derived from Gates' five and one-half years of service at DOD from 2006 to 2011?

Lesson One: Experience matters. Gates came into his job knowing a great deal about DOD, national security decision-making, and the opportunities and perils of getting anything done in Washington.

Lesson Two: Have a bold agenda. Gates arrived with an agenda for defense transformation. It went beyond weapons acquisition, but that was a very large part of his mission. He made that clear early on, and he began by getting appropriate weapons to fighters in Iraq and Afghanistan.

48.	"Hearings to Receive Testimony on the F-35 Joint Strike Fighter Program in the Review of the Defense Authorization Request for Fiscal Year 2012 and Future Years Defense Program," U.S. Senate Armed Services Committee (May 19, 2011), 1–10.
49.	Viola Gienger, "Gates says Military Troop Cuts May Protect F-35, Submarine," *Bloomberg* (May 24, 2011),
http://www.bloomberg.com/news/2011-05-24/defense-secretary-says-cuts-needed-to-protect-core-priorities.html
50.	Kate Brannen, "Budget Cuts Won't Harm National Security, Panetta Says," *Federal Times* (June 9, 2011),
http://www.federaltimes.com/article/20110609/DEPARTMENTS01/106090301/

Lesson Three: Get leeway for reform. Gates made progress in the wars he faced. This improved the situation in Iraq and Afghanistan (Iraq in particular) from what he inherited, giving him time and room to maneuver in weapons reform, particularly as it involved new weapons in development and procurement. He wanted weapons more relevant to present and future likely wars rather than the former Cold War. He exercised leadership as both a war secretary and defense manager. The latter role enlarged as the former lessened in intensity.

Lesson Four: Take advantage of a change in Presidents. Under President Bush, the Pentagon and the military industrial complex had a very generous hand from a budgetary standpoint. Obama intended to rein in spending. Gates wanted DOD employees to get raises, but understood that the budget gains of the past could not continue, especially in the wake of the Great Recession and large budget deficits. His strategy was to take control of the cuts in development and procurement rather than let others do it for him. Although he began to attack certain programs under Bush (e.g., the F-22), he greatly enlarged his reform agenda once Obama came in. He used Obama as an ally of his reforms, rhetorically and otherwise, and this alliance strengthened his hand.

Lesson Five: Target certain programs. Gates could not do everything, but he could attack the programs he believed were most in need of reform. At the beginning of the Obama administration, he announced a large "hit list" of weapons and was successful in part because he moved quickly and early in the Obama tenure.

Lesson Six: Appoint officials who help rather than hinder reform. He removed high-level civilian and military officials whom he considered out of touch with his reform goals. He delegated power to Carter as his chief weapons reform agent, who in turn alerted him to problems and helped him devise solutions.

Lesson Seven: Act dramatically and forcefully. Gates's effort to control costs on his biggest program (the F-35 Joint Strike Fighter) illuminates his approach. Not only did he replace and upgrade its leaders, but he put one of the services (the Marines) on probation to solve the JSF technical and cost problems. He was tough and personally engaged, showing he meant business. His reforms included strengthening the management office overseeing the plane's development, and also disciplining the contractor by cutting its rewards.

Lesson Eight: Protect core programs. Even as he grappled with the JSF's cost overruns and delays and made preemptive strikes against other programs, Gates constantly made clear the importance of the JSF program. He was trying to strengthen it, save it, in the time of growing austerity he saw ahead. He knew the bigger the program, the more visible the target. The DOD needed an outstanding plane, so development was protected and extended, with the number of operational planes to be purchased reduced.

Lesson Nine: Persist. Gates was stymied in some reforms, but he persisted year after year. This was seen most notably in his quest to kill the alternate engine for the JSF. He went after it frequently and threatened it with a possible Presidential veto. The program had strong support in Congress. But eventually, the congressional support weakened after the election of more deficit-oriented lawmakers. When that happened, Gates got a vote that went his way, and accelerated the termination process by a "stop-order." This move was a direct challenge to the engine's champions, and he prevailed.

Lesson Ten: Put your department in a good place before you depart. Gates got the transformation process off to a good start. He succeeded in accelerating delivery of weapons needed to the soldiers in the field, changing the portfolio of weapons to be developed to better suit wars of the future, and cutting back on expensive weapons being developed while protecting

programs of high priority. He was successful as a weapons manager because of success as a war manager. Better than any recent defense secretary, he combined these two roles to his advantage. There was much more to do, but he left a momentum for positive change for his successor. Unlike other administrative leaders, he left office when his reputation was at its height. He also had influence in the President's choice of his successor.

Lesson Eleven: Know the limits. As able as Gates was as a reformer and economizer, he saw limits to what he could accomplish. His preemption strategy allowed him to keep some control of what was cut, but could not deter the overall cuts in DOD funding that the changing political environment forced on him.

Part III: Francis Collins and His Quest to Change NIH

Introduction

On August 17, 2009, his first day as director of the National Institutes of Health (NIH), Francis Collins told his staff and reporters that he would emphasize five priorities during his tenure. One, which subsequently became his highest priority, was an initiative he called "translational research." Collins wanted to accelerate the movement of science into medicine.[51]

Trained as both a scientist and doctor, the 59-year-old Collins embodied this quest to make quick use of new knowledge. It became clear that he intended to accomplish the translational task by establishing a new institute, the National Center for Advancing Translational Sciences (NCATS). NIH already had 27 institutes, and a recent congressional statute capped the number at that figure. Hence, to set up NCATS, Collins had to abolish an existing institute, never an easy process. Moreover, most institutes had influential constituencies of external interest groups and congressional allies. Many focused on specific diseases. The NCATS institute idea came directly from Collins and would be organized around a process rather than on a disease like cancer.

Collins was seeking major reform at NIH specifically and in medicine generally. Having served previously as the director of the Human Genome Project, he was convinced that a revolution in health care was possible if the science that was accumulating rapidly could traverse what he called the Valley of Death from laboratory to bedside. NIH, in his view, was outstanding in producing knowledge, but not fully optimized in translating it into what the public needed in drugs and treatment.

Collins intended the creation of NCATS to be a catalyst for cultural reform at NIH. He wanted the agency to develop new relationships with the regulators, the Food and Drug Administration (FDA), and the medical innovators in private industry. Collins had a vision for reform born of personal and government experience. But he had to assume he had less than four years—the remaining elected tenure of the President who appointed him—to establish it. He wanted to launch his vision and get it off to a good start. To do so would require getting NCATS accepted by various NIH internal and external constituencies and into legislation. It would necessitate quelling the opposition to displacing another organization for NCATS.

Doing anything new in the period during which Collins served would be daunting. The political atmosphere favored cutting federal programs and budgets, doing less, not more, through government. To add another institute could not mean adding more money to NIH's budget. Also, many academic scientists, as well as many NIH scientists, preferred basic research and might find more applied forms, as implied in translational science, threatening. In addition, industry and its allies in Congress might be ideologically opposed to strengthening the government push

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51. Jocelyn Kaiser, "Rejecting 'Big Science' Tag, Collins Sets Five Themes for NIH," *Science,* 325, no. 5943 (2009): 927.

behind certain therapies or drugs. But Collins was passionate about this initiative and determined to succeed in what he knew was disruptive institutional innovation. To him, institutional innovation was essential to the broader cultural change he wanted to take place at NIH.

Background

NIH is an agency within the U.S. Department of Health and Human Services (HHS). With a budget of approximately $30 billion and 18,000 employees, NIH is far and away the world's dominant engine for human disease research. It supports hundreds of thousands of research personnel in its own intramural laboratories and its extramural programs supporting university research throughout the United States and in many foreign nations. More than 130 researchers supported by NIH have won Nobel prizes for their discoveries.[52]

Collins received a BS in chemistry from the University of Virginia, a PhD in physical chemistry from Yale, and an MD from the University of North Carolina at Chapel Hill. While on the faculty of the University of Michigan, he made landmark discoveries in disease genes. He was appointed to head the Human Genome Project in 1993 and soon became the first director of the National Human Genome Research Institute (NHGRI). He achieved renown as he successfully led NHGRI in sequencing the human DNA instruction book. The Human Genome Project was an unprecedented big-science activity for biomedicine, costing $3 billion and entailing new research centers in the U.S. and abroad. Collins evolved a management style that was notable for its combination of skill in dealing with people inside and outside NIH, both scientists and politicians; an ability to write and speak persuasively; and a certain relentlessness in pursuit of goals.

When he achieved the complete sequence in 2003, Collins was asked by a reporter if he was disappointed that the Genome Project had reached closure on the human effort. Collins replied: "Are you kidding me? This is the part I've been waiting for my whole life. And most of this I didn't think would happen during my lifetime."[53] Collins elected to stay as the head of NHGRI after the Genome Project reached closure, continuing to influence genomic research in the United States. With many awards for his service, including the Presidential Medal of Freedom (2007), Collins found time to write a notable book: *The Language of God: A Scientist Presents Evidence of Belief* (2006). This book reflected his evangelical religious belief. Collins argued strenuously that religion and science were compatible. In fact, his religious compassion helped fuel his zeal as a researcher and federal research manager. He revealed a sense of stewardship.[54] Having helped lead the genome research revolution at its outset, he felt a responsibility that it show positive results in health delivery.

After 15 years at NIH, Collins left government in 2008. He wrote a second book: *The Language of Life: DNA and the Revolution in Personalized Medicine* (2010). In that book he foretold the wonders for medicine that the genome breakthrough would make possible. He also revealed his sense of concern about the revolution, saying that "science moves forward at an ever-increasing pace but the process for establishing appropriate polices for implementation of new scientific findings can be frustratingly slow." He noted at the end of his book that the gap between the earliest publication of a medical discovery and its implementation is 24 years.[55]

Collins had barely spent time in private life when he was called to participate on President Barack Obama's transition team. In April 2009 Secretary of Health and Human Services

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52.   Francis Collins et. al., "Fiscal Year 2012 Budget Request," before Senate Subcommittee on Labor—HHS—Education Appropriations, May 11, 2011, http://www.nih.gov/about/director/budgetrequest/fy2012budgetrequest.pdf

53.   Chris Wilson, "Breaking the Code," *Washingtonian* (June 1, 2007).

54.   Ibid.

55.   Francis Collins, *The Language of Life: DNA and the Revolution in Personalized Medicine* (N.Y. Harper Collins, 2010), 276.

(HHS) Kathleen Sebelius asked him to return to NIH as its director. She did not give him any particular mandate except "to do a good job and serve the American people." Collins could not say no. "I thought of this work at NIH as noble," he recalled.[56]

The official nomination from President Obama came on July 8 and Collins was confirmed by the U.S. Senate on August 7. Well-known to senators and personally respected by them, he sailed easily back into government service. He came to his agency knowing what he wanted to do. He also had sufficient experience at NIH and in Washington to know the constraints he would face. While his work as head of the Genome Project had garnered him universal acclaim, he was not satisfied with what had come after the initial sequencing ended. There had been significant criticism from scientists and media that the promise of the genetic revolution had not been borne out in medical results. While he argued that time would show the fruits of advance, he wanted to narrow the gap between science and health delivery—not just in genetics but also in other fields supported by NIH. There was some evidence the gap in the Valley of Death was widening. That desire to speed medical innovation was one reason he decided to return to the Bethesda, Maryland-based agency. He wanted to finish what he had started through the Genome Project.

Inheriting a Stronger Office (2009)

The position of NIH director had historically not been a powerful one. The man under whom Collins had served when he was chief of the Genome Institute in the 1990s, Harold Varmus, had complained about the weakness of the NIH director vis-à-vis the institute directors. There was an expression often used that the NIH institute directors were the cardinals and the NIH director the pope. But the pope of NIH was not that influential, particularly with regard to controlling NIH funding. The institutes had large budgets and loyal interest group constituencies. Patient groups and their supporters lobbied Congress constantly for more money for "their" institute, such as the National Cancer Institute. NIH as a whole had a somewhat obscure identity.

The good news was that health was favored as a spending priority by Congress, and hence the NIH budget almost always went up. In fact, it doubled in a five-year period initiated under President Clinton and continued under President Bush. This doubling was a conscious policy decision by the President and Congress. The bad news was that the NIH director had little control over priorities in funding and the direction of the agency. The office did not give the director much of a base from which to be an agent of change. The Genome Project had support from Director Varmus during the 1990s.[57] But that support was more rhetorical than financial. NIH, in general, was a very bottom-heavy organization—i.e., the strength was in the individual institutes.

In the era of President George W. Bush and his NIH director, Elias Zerhouni, the director's office was substantially strengthened by the NIH Reform Act of 2006. There were many reasons for the change, but the major one was Congress's desire to see NIH better managed. It had grown, primarily due to outside pressures, to 27 separate institutes and centers. It had a tremendous amount of money. Congress wanted faster results from all the money it had provided NIH, and it wanted the NIH director to be in a better position to deliver those results, especially when work had to be done across institutes. There had also been evidence of conflicts of interest in NIH researchers and those NIH supported in universities. For these and other reasons, there was an increasing awareness that NIH needed to be better managed, and its director made more accountable.

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56.   Francis Collins, interview by author, November 18, 2010.

57.   W Henry Lambright, *Managing "Big Science;" A Case Study of the Human Genome Project*, (Washington D.C.: IBM, 2002), 18.

The NIH Reform Act provided new mechanisms to help the NIH director be a leader in fact, rather than only in name. One was a budget item called the Common Fund. This was an appropriation line item the director could use at his discretion to address issues that cut across institutes and/or were not addressed by the individual institutes. Prior to this legislation, the only money the director had was that which the various institutes were willing to provide him. The Common Fund budget grew gradually after 2006 and by the time Collins became director in 2009, the fund was up to a half a billion dollars.

Another new management mechanism the Reform Act provided was a Scientific Management Review Board (SMRB). Composed of prominent inside and external appointees, its job was to continuously monitor and advise the director on how to improve NIH's organization and performance.

Zerhouni, fully conscious that Congress wanted health results, used his Common Fund to start experimental efforts to translate science into medicine. Zerhouni drew on a "roadmap for medical research," a plan of action drawn up prior to the Reform Act that included ideas relevant to translational medicine. Collins worked with Zerhouni insofar as both wanted to see the Genome Project reach fruition as part of the translational science portfolio. Under Zerhouni, a number of new grants, called Clinical and Translational Science Awards (CTSA), were begun. Such awards were more applied than typical NIH grants, more than half of which were for basic research.[58]

With Congressional backing through the Reform Act, Zerhouni thus began a change process at NIH. Thanks to Zerhouni, Collins inherited a position that was more influential than it had been. Moreover, because of Collins' own background as head of the Genome Institute and leader of the Genome Project, he brought a deep experience and knowledge of NIH and its environment. Furthermore, because of what he had himself done in the past, Collins was personally a man of considerable stature. He brought that stature to the position and enhanced it. If anyone could make maximum use of the new advantages the director had and build on them, it was Collins. Collins wanted to do exactly that—not necessarily because he wanted power for its own sake, but influence to forward the science-based health revolution about which he had written.

Collins, in personality, did not give the impression of being a revolutionary. He was not fiery in manner, more likely to express displeasure with a frown than tirade. But he was intense, smart, hard-working, and a true believer. He meant what he said—that what NIH did was noble, but needed to be translated more surely and effectively into cures. That would take a much stronger push from NIH than it had provided in the past, and greater pressure from the NIH director.

Hitting the Ground Running (2009)

Collins came to office with a sense of urgency. There was much he wanted to do in the potentially limited tenure of a political appointee. He had his conversation with Sebelius in April 2009. Following confirmation, he took office August 17. In the period between April and August, he developed an agenda for what he wanted to accomplish. The agenda consisted of five main initiatives, and a number of other important to-do items on a list Collins carried with him.

On his first day on the job, he announced his five key initiatives publicly. He said they would guide him in his subsequent duties. Collins said that being NIH director was an "exciting,

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daunting, and perhaps the most amazing job that anybody could ever ask for." He told a town-hall assemblage of NIH employees that the mainstay of NIH would remain the individual investigator, but he made it clear he wanted the agency to do more than basic research.

He had five priorities which he termed themes:

- To promote high-throughput technologies in areas "poised for this kind of research," such as gene transcription and stem cell research

- Translational research

- Providing evidence needed for effective health care reform, including comparative effectiveness research

- Global health research

- "Empowering the biomedical research community," an action which he said included sustained funding for innovative research[59]

In explaining translational research, he cited a new NIH program to develop drugs for rare diseases. There were diseases for which there was a very limited market. Hence, drug companies let the research that NIH sponsored and which had promise lie fallow. Collins did not cite translational research as his top priority, but it gradually became obvious that this was the case.

Collins stressed continuity along with change in his initial address. He said he would retain Raynard Kington as his principal deputy director. Kington had served under Zerhouni as his deputy, and as acting NIH director in the interim between Zerhouni's leaving and Collins' approval. Collins indicated his immediate need was to deal with the $10.4 billion extra funds that NIH had received as part of Obama's Recovery Act stimulus package to help the country recover from the Great Recession. NIH had gotten more stimulus money than any agency. The money had to be spent quickly and would run out in 2011. Collins had not had anything to do with the stimulus funding, but he had to deal with its administration and plan for what would happen when it was gone.[60]

In the next weeks and months of 2009, Collins coped with a host of stimulus issues. Some 20,000 proposals came in. Some had to do with translational research, and Collins looked at a sample. He was encouraged with the ideas he saw.[61] He also formed a new leadership team. Kington soon left to take a university presidency. Collins replaced him in August with Larry Tabak, who had been director of the NIH Dental Institute. In September he brought Kathy Hudson back to NIH, first as his chief of staff and later as deputy director for science outreach and policy. With a PhD in molecular biology, Hudson had worked closely with Collins when he was Genome Project director. Then she had gone to an academic position at the Johns Hopkins University. Collins, Tabak, and Hudson worked closely together in running NIH. Collins was active as a leader both in inside management and external advocacy.

Over time, Collins increasingly focused on his stated priorities, with translational research leading the way. What his predecessor had done was a beginning, but Collins wanted to do much more. Throughout the remainder of 2009 and into 2010, he worked on various fronts. One was to talk about translational research with some of the more influential institute directors, such as Anthony Fauci of the National Institute of Allergy and Infectious Diseases (NIAID). These were directors who already were doing translational research. He had to explain to them why he felt it necessary to augment such activity. He also reached outside

59. Francis Collins, "Opportunities for Research at NIH," *Science,* January 1, 2010, pg 36–37.
60. Kaiser, "Rejecting 'Big Science' Tag."
61. Francis Collins, interview by author, November 18, 2010.

NIH to the commissioner of the Food and Drug Administration, Margaret Hamburg. He had started a conversation with her before being confirmed. He realized that accelerating the transfer of science into health required help from the regulators. Could anything be done to streamline the process of approval while maintaining safety standards? He found Hamburg willing to discuss possibilities.

Aside from talking with key people inside and outside NIH about his ideas, he used Common Fund money to start some experimental initiatives. A few involved genomic research. Like Zerhouni, he was also particularly interested in filling a much-needed niche in rare diseases and pursued work in this area.

But Collins wanted to do more. He recalled feeling driven to use a much bolder approach. He saw an analogy in the Genome Project.[62] To make success for the Genome Project possible, there had to be an institute with a legislative mandate. There had to be an organization within NIH with authority and money. Instead of a disease-oriented emphasis, or something like the Genome Project, this entity would be oriented to a generic process that could benefit NIH and all its institutes—namely turning science into health. The NIH Reform Act of 2006 set a limit of 27 institutes. The political environment of the time argued against an attempt to get Congress to add another institute. He could not create something new without getting rid of something old. Termination was the most controversial of strategies, but the constraints of the times made it the logical way to go.

Using the Scientific Management Review Board (2010)

By May 2010, Collins decided it was time to make a move. He asked the Scientific Management Review Board (SMRB) to seriously consider issues of translational medicine, and mechanisms for greatly enlarging NIH's role therein. He urged the SMRB to move quickly. He wanted to be able to have a proposal that could become part of the NIH budget for FY 2012. That meant getting something to his parent department (HHS) in December, if not before, and then through OMB and the White House. Ideally, in Collins' view, the institutional reform he contemplated, an institute, could get started in October 2011, when the new fiscal year began. That assumed Congress would authorize and fund it.[63]

Some people told Collins he might be trying to move too fast. But he had moved fast when leading the Genome Project, he said, and believed the goal was worth the effort to try.[64] Under prodding, a working group of the SMRB, headed by Arthur Rubenstein, dean of the University of Pennsylvania School of Medicine in Philadelphia, began holding meetings to gather ideas about the possible changes Collins espoused.

The charge to SMRB was how to improve the NIH existing effort. The solution might not be a new institute, of course. But the stronger the push, the more it would have to have organizational influence behind it. Given the NIH culture, an institute seemed desirable. Collins wanted an organization specifically dedicated to developing and applying knowledge about the translational process, and eventually the SMRB came around to the same view.

In November, the SMRB working group produced a draft report that moved in the direction of the new institute. It became known that a new unit of NIH was being promoted at the expense of an existing unit. On December 7, the SMRB as a whole met to vote on whether to establish

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62. Ibid.

63. Meredith Wadman, "NIH Director Wins Bid for Translational Medicine Center," *Nature*, http://www.nature.com/news/2010/081210/full/news.2010.650.html

64. Francis Collins, Congressional testimony, May 11, 2011.

the new center. There were 13 members of the board present. They included directors of various NIH institutes and high-level medical research and administrative people from outside government. Also present in the audience were critics of the possible institute. The chief critics were those who saw threats from the new institute. The proposal that SMRB considered would move the Clinical and Translational Science Award Program, set up by Zerhouni in the National Center for Research Resources (NCRR), to the new institute. What would that mean for the $1.2 billion NCRR? The program to be transferred was the single largest program NCRR had. What would happen to other units of NCRR, which supported facility construction, instrumentation, primate work, and grants to minority investigators and rural states that were "have nots" in terms of NIH funding?

Twenty groups and investigators supported by NCRR came to the meeting to protest. "It's a very large organization being done with a very fast time scale, and the community that will be affected needs more time to provide input," said biochemist Mark Lively of the Wake Forest University School of Medicine. Lively was a member of NCRR'S advisory council.[65]

Under the reorganization, the proposed new institute would house several existing NIH programs, such as the Molecular Libraries screening activity, an entity to develop drugs for rare and neglected diseases, and NCRR's Clinical and Translational Science Awards. It would also include a Cures Acceleration Network, a drug-development effort created by the 2006 NIH Reform Act. Not yet funded, the Cures Acceleration Network would also have links to NIH's intramural Clinical Center.

Decision (2010)

Discussions at the meeting raised issues about whether other existing institutes would lose money to the new center, and how far NIH should move into drug development currently performed by industry. But the most divisive issue was about the fate of NCRR. Barbara Alving, the director, who would lose her position under the change, argued that the best way to get translational medicine established was to build upon what NCRR was already doing.

There was also the option of waiting for another reorganization to take effect that was in planning—one that involved a merger of the National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism. This combine would drop NIH's institute number to 26. But this merger was moving slowly, and Collins and his allies on SMRB wanted to move very quickly.

Moreover, Rubenstein argued it was important to have a new organization that would start with the relevant effort now under NCRR, but add what was needed in a coherent way. The fact was that a new organization would give Collins the maximum leeway to design a center as he saw fit.

Eventually, the SMRB took a vote. It went 12 to 1 to create the new institute. The only negative vote was cast by Jeremy Berg, Director of the National Institute of General Medical Sciences. He was visibly upset and rushed from the room after the vote. He said he was "concerned that the implications for the rest of NIH hadn't been adequately discerned."[66] Berg's influence was blunted, however, by the fact that he was known to be leaving NIH for another position in the not-too-distant future.

65. Martin Enserink, "A Government Niche for Translational Medicine and Drug Development," *Science*, 330, no. 6010 (2010): 1462-1463.
66. Ibid.

The vote was seen by some as potentially one of the most significant events in NIH history for what it portended for NIH's role vis-à-vis drug and therapy development. Collins declared the decision to create the center "a momentous occasion." "Basic science has exploded, but it has not translated into benefit for the public," said Rubenstein. Collins directed his deputy, Tabak, to report back in three months on the fate of NCRR activities. "We want to protect the program and the people," Collins said, trying to reassure those who saw themselves as losers under the reorganization.[67]

Getting NCATS into the FY 2012 Budget (2011)

Collins wanted the new National Center for Advancing Translational Sciences (NCATS), as it would be called, to get into the new budget bill and get officially authorized by Congress. Such legitimation would mean it would survive after Collins left. Some said that it was too late to get into the budget. Collins wanted to try and thus start NCATS in October, the new fiscal year's beginning.

Because NIH was subordinate to HHS, he had to go through Secretary Sebelius. Sebelius was already well briefed and ready to move forward. Sebelius in turn would write letters to the chairs and ranking members of relevant congressional committees, giving them official word of HHS-NIH's plan to establish NCATS. NIH legislative liaison staff, meanwhile, fanned out to discuss the plans with congressional staff of the key committees. Everything was moving fast. "Wait for FY 2013," some continued to advise. Collins did not want to wait a year and pushed harder.

There were a lot of questions about what would be in or not in NCATS and what would happen to units of NCRR that did not fit. The uncertainties were reflected in the letters Sebelius sent to Congress. On January 14, 2011, Sebelius wrote about the plan to establish NCATS. Although she mentioned some elements to go in the new center, she was vague about NCRR programs, except to say the center would face "abolishment." She said that NIH would "undertake a thorough review of NCRR programs."

Collins and Sebelius had agreed that in the current political climate, it would be unwise to ask for more money to support the change. Hence, the letter stated: "Funding for the new organization is intended to come from existing resources of the programs that would move to NCATS." As Collins would put it to those who asked: the change was "budget neutral." Sebelius made it clear in the letter that NIH wanted to put the institute on a fast track and get underway "at the beginning of FY2012 in October 2011."[68]

With Congress informed, the next step was to get NCATS into the President's budget. That meant getting the White House and especially OMB to move quickly. The overall FY 2012 budget was just about finalized and would be announced in early February 2011. There was no opposition expected from the Obama administration. After all, the President had made health reform his signature initiative and also said science was a priority. Obama had even paid a visit to NIH to dramatize this interest. That visit, incidentally, had been one of Collins' to-dos.[69] The problem was not about White House policies, but about how fast and easily White House-OMB machinery could move. Meanwhile, Collins began an advocacy campaign to himself build support and head off criticism to NCATS.

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67. Jocelyn Kaiser, "NIH to Create Translational Science Center," *Science Insider*, December 8, 2010, http://news.sciencemag.org/scienceinsider/2010/12/nih-to-create-translational-science.html.

68. Kathleen Sebelius, Letter to the Chair and other Ranking Members of Senate Subcommittee on Labor—HHS—Education Appropriations, January 14, 2011, http://www.nih.gov/icd/od/foia/library/NotificationLtrsFinalAuthorizors.pdf.

69. Francis Collins, interview by author, November 18, 2010.

A Problematic Interview (2011)

Collins was eager to mold a public constituency beyond Washington for NCATS. While the bureaucratic and budgetary machinery ground forward in late January, he granted an interview to the *New York Times*. It was an interview that proved a mistake. Forthright as usual, Collins in the article, published January 23, 2011, waxed broadly on NCATS. The writer, Gardiner Harris, captured well Collins' unhappiness with the drug industry's slowness in picking up on the research NIH performed, and the need, therefore, for the government to do more. "I am a little frustrated …. how many of the discoveries that look as though they have therapeutic implications are waiting for the pharmaceutical industry to follow through with them," he said.

So NIH was moving into the drug development business, or so the article implied. Also, Harris wrote that Collins "hinted that he is willing to cannibalize other parts of the health institution to bring more resources to the new center." What Collins said was: "There are some people that would say this is not the time to do something bold and ambitious because the budget is so tight. But we would be irresponsible not to take advantage of scientific opportunity, even if it means tightening in other places."[70]

The article, which appeared on the first page of the *New York Times*, added fuel to the firestorm already beginning to erupt over the change among critics inside and outside NIH. The agency opened a feedback site, and on January 24 provided a statement saying the article had "misleading statements." It declared NCATS was "not intended to be a drug company." It would be a "facilitator" of work underway by other institutes, and would not "cannibalize" the budgets or programs of other NIH institutes.[71]

Tabak posted online in mid-January a "straw model" indicating how parts of NCRR would be distributed, no doubt to assure those affected that they would have a home somewhere in the NIH. But key units were put in an "interim infrastructure unit" in Collins' office. Many were not reassured at all.

Science magazine wrote of the "furor" the reorganization caused on January 28. More than 1200 comments had come to the NIH feedback site, many angry. "The SMRB process simply backed into a foregone conclusion," and NCRR staff have received "an astounding level of … disrespect," said one commenter on the feedback site that *Science* quoted. "Dr. Collins is accustomed to getting what he wants," said Lively, the NCRR advisory council member. Collins told *Science* he understood the anxiety created by change. But "I will not be apologetic for wanting to see the scientific opportunities that relate to translation approached in a very bold way."[72]

Collins had to be worried about the reaction of Congress, which could keep the reorganization from happening. John Bartrum, a staff member on the House appropriations subcommittee that oversaw HHS's budget and who had once worked for NIH, sent a list of questions to HHS and NIH. Bartrum wrote in an e-mail that "we have not taken any position" on either NCATS or NCRR, but requested information on the NCATS missions, budget, and how NIH chose to terminate NCRR.[73]

Various lawmakers wrote Collins expressing concern about the reorganization, including Senators Daniel Inouye (D-Hawaii) and Mark Begich (D-Alaska).[74] What worried many senators was the

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70. Gardiner Harris, "New Federal Research Center Will Help Develop Medicines," *New York Times,* January 23, 2011, http://www.nytimes.com/2011/01/23/health/policy/23drug.html.

71. "Separating Fact and Fiction: News About the Proposed National Center for Advancing Translational Science," *National Institutes of Health,* January 24, 2011, http://feedback.nih.gov/index.php/ncats/fact_fiction/.

72. Jocelyn Kaiser, "Collins Sparks Furor With Proposed NIH Reshuffling," *Science,* 331, no. 6016 (2011): 386.

73. Ibid.

74. Jocelyn Kaiser, "Senators Oppose Plan to Dismantle NIH Resources Center," *Science Insider,* February 11, 2011, http://news.sciencemag.org/scienceinsider/2011/02/senators-oppose-plan-to-dismantl.html.

fate of NCCR's program to provide funds to states that traditionally did not receive much NIH money. Others also worried about a new institute in money-short times. How much would it cost? There was no question the *New York Times* article and speed with which Collins seemed to be moving were causing a pushback. Collins himself admitted that it might have been good to have had time to talk to more people about what he wanted to do. But he was up against FY2012 budget deadlines.

Building Support, Neutralizing Opposition (2011)

As it turned out, NCATS did not make OMB's schedule for inclusion in the new budget. The President proposed a modest raise for NIH in the budget released in early February. Since the White House was in favor of what Collins wanted to do, the issue was about when, not whether to move forward. Collins decided to keep pushing. "Change requires action," he said after a meeting later in February with advisers.[75] NIH would now go for an amendment in the budget that had recently gone to Congress. Collins knew he would have to campaign for his new institute. There was significant resistance within and outside NIH.

In March, however, he got some influential support. The journal *Nature* on March 10 wrote an editorial, "Embrace Change," aimed at the biomedical community. It admitted that Collins was proceeding hastily, and he had "alienated a significant element of the NIH-funded community." But *Nature* called the change Collins sought necessary and better accomplished quickly than drawn out over a long time.

Nature said Collins made an "executive decision, taken quickly in December and presented to the NIH community effectively as a fait accompli." There were risks in what he wanted to do. "But Collins was hired to lead, and leading he is." Significantly, *Nature* warned its readers that they had better not be distracted by the NCATS issue. The real challenge was to protect NIH generally and protect its budget in hard times. The fighting over NCATS would be "a political liability on Capitol Hill, where lawmakers with their knives out for expendable programs may find disunity an invitation."[76]

A few days after the editorial appeared, Collins held an open meeting at NIH to outline his vision for NCATS and answer critics. He apparently was persuasive. A journalist who attended the meeting noted insiders appeared to be warming to the idea.[77] Not Jeremy Berg, the one vote against NCATS at the December SMRB meeting. He was leaving NIH in June, but was making his views known. In a profile of Berg in *Science*, Berg chastised Collins for not consulting more with the scientific community. "This is the first time in the history of NIH," Berg complained, "that a center has been abolished, and to do that in this manner is a very bad precedent. … If this is representative of his leadership style, it is going to impair the effectiveness of the organization."[78]

But Berg was on his way out. Collins was still there, and working hard to build support for NCATS. While there were interest groups associated with NCRR against him, there were others for him. A patient advocacy organization called Faster Cures arranged a series of town hall meetings outside NIH. Collins also granted additional interviews to the media to tout NCATS, being more careful this time than when he had spoken with the *New York Times*. He honed

75. Paul Basken, "NIH Pushes Ahead on Research Division to Speed Drug Development, Despite Protests from Scientists and Others," *Chronicle of Higher Education,* February 23, 2011, http://chronicle.com/article/NIH-Pushes-Ahead-on-Research/126500/.

76. "Embrace Change," *Nature* 471 no. 7337 (2011): 135.

77. Jocelyn Kaiser, "NIH Scientists Warming to New Translational Center," *Science Insider*, March 15, 2011, http://news.sciencemag.org/scienceinsider/2011/03/nih-scientists-warming-to-new-tr.html.

78. Jocelyn Kaiser, "Jeremy Berg: An Independent Scientist Departs NIH's Ranks," *Science,* 332, no. 6029 (2011): 533.

his message more artfully to make the change less threatening. He had to deal with a host of other hot-button issues as NIH director, such as continuing conflict over stem cell policy, but he kept his eye on NCATS. He also continued to meet with Hamburg of FDA. In April, they teamed up to form a Joint NIH-FDA Leadership Council to "accelerate the process from scientific breakthrough to the availability of new, innovative medical therapies for patients."[79]

Senate Hearings (Spring 2011)

On May 11 Collins testified before the Senate Subcommittee on Labor-HHS-Education Appropriations. He brought some high-profile institute directors with him to these hearings. Anthony Fauci, head of the Infectious Diseases Institute, came. So did Harold Varmus, former NIH director and recent president of Memorial Sloan-Kettering Cancer Center. Collins had persuaded Varmus to return to NIH to run the National Cancer Institute. Fauci and Varmus came as prestigious allies of Collins insofar as welcoming NCATS. The hearing went beyond NCATS, but NCATS was clearly a matter the senators wanted to discuss.

Collins explained the purpose of NCATS and its aim to be a catalytic force within NIH generally and between NIH and industry. Fauci and Varmus both said NCATS would help what they were already doing to speed science into health. The senators all seemed favorably disposed to NCATS, especially the chairman, Tom Harkin (D-Iowa). The ranking member, Richard Shelby (R-Alabama), was critical of the Obama administration for not getting a budget amendment and details of the reorganization to Congress by now. But there was no indication Shelby or the other senators were against NCATS. It was a friendly hearing. Collins emphasized NCATS would give better and faster health delivery at essentially no greater cost. Collins said NCATS would improve "the discipline of translational research."[80]

On June 6, Sebelius sent a budget amendment to Congress along with details of what units would go into NCATS, and where the components of the former NCRR would be specifically placed. Nothing from NCRR was lost. She emphasized that NCATS was planned to begin in the new fiscal year "within the funding level identified for NIH in the FY2012 President's budget."[81]

Trouble in the House (Summer 2011)

With the budget amendment, it seemed clear Collins had the key Senate committee on his side. The House was another matter. Now under the control of the conservative Republicans, the House had Denny Rehberg (R-Montana) as chair of the House Labor and Health and Human Services Appropriations Subcommittee. Rehberg was advised by staffer Bartrum. The result was a certain "unenthusiasm" about what was happening with NCATS. This attitude became more pronounced when Collins announced that NIH had begun a search for an NCATS director. Rehberg issued a warning that such an action was premature. Congress, he pointed out, had not authorized its establishment. Other House members seconded his criticism.[82]

NCATS was coming into visibility at a time of sharp acrimony between the House of Representatives and the Obama administration. There was one fight after another, mainly over money. Cutting the budget deficit was overshadowing all other policy matters and the partisan

79.   Alex Philippidis, "NIH and FDA Taking Partnership for Regulatory and Translational Science One Step at a Time," *Genetic Engineering and Biotechnology News*, April 17, 2011, http://www.genengnews.com/insight-and-intelligenceand153/nih-and-fda-taking-partnership-for-regulatory-and-translational-science-one-step-at-a-time/77899393/.
80.   Francis Collins, Congressional Testimony, May 11, 2011.
81.   Kathleen Sebelius, Letter to Chairman Tom Harkin and other Ranking Members of Senate Subcommittee on Labor—HHS—Education Appropriations , June 6, 2011, (Letter provided author by NIH).
82.   "NCATS Drawing Congressional Criticism," *AAAS*, June 29, 2011, http://www.aaas.org/spp/policyalert/policyalert20110629.html.

divide was growing worse. It was hard to get anything done in Congress. The stalemate included getting a budget passed. The government was kept running through a continuing resolution.

It was a terrible time to get anything new through Congress. In an article entitled, "Reengineering Translational Science: The Time is Right," published online in July, Collins argued strongly for NCATS, setting forth what it was and what it was not.[83] Collins persevered, writing and giving public talks in which he expressed the vital need for NCATS. But he had to be careful in what he said. He had to push, but not assume NCATS was a done deal. Nothing was certain in the Washington of summer 2011. The House subcommittee asked for more information on NCATS. Then it wanted more details, and NIH sent more details.

But it appeared there would be no action, as Obama and the House went into a confrontation on the normally routine measure to raise the national debt ceiling. A group of tea-party Republicans were demanding huge budget cuts as a price for raising the debt ceiling, and failure to raise the ceiling would cause a financial catastrophe in the view of most economists.

In this context, Collins kept talking to congressmen informally about the importance of NIH generally and NCATS particularly. He spoke with people who were for and who might be against NCATS for some reason. Interest groups concerned with NCRR components were registering their opposition on the Hill. There were groups concerned with minority grants, rural states, animal and facility grants, and the like, who saw change as threatening. Collins responded to invitations (usually made in response to NIH overtures) to talk to lawmakers and/or their staffs on the Hill. He also went to social occasions in Washington where he could meet informally with legislators and reassure them that the NCATS change would not hurt interests they supported. Ordinarily, health was such a positive value that an NIH director did not need to be such an active advocate. But these were different times. NIH's last budget received a 1% appropriation decrease from Congress. A cut was virtually unheard of for an agency with typically bipartisan support. In speaking with lawmakers, Collins pointed out where the NIH money went—relatively little to Bethesda labs, most to universities and medical schools in congressional districts.

Such strategies had positive and negative impacts. The positive was to win support. The negative was the spread of unfounded rumors that NCATS would go to particular districts. An article in a Raleigh, North Carolina paper even said that city was poised to get the center.

Worried about whether and when Congress would pass the FY2012 budget, Collins directed staff to come up with a Plan B. Was there any legal way, for example, to start NCATS without official authorization from Congress? As staff studied contingencies, there was muttering at NIH that Collins might be spending too much time on NCATS. Aside from the overarching issue of budget, stem cell policy and other controversial questions continually arose. Collins had his priorities set when he arrived, but unanticipated fires came up and needed to be extinguished.

Collins was helped in the summer of 2011 when a subcommittee on NCATS of the Advisory Committee to the Director rallied behind him. This group included many prestigious individuals from outside government. These included Subcommittee Chair Maria Freire, President, Albert and Mary Lasker Foundation; Susan Desmond-Hellman, Chancellor, University of California-San Francisco; Brook Byers, Senior Partner, Kleiner Perkins Caufield and Byers; and Moncef Slaoui, Chairman, Research and Development, Glaxo Smith Kline.[84] In late August, the chief opponent—

83.   Francis S. Collins, "Reengineering Translation Science: The Time is Right," wwwScienceTranslationalMedicine.org, July 6, 2011, Vol 3, Issue 90.
84.   ACD Working Group Activities: National Center for Advancing Translational Sciences (http://acd.od.nih.gov/reports/NCATS_TRND_Report.pdf)

and casualty—of NCATS, Barbara Alving, director of the doomed NCRR, decided to leave the field of battle. She announced she was resigning at the end of September. She took a parting shot at Collins, saying the process was not handled "optimally" and that he had "tried to get community buy-in," but only "after the fact."[85] Collins praised her, but had to be quietly relieved. With Berg and Alving gone, the most outspoken dissenters within NIH had left. But there was still Rehberg, whose agreement was essential.

Budget Politics (Fall 2011)

Would there be a budget bill passed by Congress by October 1? In late September, the Senate health appropriations panel approved a FY2012 spending bill that would slightly trim the budget of NIH, cutting it by $190 million to $30.5 billion. The bill approved the establishment of NCATS and dissolution of NCRR. But in a report accompanying the bill, the subcommittee scolded NIH for a poorly conducted process of change.[86] The full committee and Senate followed suit, in passing the bill.

Shortly afterward, the relevant health appropriations subcommittee in the House acted. It gave NIH a larger increase to $31.7 billion. But it did not authorize the creation of NCATS. For reasons having nothing to do with NCATS, NCRR, or NIH, the House and Senate could not agree on a FY2012 budget generally. The result was a last-minute continuing resolution to keep the government running through November 18 at a rate $7 billion below FY2011 levels. For NIH, that meant a reduction of 1.5% from FY2011. There was no authorization for NCATS in the continuing resolution.[87]

NIH could not start NCATS. NCRR would somehow continue. Plan A was now to get the needed approval if Congress passed a budget after November 18. Plan B was to get NCATS approved in a subsequent continuing resolution if Congress could not agree on a budget. Ordinarily a continuing resolution simply kept government moving as it was, and did not authorize substantive change in programs. So Plan B was called an "anomaly," an exception to the normal rule, assuming the House could concur with the Senate, which had gone on record favoring NCATS.

Meanwhile, Collins had to worry about the budget for FY 2013. That was being assembled in October, 2011, and Collins again stressed his priorities, which included "advancing translational science." Presumably, "Plan C" would be getting NCATS into the FY2013 budget if the first two plans failed. No one really knew what Congress was going to do—but Collins was relentless in talking up NCATS at every opportunity, and trying to enlarge congressional and public support for NIH generally. When the President gave an address on technology-based economic development in mid-September, NIH used its White House contacts to get points in the speech about biomedical innovation. The President, touting the proposed institute, declared: "When scientists and researchers at the National Institutes of Health discover a new cure or breakthrough, we're going to make it easier for startup companies to sell those products to the people who need them." The message was that translational research was not only about health, but about economic development.[88]

85. Jocelyn Kaiser, "Departing Director Reflects on NCRR Breakup," *Science Insider*, August 23, 2011, http://news.sciencemag.org/scienceinsider/2011/08/departing-director-reflects-on.html.

86. Jocelyn Kaiser, "NIH Chided on Translational Center, Warned of More Budget Cuts," *Science Insider,* September 23, 2011, http://news.sciencemag.org/scienceinsider/2011/09/nih-chided-on-translational-center.html.

87. "Congress Passes Resolution to Fund Federal Government Through November 18," *American Society of Hematology,* October 5, 2011, http://www.hematology.org/News/2011/7094.aspx.

88. "Remarks by the President at Signing of the America Invents Act," *White House*, September 16, 2011, http://www.whitehouse.gov/the-press-office/2011/09/16/remarks-President-signing-america-invents-act.

Endgame (December 2011)

The November 18 continuing resolution was extended to December 16, as Congress and the White House sloughed forward. Congress had raised the debt ceiling earlier and created a "Super Committee" to resolve the long-term deficit reduction issue that was holding up other decisions, including an NIH budget. The Super Committee, however, disbanded in failure in late November. "These are not just stressful times," said Collins, "but potentially disastrous times … It's hard to know what trajectory we are on."[89]

Collins talked with many lawmakers about NCATS, including Eric Cantor (R-VA), the House majority leader. The key legislator Collins had to persuade, whether talking about Plan A, B, or C, was Rehberg. Collins had Rehberg out to NIH in December. He gave him a tour of the Bethesda campus. He did his best to assuage the lawmaker's concerns. He said that pro-grams of NCRR about which Rehberg cared were secure under the change. Collins told him the grants made under NCRR would continue under NCATS or the new locations where former NCRR components would go. He assured Rehberg that the program to aid rural states (like Montana, Rehberg's home state) would be safe. The interchange apparently worked.[90]

The logjam on federal funding, and thus NIH, broke in December. Instead of another multi-month continuing resolution, Congress passed a regular FY2012 appropriation. What this meant for NIH was $30.7 billion. The bill specifically dissolved NCRR and created NCATS, providing $575 million to get it started.

Collins was so excited that he moved faster than the President, who had to sign the bill for it to be law. At 6:57 pm EST, on Saturday, December 17, Collins sent his agency an e-mail enti-tled "Changes at NIH." Speaking of NCATS's creation, Collins said: "This is an important step forward," and announced he was putting Thomas Insel, the director of the National Institute of Mental Health, as Acting Director. Indicating how serious he was in monitoring the startup of NCATS, he also said his close aide, Kathy Hudson, would be acting deputy director of NCATS. Both appointees would add the NCATS jobs to their current roles, while NIH looked for permanent NCATS leaders. The media noted that Collins had "jumped the gun" on the President, but it did not matter.[91] Obama was going to sign the bill to fund the government and soon did so.

On December 23, Obama signed the bill into law. Now implementation could begin.

Conclusion

Francis Collins succeeded in getting NCATS established. This is an example of success in gov-ernmental change. But doing so was not easy. A number of lessons may be learned from this experience.

Lesson One: Be clear about goals and priorities at the outset. Collins said what he wanted to accomplish on his first day. He had five priorities, and one was to move NIH more forcefully toward translational research, and it became clear that this was his top priority.

89. "NIH Moves Forward on Main SMRB Recommendations," *NIH Record,* November 11, 2011, http://nihrecord.od.nih.gov/newsletters/2011/11_11_2011/story2.html.
90. John Burklow, interview by author, July 15, 2011.
91. Jocelyn Kaiser, "NIH Director Jumps Gun with Memo Announcing New Center," *Science Insider*, December 19, 2011, http://news.sciencemag.org/scienceinsider/2011/12/nih-director-jumps-the-gun-with.html.

About NCATS

(From NCATS website: www.ncats.nih.gov)

Mission

The mission of the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH) is to catalyze the generation of innovative methods and technologies that will enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions.

Implementing the NCATS Mission

To carry out its mission, NCATS has established an organizational structure consisting of diverse representation, including those from disease advocacy organizations and private equity firms, along with renowned scholars in translational science and regulatory review. Guided by a national advisory council and a Cures Acceleration Network Review Board, NCATS and its leaders receive expert advice on how best to use budgeted resources and set policies.

This strategic guidance, coupled with input from the NCATS director and from scientific advisory groups, steers the Center toward achieving its goals, such as:
- Using science advances to overcome translational pipeline barriers
- Testing pipeline innovations with promising research projects
- Cultivating strong partnerships
- Increasing collaboration with the U.S. Food and Drug Administration
- Supporting an innovative and collaborative training program

Research at NCATS

Research projects at NCATS focus on addressing scientific and technical challenges to reduce, remove or bypass bottlenecks in the development of new treatments and tests that will ultimately improve human health. The Center aims to make translational science more efficient, less expensive and less risky. NCATS is:
- Facilitating — not duplicating — other translational research activities supported by NIH
- Complementing — not competing with — the private sector
- Reinforcing — not reducing — NIH's commitment to basic research

One of NCATS' primary activities is to collaborate closely with the other NIH Institutes and Centers to establish its research priorities as well as to develop translational tools and resources that facilitate research across NIH. NCATS unifies programs in the following three areas:
- Clinical and Translational Science
- Rare Disease Research and Therapeutics
- Re-engineering Translational Sciences

Partnering at NCATS

As a hub for catalyzing innovations in translational science, NCATS works closely with partners in the regulatory, academic, nonprofit and private sectors to identify and overcome hurdles that slow the development of effective treatments and cures. Through these partnerships, NCATS also focuses on policy issues important to and affecting translational sciences.
- **Models for Precompetitive Collaboration.** NCATS aims to re-engineer the translation process by bringing together expertise from the public and private sectors in an atmosphere of collaboration and precompetitive transparency.
- **Translational Research Policy.** Through collaborative efforts, NCATS will work through policy roadblocks in strategic areas including therapeutic target validation, medicinal chemistry, preclinical toxicology, efficacy testing, virtual drug design, clinical trial design and post-market events.
- **Intellectual Property for Collaborative Projects.** Patenting and licensing are used to help ensure new technologies are developed fully and commercialized to advance public health, but they can sometimes be seen as impediments to moving collaborative science projects forward.
- **Ethical Issues in Clinical Trials.** Clinical trials, whether "first in man" or for a new indication of an existing therapeutic, are generally intricate, costly and challenging to implement.

Lesson Two: Be clear about how to accomplish this leading goal. Collins brought great experience to his leadership position. He knew the NIH culture and he knew that, to accomplish this broad policy goal, he had to first achieve institutional change, a permanent organization with legitimacy and budget. Thus, NCATS became his initial means, or—more precisely—an interim goal, since the ultimate goal represented large-scale change for NIH and health generally.

Lesson Three: Get started as soon as possible, and use the tools at your disposal. Collins did hit the ground running, and began talking to key people inside and outside in formulating his strategy, quickly. Indeed, he had started talking about ends and means between his talk with Sebelius in April 2009 and Senate confirmation in August. He made use of his Common Fund to initiate pilots in translational research. It appears he did not move into a higher gear for change, however, until May 2010, when he got the Scientific Management Review Board to start considering the NCATS innovation. He might thus have made this accelerated move for change even earlier. But once he decided to press fully forward, he moved faster than many advisers thought possible or wise.

Lesson Four: Build internal and external support for change. This was top-down innovation, and many writers about leadership and change call for more participatory strategies. Collins' strategy sought buy-in from internal and external constituencies, but this was director-initiated change and an institutional innovation he wanted. Most of the acceptance came after the fact of its introduction, and not without resistance. The key challenge Collins faced was time. It takes a lot of time to win converts without a widespread sense of urgency within an organization and outside of it.

Collins felt a sense of urgency about translational medicine given his own limited time as head of NIH. Many others did not feel urgency. NIH was a conservative organization, anchored in existing institutes, more accustomed to incremental, bottom-up change. This change was potentially transformative, and threatening to some. Moreover, it entailed a strategy of displacement—removing an existing institute to make way for a new one.

It may be that this kind of disruptive change does not lend itself to bottom-up participative techniques, and must be imposed from the top. In any event, it is important to emphasize the positive in bold change, and build support along the way. In so doing, it is essential to pay attention to those whose support is most critical—such as a Fauci, Varmus, or SMRB chair. Also, as Collins found, one early interview in the media can derail change if it comes across as too threatening to key interests in an organization and Congress. Hence, the leader's marketing task is all-important.

Lesson Five: Be focused and relentless when the political context is negative and distractive. The toxic politics between the White House and Congress (especially the Republican-controlled House) made it extremely difficult to do anything new that appeared to add budget costs. Hence, the strategy of displacement and budget-neutrality was key to getting acceptance.

Most agency heads were maintainers rather than change agents in the timeframe during which Collins sought to create NCATS. Collins never gave up in his quest, devoting perhaps 25 percent of his time to pursuing his NCATS vision. He admits to having been driven by this quest—not because of NCATS per se, but because he truly believed in translating science into health. His zeal put off some observers inside and outside NIH, but he was confident that his vision would pay off for the agency and public. If the criticism he received for how he went about the change process bothered him, he did not let it curtail his effort. Leadership is not for the timid.

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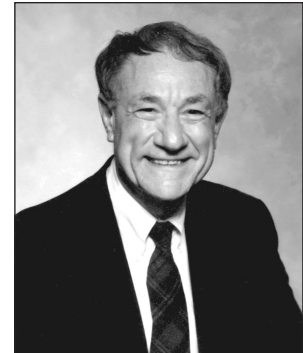
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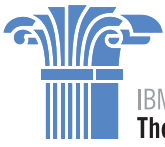*Engaging a Multi-Generational Workforce: Practical Advice for Government Managers* by Susan Hannam and Bonni Yordi
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