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By John F. Early and Terence Kealey

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Mission Lost: How NIH Leaders Stole Its Promise to America

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Abstract

The National Institutes of Health (NIH) claims its research will improve Americans' health and longevity. That worthy objective and an occasional scientific breakthrough have worked to insulate NIH from budgetary scrutiny. Based on the record through the year 2024, NIH spending has not only been wasted, but it has also harmed progress toward improved health. Beginning in 1960, the annual increase in NIH spending started rising five times more per year in inflation-adjusted dollars than previously. At the same time, the rate of improvement in longevity dropped suddenly by more than half. These perverse results arise from strategic failures by NIH. It has abandoned mission research focused on specific health outcomes in favor of a linear model that spends on "basic" research, a model that has been shown to fail in government agencies and was discarded long ago by successful research efforts in the private sector. Detailed analysis of NIH projects shows substantial funding is spent on projects that clearly have no relationship to improving health and violate basic scientific methods and standards of proof.

Keywords: NIH, National Institutes of Health, Health, Health Data, Cancer, Deaths, Health Behavior, Infectious Disease, Morbidity, Mortality

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1 What's the problem?

The National Institutes of Health (NIH) describes its mission as to advance research that will "enhance health, lengthen life, and reduce illness" for Americans.[1] But is NIH delivering on that promise? That worthy objective has worked to insulate the NIH from scrutiny of its spending by both the executive branch and Congress, leading to an ever- growing budget over the past six decades. Yet, this increased spending has been accompanied by a slowdown in the improvement of longevity, which has grown only half as fast as before.

In modern science, a research organization will follow one of two possible models. The "mission" model focuses the research on fulfilling a mission such as developing a cure for a specific disease. The "linear" model undertakes what it considers to be "pure" science based on the belief that looking at a variety of different underlying topics will eventually generate something useful. Yet experience shows that the mission the model yields superior results. It is by far the dominant model in the private sector, yet it is used only rarely—but then successfully—in government research.

NIH began life doing mission research, but by 1960 it had shifted to the linear model, increased its annual spending five times faster, and delivered weaker results. This white paper shows in detail how this failed model has led to poor outcomes for NIH and why it needs to abandon the failed linear model and make the many transformations needed for a successful transition toward mission research.

Moreover, increasingly large government spending has crowded out useful research in the private sector by hiring many competent scientists to engage in marginal or even useless research when they would otherwise have been employed on effective mission-driven research projects in the private sector. We show that NIH has spent too many of its resources to please groups with political influence rather than on the most pressing health needs as guided by scientific insight. As a result, its control of a major share of research dollars in the broader economy has limited or even outright prevented the investigation of diseases or alternative theories of cause that offer opportunities for significant improvements in health outcomes.

Of course, NIH has scientific achievements of which to boast, but with fiscal year 2024 spending exceeding $50 billion,[2] and similarly large amounts in prior years, it must necessarily have made some advances. The questions are: (1) would medical science have advanced faster had that money not been spent

[1] National Institutes of Health, "Overview of 2024 President's Budget," in *The National Institutes of Health Congressional Justification Fiscal Year 2024* (National Institutes of Health).

[2] Outlays for fiscal year 2024 were $54 billion. USAspending.gov, "Department of Health and Human Services (HHS), Spending Profile, FY 2024," U.S. Department of the Treasury. Other measures such as appropriations, obligations, and budget requests are slightly different but of same magnitude.

by the federal government, as it crowded out private money that would have been better spent and (2) would health outcomes have been better had the federal government spent that money in 2024 and earlier on *mission*-driven—rather than on *basic*—science research? The evidence shows that the answer to both questions is a resounding "Yes."

In later chapters, we will show that NIH budget submissions to Congress do not target spending to reduce the diseases with the greatest mortality (death) or morbidity (suffering from a disease or condition). It even spends research money on smallpox, a disease that has been totally absent from the entire globe for 47 years. The budget sets almost no quantitative health goals. The 2024 budget contains only two strategic goals: (1) to reduce America's age-adjusted death rate due to cancer by 50 percent over 25 years and (2) to lower new HIV infections by 75 percent by 2025 and by 95 percent by 2030. It sets no goals for the greatest cause of American deaths, cardiovascular disease. We will look at each of these strategic foci in depth and show that they are poorly defined, lack explicit plans to achieve their objective, and lack quantitative tracking toward their goals. NIH has refused to provide any data to justify its actual spending by disease or condition. Budget justifications are based on activity—new organizational units, number of projects, the diversity of the workforce, etc.—not improved health results.

Detailed analysis of NIH projects shows substantial funding is dedicated to projects that have no relationship to the reason NIH was created, namely, to improve health. Among projects that do relate to health, millions of dollars are spent on projects that violate basic scientific methods and standards of proof so that their results are unreliable. Some of the funded work potentially endangers Americans by empowering a government agency to manipulate people's behavior or define what is ethical.

Our analysis of the NIH budgetary process and structure draws heavily from the 2024 Congressional budget submission from NIH, which was the latest completed budget when the analysis began. The analysis stretches across several years, however, because recent NIH budgets have been very similar from one year to the next. The typical NIH project is financed over a five-year period, and some for more than 20 years, with approximately 80 percent of the research projects carrying over from the previous budget year. Most of the project-specific material in our analysis draws on multiple years of performance to support our assessment of the cumulative impact of the NIH research, not just a single year's appropriations.

The federal government takes up a huge share of national income. It spends 25 percent of the total value of goods and services produced in the United States (Gross Domestic Product or GDP),[3] and state and local

[3] "Table 1.2 - Summary of Receipts, Outlays, and Surpluses or Deficits (-) as Percentages of GDP: 1930 – 2029," U.S. Office of

governments spend another 14 percent, for a total of 39 percent.[4] NIH spending is not one of the largest sources of this massive expenditure, but it is still significant, and gaining control of government expenditures requires that all spending receive careful evaluation. Because the NIH has the objective of improving health, that lofty objective seems to have shielded its spending from scrutiny. This white paper lays out both a strategic framework and specific tactical details to help evaluate and control NIH spending.

The remainder of this chapter provides some general background on medical research and the early history of government involvement in scientific research. Chapter 2 relates the early history of NIH and how NIH arrived at the failed pipeline model of research. Chapter 3 traces the post-Sputnik explosion in government research generally, and Chapter 4 looks at the effects on NIH funding and the ensuing slowdown in the improvement of life expectancy. Chapter 5 outlines how biomedical research is being performed and how NIH distorts the process and slows progress. Chapter 6 introduces the main problematic elements of the NIH budget process. Chapter 7 identifies the underlying strategic issues the budget ignores. Chapter 8 covers broad areas of funding that are bureaucratic overreach beyond the scope of improving health. Chapter 9 lays out a framework for evaluating the tactical execution of projects that NIH funds.

Each of the next four chapters is devoted to one of the four leading types of failures in tactical execution. These chapters concentrate on the details of how NIH selects, funds, and operates individual research projects. While a single project can suffer from several different flaws, each of these chapters focuses on project categories that seem to frequently suffer from the same type of failure. Chapter 10 features project categories that suffer from failures to observe foundational principles of scientific research. Project categories in Chapter 11 frequently endanger liberty. Chapter 12 project categories spend large amounts of money on work irrelevant to NIH's mission, and Chapter 13 features spending that is inherently wasteful. Finally, Chapter 14 summarizes our findings and identifies opportunities for improvement.

The Trump administration entered office after this report had already been drafted. We have made a few updates to reflect its activities, but for the most part this paper applies to the state of affairs before January 2025.

1.1 Background for NIH Research

The National Institutes of Health claimed to need $51.1 billion in Fiscal Year 2024 in order "to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance

Management and Budget, "Historical Tables," The White House.

[4] "Table 3.3. State and Local Government Current Receipts and Expenditures," Department of Commerce, Bureau of Economic Analysis.

health, lengthen life, and reduce illness and disability."[5] That claim is an expression of the linear or pipeline model of science funding, which can be expressed as follows:[6]

government-funded pure science → technology useful to medicine, business, and defense

The National Science Foundation (NSF), the NIH's sister agency, also operates on the linear or pipeline model. Its current Strategic Plan opens with the words: "Strategic investments by the U.S. National Science Foundation are advancing many industries, tools and products that are fueling economic growth."[7] This NSF claim for fueling economic growth has been discredited by government's own audits,[8] which we will review in more detail shortly.

Government leadership in general and NIH in particular should have learned from this long history of failure with the government-funded linear research model.[9] Mission-directed research is practiced in the private sector and in most defense-related research. It can be expressed as follows:

mission-directed research → real advances in medicine, business, and defense

In this white paper we shall show that the NIH's funding has not translated effectively into advances in health, for at least three reasons.

First, NIH has largely abandoned mission research in favor of the failed linear research model. The superior mission model works, but it has been displaced within the NIH, NSF, and most other federal research agencies by the linear model. Mission-driven research is now largely restricted to the private for-profit sector, where it works supremely well.

Second, NIH crowds out useful research, thereby slowing progress. When the government funds science, it pulls scientists out of the private sector, where they are more likely to generate useful advances.[10] Even more fundamentally, the effects of huge government funding of its preferred theories of cause crowds out research on competing theories of cause.

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[5] National Institutes of Health, Congressional Justification Fiscal Year 2024: Overview of FY 2024 President's Budget (U.S. Department of Health and Human Services, 2023), p. 2.

[6] See for example, Terence Kealey and Martin Ricketts, "Innovative Economic Growth: Seven Stages of Understanding," Cato Institute Economic Policy Brief no. 3, April 6, 2020. The exact form varies slightly by context.

[7] Sethuraman Panchanathan, "Message from the NSF Director," *U.S. National Science Foundation 2022-2026 Strategic Plan* (National Science Foundation, March 2022), p. 3.

[8] Terence Kealey, "Don't Be like China: Why the U.S. Government Should Cut Its Science Budget," Cato Institute Economic Policy Brief no. 4, May 25, 2021.

[9] Nathan Rosenberg, *Inside the Black Box: Technology and Economics* (Cambridge University Press, 1982).

[10] Sebastian Damrich et al., "Crowding in and Crowding out within a Contribution Good Model of Research," *Research Policy* 51 (2022): 104400.

Third, like all government agencies, NIH exhibits "public-choice behavior," which describes how government workers respond to incentives. Private companies grow and reward their owners by providing goods and services that individual consumers voluntarily, even eagerly, consume. Government functionaries respond to a different set of incentives. They increase their financial rewards by expanding the scope, activity, and power of government. While mission research has been successful in government settings, the incentive structure of government tends to corrupt it and drive government research toward the linear model.

1.2 A brief history of the U.S. government funding of science, 1776-1957

Following the birth of the republic, the federal government systematically assumed responsibility for particular missions consistent with the enumerated powers of Congress in Article I Section 8 of the Constitution. To that end, Congress founded a succession of agencies: the Library of Congress in 1800, the Coast Survey in 1807, the Surgeon General's office and the Army Medical Department in 1818, and a Depot of Charts and Instruments in 1830. In support of such agencies, the federal government might commission research, but that research was always focused on the agencies' missions and consistent with Article I Section 8 of the Constitution.

A further mission the federal government undertook was defense, and though peace-time defense research was delegated to the armed services themselves, special research agencies would be created during wartime. These included the National Academy of Sciences in 1863, during the Civil War, and the National Research Council in 1916 as German U-boats were sinking American ships just prior to America's entry into World War I. But with the resumption of peace, the wartime agencies' systematic government funding ended. Though the agencies themselves might survive, further federal funding (if any) would be only for discrete projects on a contractual basis.

The Second World War saw the same pattern. In 1941 the Office for Scientific Research and Development (OSRD) was created, with huge budgets totaling some $2.5 billion during its existence, or about $34.7 billion in 2022 dollars, and with major responsibilities, ranging from the development of antibiotics (particularly to meet the needs of wounded soldiers) to the Manhattan Project. The OSRD delivered on these challenges, yet in 1947 it was shuttered, and its residual projects were transferred to other agencies including the Office of Naval Research, other various agencies in the Department of Defense, the Atomic Energy Commission, and the National Institute(s) of Health.

In 1945, to try to save the OSRD, its director Vannevar Bush published his famous book, *Science, the Endless Frontier*, to propose that the federal government depart from its long-standing policy of funding only mission

research, and instead to copy the Germans and the French in funding pure or basic science. Bush claimed that such research was neglected by the market.[11] In short, Bush advocated for the linear or pipeline model.

Bush offered no evidence to support his assertion of market neglect. And contrary to his claim, there is no evidence that the market neglects pure or basic science, just as there is no evidence that the government funding of such science stimulates GDP per capita growth.[12] Because there was no evidence that the government funding of science stimulated economic growth, Bush's claims initially gained little traction. But the opening phases of the Cold War persuaded President Harry Truman that the United States again needed a federally funded, military-focused, research agency, so in 1950 the National Science Foundation was created. However, its founders clashed over its funding model. That clash reverberates to this day and informs much of the analysis in this white paper.

In 1947, coinciding with the closure of the OSRD, Congress sent President Truman a bill to create its NSF, but Congress's funding model was in Bush's image—it was in the image of the linear model—and Truman vetoed it. In mission research, to use a phrase attributed to Winston Churchill, scientists are "on tap and not on top." But in the linear model the scientists are on top. And Truman was not having that. In his veto he wrote:

> This bill contains provisions which represent such a marked departure from sound principles for the administration of public affairs that I cannot give it my approval. It would in effect vest the determination of vital national policies, the expenditure of large public funds, and the administration of important government functions, in a group of individuals who would essentially be private citizens. The proposed National Science Foundation would be divorced from control by the people to an extent that implies a distinct lack of faith in democratic processes.[13]

The key question was encapsulated in V.I. Lenin's famous phrase, "Who, whom?"[14] Who would control the distribution of funds? In mission research, the inauguration and direction of a research project are determined by elected officials. But under the linear model, the inauguration and direction of a research project are determined by the scientists themselves and validated through peer review. And as Truman's veto showed, he was not a peer review man.

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[11] Vannevar Bush, *Science, the Endless Frontier: A Report to the President by Vannevar Bush, Director of the Office of Scientific Research and Development. July 1945* (University of Michigan Library, 1945).

[12] Terence Kealey, "The Case against Public Science," Cato Unbound, August 5, 2013; Terence Kealey, "Don't Be like China: Why the U.S. Government Should Cut Its Science Budget," Cato Institute Economic Policy Brief no. 4, May 25, 2021.

[13] Harry S. Truman, *Public Papers of the Presidents of the United States: Harry S. Truman, 1947* (Government Printing Office, 1963), p. 368.

[14] V.I. Lenin, *Polnoe Sobranie Sochinenii*, vol. 44 (1970), October 17, 1921, quoted in *Oxford Essential Quotations*, 5th ed., ed. Susan Ratcliffe (Oxford University Press, 2017).

By 1950, however, the federal government recognized it was embarking on yet another war, a Cold War; so Truman, having accepted that the United States again needed a federally funded, military-focused, research agency, allowed the NSF to be created. The early NSF, though, was created not so much to fund science per se but, rather, at the urgings of Senator Kilgore (D-WV), to fund the training of scientists who might potentially be mobilized in the Cold War effort.

As Chairman of the Senate's Subcommittee on War Mobilization, Senator Kilgore held hearings in 1942, 1943 and 1945 on the United States' shortage of scientists. The peacetime cohort was too small for the urgent needs of total war, he argued, so he wanted to train a reserve of scientists to be mobilized in the event of the Cold War heating up. Consequently, the NSF's early budgets were not only small ($3.5 million in 1953, about $40 million in 2023 dollars), but also training-focused (43 percent was for training and only 29 percent for research grants, which were funded chiefly because they were a good way to train young researchers.)[15]

The NSF's focus on training made it, however, dependent on the universities, who would do most of the training on NSF grants, and the universities would not accept a subordinate role as contractors conducting mission research directed by elected officials. So, a compromise was forged, in which the NSF would be a peer-reviewing body but whose director would be appointed by the President.

[15] National Science Foundation, *The Second Annual Report of the National Science Foundation: Fiscal Year 1952* (Government Printing Office, 1952), p.75.

2 Origins of NIH and Its Research Model

2.1 A brief history of the NIH, 1887-1957

The NIH traces its origins to a one-man lab that was set up in 1887 within the US Public Health Service, which was part of the Marine Hospital Service, which in turn was established in the early 19th century to prevent sailors from carrying diseases into the country. The lab was renamed the National Institute (singular) of Health in 1930, and it was joined by a new National Cancer Institute in 1938.[16] In 1948, after it incorporated some of the OSRD's residual functions, it became the National Institutes of Health, in the plural.

In 1938 the future NIH had an individually identified budget that totaled $464,000 in or $7.6 million in inflation-adjusted 2022 dollars.[17] From 1938 to 1960 the NIH budget remained relatively modest, growing to $3.1 billion in 1960 (in 2022 dollars), an average increase of $139 million per year in inflation-adjusted dollars.

The NIH continued grow and, as it grew, its philosophy changed: originally a mission-oriented laboratory within the Marine Hospital Service, in its new incarnation as the National Institutes of Health, it was later captured by bureaucrat scientists pursuing a linear model of research, who would thereafter be on top. As we will show in this white paper, NIH's research became misdirected when the agency abandoned the mission model for the linear model. The solution is to revert to the pre-1950 model of the federal government funding only mission research, directed by elected leaders for appropriate public ends authorized by the Constitution and not by scientists without a specific and appropriate public mission. This arrangement requires Congress and the President to determine that the public mission is not only within the scope of the Constitution, but that it can only be achieved through public funding.

2.2 The difference between mission and linear model research: a government health example

The most famous example of mission research in history is the Manhattan Project, which was directed not by a scientist but by General Leslie Groves. Less famous but equally impressive has been the Department of Defense's Breast Cancer Research Program (BCRP), which not only was also directed at its founding by General Richard Travis, but has continued to be led by an Army general. As the Department of Defense writes (DoD) in its Breast Cancer Research Program, all its research to this day requires, "Approval of Commanding General."[18]

[16] The National Institutes of Health, "History."
[17] National Institutes of Health, Congressional Appropriations, 1938–1949 (NIH Office of Budget, n.d.).
[18] U.S. Department of Defense, *Breast Cancer Research Program*, Congressionally Directed Medical Research Programs (January 2023), p. 2.

The BCRP was born of the dissatisfactions of a Philadelphia trial lawyer called Fran Visco. After being diagnosed with breast cancer, Visco was disappointed with the current state of treatment, so in 1987 she helped set up the National Breast Cancer Coalition (NBCC) as a political advocacy group. And by 1992 the NBCC had identified some $300 million worth of potential research projects that, if funded, offered promising prospects.

Congress was persuaded, and it voted to appropriate the funds, but by a budgetary quirk most of the money ($210 million) was handed not to the National Cancer Institute (which is part of NIH) but to the DoD. The details of the quirk are slightly obscure. The same source offers two slightly different versions of how some breast cancer research became a continuing part of DoD. Either the money was part of the "peace dividend" at the end of the Cold War and simply reprogramed from military to civilian purposes in the DoD budget,[19] or adding the program would have exceeded a previously agreed cap on non-defense spending, so Congress avoided the issue by adding it to the DoD budget.[20] Either way, the extra money for breast cancer research found itself in the docket of the Army.

The near-universal assumption at the time was that the money would soon be redirected to its "proper" home, the National Cancer Institute (NCI) within NIH. But then a strange thing happened—Fran Visco and the NBCC fell in love with the Army. Daniel Sarewitz tells the story:

> [W]hen Visco and her NBCC colleagues met with NCI officials to discuss how best to spend the new dollars, Director Sam Broder explained how difficult it was to influence the momentum of science because priorities were established by the bottom-up interests of the research community itself. This, Visco said, "gave us absolutely no comfort that he was going to do anything differently."
>
> When Visco went to the DoD, "it was a completely different meeting." With Major General Richard Travis, the Army's research and development director, "it was, 'you know. We're the Army, and if you give us a mission, we figure out how to accomplish that mission.'" It was "Ladies, I'm going to lead you into battle and we're going to win the war."
>
> Although Visco was at first "terrified" to find herself working with the military, she also found it refreshing and empowering—"a fantastic collaboration and partnership."[21]

So Visco and the NBCC stayed with the Army, and the results were impressive. Here is a 2017 report from the Army:

[19] Eliot Marshall, "Breast Cancer's Forced March?," *Science* 258 (October 30, 1992): 732–34.
[20] Eliot Marshall, "The Politics of Breast Cancer," *Science* 259 (January 29, 1993): 616–17.
[21] Daniel Sarewitz, "Saving Science," *The New Atlantis*, Spring/Summer 2016.

> The Department of Defense, Congressionally Directed Medical Research Program, Breast Cancer Research Program (BCRP) has helped to fund the development of four FDA-approved therapeutics currently used to treat patients with breast cancer [Herceptin, Ibrance, Kisqali, and Verzenio]. The BRCP also provided funding for a study [ATLAS, Adjuvant Tamoxifen Longer Against Shorter] that led to a change of clinical practice . . .[22]

The BCRP's current docket of research looks equally impressive.[23] Compare this direct statement of results with the vague leadership statement from the Director of the National Cancer Institute within NIH.

> In February 2022, President Biden unveiled a series of bold, compelling goals to end cancer as we know it: . . . I want to highlight two prominent Cancer Moonshot priorities—doubling accruals to cancer clinical trials and transforming NCI's Cancer Moonshot Data Ecosystem into an engine that drives cancer discovery and ensures that the knowledge gained through research is broadly available to researchers and clinicians.[24]

NIH is building its bureaucratic infrastructure to recruit more people into clinical trials and developing a better computer database at the expense of achieving specific improvements in treatments and cures. Of course, those two items may be useful tactical activities as supporting parts of a strategic initiative, but any competent research organization should be able to do them as a matter of course. Emphasizing and budgeting expenditures for overhead and administration as though they were research underemphasizes the core of research and desired health outcomes and builds a bureaucracy of clerks, database managers, project managers, and the like.

[22] Erin Bolling, "DOD Supports Breast Cancer Research to Develop a Cure," *U.S. Army*, October 13, 2017.
[23] U.S. Department of Defense, *Congressionally Directed Medical Research Programs: Breast Cancer Research Program*.
[24] Monica Bertagnolli, "Director's Overview," *National Cancer Institute, Congressional Justification FY 2024* (National Cancer Institute, 2023), NCI-3–NCI-4.

3 And then there was Sputnik

3.1 A brief history of the U.S. government funding of science, 1957-

The United States governments' 150-year history of modest funding of peacetime research ended on October 4, 1957, when the Soviet Union launched Sputnik, the first artificial satellite. That traumatized America. As President Lyndon B Johnson later recalled that day, "Now, somehow, in some new way, the sky seemed almost alien. I also remember the profound shock of realizing that it might be possible for another nation to achieve technological superiority over this great country of ours."[25] In the words of Wernher von Braun, the German-born United States rocket scientist:

> *Sputnik* triggered a period of self-appraisal rarely equaled in modern times. Overnight, it became popular to question the bulwarks of our society; our public education system, our industrial strength, international policy, defense strategy and forces, the capability of our science and technology. Even the moral fiber of our people came under searching examination.[26]

In the words of Roger Launius, NASA's official historian: "The only appropriate characterization that begins to capture the mood on 5 October involves the use of the word hysteria."[27] One of us (Early) was age 13 at the time and remembers vividly how Sputnik and the accompanying publicity dominated attention both at school and home, creating a society-wide mission focus.

In 1958, in urgent response to Sputnik and its associated challenges, the federal government launched three vast initiatives and three smaller but still large ones:

- The National Aeronautics and Space Administration (NASA) was created to challenge the Russians in space.
- The National Defense Education Act was passed to boost the education of many more scientists.
- The Advanced Research Projects Agency (ARPA, later the Defense Advanced Research Projects Agency or DARPA) was created to revert to the mission or OSRD model of research, by which technological goals are set under the direction of elected officials, and science is funded only so

[25] Richard Van Atta, "Fifty Years of Innovation and Discovery," in *The DARPA Model for Transformative Technologies*, William B Bonvillian et al., eds. (Open Book Publishers, 2019), pp. 27–44, at p. 29.
[26] Robert D Lapidus, "Sputnik and Its Repercussions: A Historical Catalyst," *Aerospace Historian* 17, no. 2/3 (1970): 89.
[27] Roger Launius, *Sputnik and the Origins of the Space Age* (NASA, n.d.).

far as it advances those goals.[28] That is in contradistinction to the NSF or linear model, where the government funds basic scientists to follow their own interests and ideas, trusting that their advances would naturally diffuse to generate new technologies. The distinction between the NSF and ARPA models was made explicit by DARPA's Deputy Director, Dr. Lee Buchanan, when he said, "I get nothing from basic science—[I] could drop that science funding and never miss it."[29]

- After 1958, the NSF's budgets were increased manyfold. The NSF was deemed to have failed America—the Russians were in space!—but over the next few years its budgets were nevertheless increased nearly 10-fold to boost training of scientists' and reinforce the National Defense Education Act of 1958.[30]
- The Small Business Investment Act of 1958 provided federal support for small businesses.[31] The worry was that American free-market capitalism had been failing early-stage entrepreneurs.
- Although NIH was not directly tied to the space program, the general flurry of activity to close the science gap with the Soviet Union resulted in a four-fold increase in the NIH budget in four years.

These 1958 initiatives presented the federal government with an ideological problem, because they were uncomfortably similar to Soviet policies. Riding to the ideological rescue came the RAND (Research and Development) Corporation. RAND had been created in 1945 by the US Air Force and the Douglas Aircraft Company, with the support of Vannevar Bush, an engineer who headed the Office of Scientific Research and Development during World War II, to lobby for government funding of research. After 1957 it sprang into action by funding two gifted young economists, Richard Nelson, the future doyen of the economics of science, and Kenneth Arrow, the future Nobel laureate, to justify the governments of capitalist countries funding research—but only research!—on the Soviet model. In the words of RAND's official historian, David Hounshell:

> RAND's economics-of-R&D project also yielded two of the foundation papers in the field: Richard Nelson's "The Simple Economics of Basic Scientific Research" and Kenneth J Arrow's "Economic Welfare and the Allocation of Resources for Invention" . . .

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[28] William B Bonvillian et al., eds., *The DARPA Model for Transformative Technologies* (Open Book Publishers, 2019), pp. 27–44, at p. 29.

[29] Lee Buchanan cited in William Bonvillian, *Innovation Systems for Science, Technology, Energy, Manufacturing and Health*, Class 1, Part 1: "Economic Growth Theory and the Direct Elements in Innovation" (Massachusetts Institute of Technology, 2017), at 34 minutes, 35 seconds.

[30] National Science Foundation, *NSF Requests and Appropriations By Account: FY 1951-FY 2022* (National Science Foundation, 2022).

[31] U.S. Congress, *Small Business Investment Act of 1958* (U.S. Government Publishing Office, December 27, 2020).

> Nelson's and Arrow's papers provided appealing economic theories as to why the nation would systematically underinvest in basic research. Their theories had clear policy implications: the U.S. government should invest more in basic research owing to "market failures" in the private sector. These theories have been largely internalized within the now dominant neoclassical economic tradition . . .[32]

Nelson and Arrow's claims have only rarely been subjected to rigorous testing against actual market performance, so their view—that even in free-market capitalist systems governments should fund science to compensate for market failure—has become economic conventional wisdom. Yet Nelson's and Arrow's claims do not stand up to scrutiny for two reasons.

First, they argued, the private sector *should not* fund science because that would confer competitive advantage on the companies that funded it. In Nelson's words, companies possessing market power from their research would "undermine many of the economic arguments for a free-enterprise economy."[33] In Nelson and Arrow's day, it was typical for economics to be taught starting from a "perfectly-competitive" economy model in which an infinite number of producers and an infinite number of consumers trade an infinite number of interchangeable goods under conditions of "perfect" knowledge (i.e., no one possesses proprietary knowledge). This theoretical—and totally fictitious—model was used for didactic purposes to explain how supply and demand would reach an equilibrium point at which the market would "clear"—that is, all products would be sold and purchased at a price acceptable to both buyer and seller.

The "perfect competition" model was never meant to be the end of the discussion but was rather a simplification to be perturbed in analysis by various exogenous variables such as taxes or drought. Even in the most sophisticated and complex expositions of this model, such as Paul Samuelson's *Foundations of Economic Analysis*[34] (not to be confused with his textbook for first-year economic students: *Economics: An introductory Analysis*) there was never any claim that this "perfect competition" was a desirable real-world system. Serious economists were also well aware that this "perfect competition" model could not be used to explain one of the most important phenomena in economics, namely economic growth from invention and innovation. As Samuelson concludes his magnum opus:

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[32] David Hounshell, "The Cold War, RAND, and the Generation of Knowledge, 1946–1962," *RAND History Project* (RAND, 1998).

[33] Richard Nelson, "The Simple Economics of Basic Scientific Research," *Journal of Political Economy* 67, no. 3 (1959): 306.

[34] Paul Anthony Samuelson, *Foundations of Economic Analysis* (Harvard University Press, 1947; repr., Atheneum, 1963).

> The further development of analytical economics along the lines of comparative dynamics must rest with the future. It is to be hoped that it will aid in the attack upon diverse problems . . . even to the majestic problems of economic development.[35]

Nelson's and Arrow's economic education surely included Samuelson, but they ignored his ultimate warning that the static equilibrium model of perfect competition could not be used to explain the dynamics of economic growth and development because there was no endogenous provision for invention and innovation.

Second, Nelson and Arrow claimed that, in a real market, science would be underprovided in any case because knowledge "spills-over" for free, so the company that devotes resources to R&D will be driven into bankruptcy by its competitors, who will copy the inventor's innovations at no cost, leaving the inventor burdened by the costs of the original research and no higher relative market value. Consequently, the private funding of R&D in real markets will be disincentivized. This argument also fails to stand up to scrutiny. Most knowledge from research is tacit knowledge, which the Cambridge Business English Dictionary defines as "knowledge you do not get from being taught, or from books, etc., but get from personal experience." Research yields little in the way of explicit knowledge that "can be articulated and easily communicated between individuals and organisations."[36] As a result, it does not spill over for free, but is available only to those who have acquired it by their own contributions to research.

Furthermore, the Nelson-Arrow argument carries an inherent internal contradiction. Are researchers and innovators unfair competitors because they drive out the competition? Or are they bankrupt chumps because their competitors can copy their innovations without paying for them, leaving the innovator with the cost but no benefit? Which is it? This contradiction arises from their use of a static equilibrium model to explain a dynamic growth phenomenon.

Nelson's and Arrow's claims are also inconsistent with history. The industrial revolution and all the innovations that it generated prospered most strongly in the United Kingdom and the United States without any significant government-funded research except that supporting the mission of national defense. The result was robust and widespread innovation and growth. Companies were driven out of business not because they invested in research but because competitors did more and better research and thus innovated to move the technology frontier forward.

Nelson and Arrow in effect claimed that science is a "public good." Public goods are provided by government because their consumption is "nonexcludable" and "nonrivalrous."[37] Nonexcludable goods cannot prevent "free

[35] Samuelson, p. 355.

[36] *Cambridge Business English Dictionary* (Cambridge University Press, 2011).

[37] For a discussion of multiple examples in other policy areas that claim to meet these criteria but, in fact, do not, see David Boaz, *The Libertarian Mind, A Manifesto for Freedom* (Simon & Schuster, 2015), pp. 325–56.

riders" who did not pay for the goods from benefiting from them, so the assumption is that no one would produce them because they couldn't sell them. Consumption is nonrivalrous when consumption by one person does not reduce the consumption available to another. For example, national defense protects all of a nation's residents from invasion by a hostile power; no one can be excluded. Making one person secure from foreign invasion will not reduce the security of another.

Scientific research is different. It is a "contribution" good that delivers benefits only to those who contribute to the creation of the relevant knowledge base.[38] As a result, real markets supply science optimally, because companies will increase their funding up to the point where it ceases to be profitable.

The point at which diminishing returns from scientific research make it unprofitable is not some unique single point. There are literally millions of potential paths for research, each with its own break-even point at any given point in time. Those break-even points are determined not only by the scientific inquiry but also by consumer demand—how much, if anything, are consumers willing to pay for the resulting good or service. They are also determined by the cost of other factors of production to deliver the result to the consumer—new production facilities such as factories, hospitals, or server farms; raw materials and their supply chains; and workers with the necessary human capital and training. Once an invention becomes successful, diminishing returns from further innovation will eventually set in because the establishment of the necessary infrastructure will halt or slow the translation of further invention into innovation or because there is insufficient consumer demand for further innovation. But such diminishing returns are a necessary consequence of successful invention, so they are fully compatible with the market funding the optimal amount of science.

Nelson and Arrow nonetheless concluded that governments should fund science for the two reasons that emerge from the two false claims discussed above:

1. Governments should fund science to crowd out private companies from doing science. To approach a perfectly competitive market, the government should do all the necessary science research and then distribute it freely to all companies equally.
2. Governments should fund science to compensate companies for the disincentive of their competitors copying them for free.

Despite its obvious faults, Nelson and Arrow's work remains foundational in much conventional thinking and has been cited with increasing frequency as seekers of government research grants attempt to justify their

[38] Terence Kealey and Martin Ricketts, "Modelling Science as a Contribution Good," *Research Policy* 43, no. 6 (2014): 1014–1024.

requests, while government ignores the evidence to the contrary, which we have outlined above and will elaborate throughout this book. Nelson's paper has been cited nearly 5,000 times since its publication, with a peak as recently as 2012-2017, according to Google Scholar. Arrow's paper has been cited no fewer than 17,000 times and has averaged more than 700 citations a year since 2015, which is more than double its average citation rate over its 61-year history. It remains so influential that the National Bureau of Economic Research hosted a conference in 2010 to celebrate the 50th anniversary of its publication.[39]

3.2 Mission creep

As with many government initiatives during the last half century, mission creep has also bedeviled the federal government's funding of science over the same period. The perennial problem is that agencies are founded to serve specific missions but are then captured by researchers and other bureaucrats to serve their own private missions, namely pure science under the linear model, which optimizes rewards to government employees and contract researchers. This type of activity has been called public choice behavior because, unlike the market economy, which generates income by meeting customer needs in the marketplace, government employees and contractors increase their income by using political processes to expand their scope, authority, and budgets. In the course of this analysis, we will point to specific examples within NIH.

Consider the evolution during the 1960s of ARPA (as it was initially called.) Traumatized by the US military's failures in Vietnam, in 1969 the Office of the Director of Defense Research and Engineering conducted an audit of 700 research "events" that had led to the development of 20 weapons systems and published the results as *Project Hindsight*. The report showed that only 2 of those 700 research events were in pure science.[40] Vannevar Bush's argument in *Science: The Endless Frontier* had been disproved: the government funding of pure science did not strengthen the America's defense capabilities.

Alerted by early reports of *Project Hindsight*'s conclusions, in 1968 the National Science Foundation, seeking to defend its grants, published *Technology in Retrospect and Critical Events in Science*, which found examples of science feeding military technology. To find the items, however, NSF had to go back 50 years, to when pure science was mostly funded privately.[41] Unintentionally, the NSF's response only confirmed the Department of Defense's finding that the government funding of pure science did not feed into useful technology.

[39] Josh Lerner and Scott Stern, eds., *The Rate and Direction of Inventive Activity Revisited* (University of Chicago Press, 2012).

[40] Office of the Director of Defense Research and Engineering, *Project Hindsight* (Office of the Director of Defense Research and Engineering, 1969).

[41] National Science Foundation, *Technology in Retrospect and Critical Events in Science* (National Science Foundation, 1968). This was published after the release of early drafts of *Project Hindsight*.

Then-Senate Majority Leader Mike Mansfield (D-MT, Senate Majority Leader 1961-1977) was dismayed not only by *Hindsight*'s demonstration that government-funded pure science had no military value but also by the realization that though ARPA had been created to fund goal-orientated or mission research, it had—in a classic example of producer capture and public choice behavior—crept back toward the linear model: ARPA's scientists were doing a lot of pure science for its own sake and to enhance their own careers, not toward outcomes for defense.

Then, during the 91st Congress (1969-1970) and again in 1973, Mansfield pushed through amendments to the Military Authorization Acts to block ARPA's further funding of pure science.[42] In reaction to Mansfield's first amendment, ARPA in 1972 changed its name to DARPA, the Defense Advanced Research Projects Agency, in the hope Mansfield would spare it. He didn't and thus made DARPA's pure or basic scientists' positions redundant.[43]

At the time, Mansfield's amendment was widely blamed for destroying American science by causing so many pure D/ARPA scientists to be laid off.[44] However, in the meantime, D/ARPA's newly redundant researchers streamed out to Xerox PARC in Silicon Valley, which was then directed by Bob Taylor, who also had come from ARPA.[45] The results at Xerox PARC were impressive, and offer important lessons.

In the early 1970s the best computer scientists were employed by D/ARPA, and only when they were fired did Xerox recruit them and translate their expertise into commercially and socially revolutionary work. And it was the former ARPA researchers who, under Taylor's leadership and transplanted to Xerox PARC, invented the whole concept of the graphical user interface as realized in windows, pop-up menus, the trash can, and many other elements. They also developed the mouse, the laser printer, and the personal computer (including, of course, the Alto, which featured a mouse and graphical display), while also helping to pioneer an Ethernet network and sending things called "emails."

In short, it was D/ARPA's discontinuing of its program in pure science that allowed Xerox PARC to pioneer today's high-tech revolution. In other words, D/ARPA's foray into pure science had crowded out the IT revolution for a time. Crowding out is the phenomenon whereby the government, by funding science on terms that are attractive to scientists (namely by allowing them to determine their own research projects and programs), draws almost all the best scientists out of the market (where scientists are accountable to shareholders and executives)

[42] Mansfield was also a defense sceptic, and his amendments also sought to halve the U.S. military's overseas commitments.

[43] National Science Board, "The Mansfield Amendment" in *The National Science Board: A History in Highlights, 1950–2000* (National Science Foundation, 2001).

[44] Philip Boffey, "Science Adviser's Critique of Mansfield Amendment Draws Sharp Rebuttal from Senate Majority Leader," *Science* 169 (24 July 1970): 356–57.

[45] Charlie Gere, Digital *Culture* (Reaktion Books, 2002), pp. 130–31.

into labs that, in the *cliché*, are ivory towers buffered from the market.[46] Consequently, companies cannot readily find good scientists, so they cannot get good returns on their investment in R&D, and therefore they shift their investments into other activities such as operational efficiency, vertical and horizontal integration, and marketing.

That brings us to a crucial question that NIH should answer: Is it similarly crowding out the private funding of health research? The top 10 pharmaceutical companies in the United States historically have spent about 35 percent of income on marketing and administration , but only 11 percent to 14 percent on R&D.[47] One reason the proportion spent on R&D may seem small is that the federal government spends 74 percent of discovery and translation research dollars, leaving only 24 percent for private industry and another 2 percent for university and foundation spending from their own funds.[48]

Government agencies perform very poorly when their claims are audited. Consider again D/ARPA. The agency frequently boasts of being the best in human history, but how can we know this? Its Project AGILE in Vietnam failed to simulate and predict Vietcong behaviors using quantitative battlefield data, while its interviews with the local population proved to be unreliable.[49] ARPA is often celebrated for its development of the ARPANET, the forerunner of the internet, but the packet-switching technology that underpinned it owed little to ARPA. Rather, it was developed by Paul Baran of RAND as part of his mission-driven project to make American communications more secure from Soviet threats, along with Donald Davies at the National Physical Laboratory in the United Kingdom working on a mission-driven project to speed up message transmissions.[50]

ARPA gave us the TCP/IP (transmission control protocol and internet protocol) suite, but that is not much in the context of total government spending. Defense research in the United States is *huge*, and of course *something* must come out of it. The question is: Has ARPA pushed the technology faster than it would otherwise have gone? We cannot know because ARPA simply avoids auditing. In 2019 a book entitled *The DARPA Model for Transformative Technologies* published a series of essays in celebration of the Agency. One of those essays was written by a team from MIT headed by an economist called Michael Piore, and it sought to assess how successful D/ARPA had actually been. But the MIT team was driven to write how D/ARPA

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[46] Sebastian Damrich et al., "Crowding in and Crowding out within a Contribution Good Model of Research," *Research Policy* 51 (2022): 104400.

[47] Marcia Angell, "Excess in the Pharmaceutical Industry," *Canadian Medical Association Journal* 171 (2004): 1452. Although published in a Canadian journal, Angell held a United States university appointment, and the data are for the United States.

[48] Calculated by authors from Kavisha Jayasundara et al., "Estimating the Clinical Cost of Drug Development for Orphan Versus Non-Orphan Drugs," *Orphanet Journal of Rare Diseases* 14 (2019): 12, 4. And Research!America and TEConomy Partners, LLC, U.S. Investments in Medical and Health Research and Development, 2016-2020 (Research!America and TEConomy Partners, LLC, January 2022).

[49] Jill Lepore, *If Then: How the Simulmatics Corporation Invented the Future* (Liveright Publishing Corporation, 2020), pp. 213–31.

[50] Paul Baran, *Digital Packet Switching*, U.S. Patent No. 4,438,511, issued March 20, 1984; Internet Hall of Fame Pioneer, Posthumous Recipient Donald Davies.

> . . . has proven to be very resistant to systematic evaluation. The resistance is in part conceptual—it is hard to know how the agency should be evaluated. But it is also institutional: DARPA has refused quite explicitly to help support an attempt at evaluation, at least in connection with this study. It rejected our request for data which would have enabled us to define a list of projects, trace the participants drawn into the agency's orbit, and assess the impact upon conventional measures of scientific output such as patents and citations in scholarly journals. Their claim is that the agency has to be evaluated in terms of its contribution to the mission of the armed forces, a mission that is notoriously difficult to define.[51]

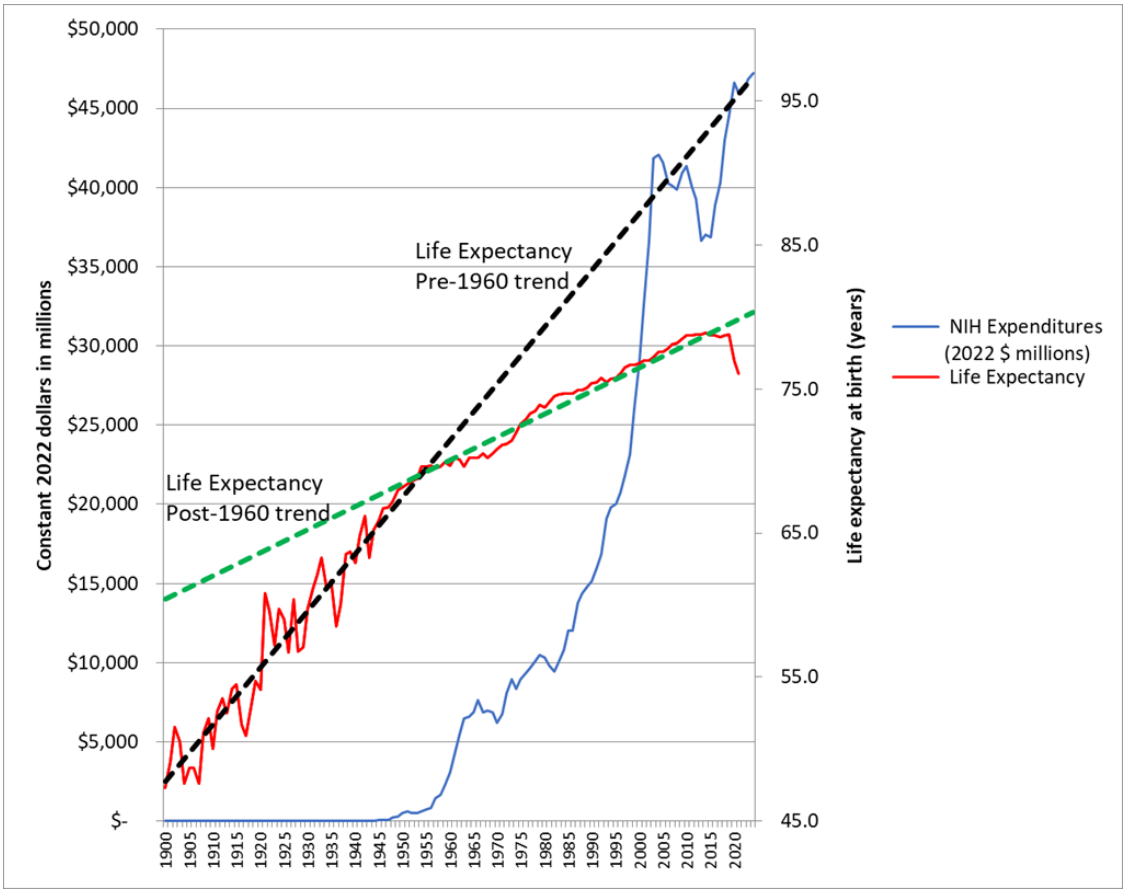
Piore and his coauthors then go on to criticize an earlier attempt at evaluating DARPA, *DARPA Technical Achievements* (1990-1991) that, as the title suggests, limited itself to chronicling ARPA's successful projects rather than attempting a cost-benefit analysis that would have balanced them against the costs of the agency's failed projects.

[51] Michael Piore et al., "NSF and DARPA as Models for Research Funding: An Institutional Analysis," in *The DARPA Model for Transformative Technologies: Perspectives on the U.S. Defense Advanced Research Projects Agency*, William Bonvillian et al., eds. (Open Book Publishers, 2019), p. 49.

4 NIH and Reduced Improvement in Life Expectancy

The story of the NIH parallels that of its sister scientific agencies. The NIH's funding increased by about $139 million per year in inflation-adjusted dollars from 1938 to 1960. But from 1960 to 2019, it grew by an average of $703 million per year, more than five times as much. See Figure 4.1.[52]

Figure 4.1. National Institutes of Health (NIH) Appropriations in 2022 dollars and life expectancy at birth, 1900 – 2022



Source: NIH Expenditures: National Institutes of Health, Office of Budget, "Congressional Justification Fiscal Year 2024" https://officeofbudget.od.nih.gov/pdfs/FY08/FY08%20COMPLETED/appic3806%20-%20transposed%2038%20-%2049.pdf, https://officeofbudget.od.nih.gov/pdfs/FY16/Approp%20History%20by%20IC%20FY%202000%20-%20FY%202016.pdf. https://officeofbudget.od.nih.gov/pdfs/FY19/Mechanism%20Detail%20for%20NIH%20FY%202000%20-%20FY%202017%20(V).pdf.
Life Expectancy: National Center for Health Statistics, "Mortality Trends, Death Rates and Life Expectancy," https://www.cdc.gov/nchs/data-visualization/mortality-trends/index.htm and 2019-2021 https://www.cdc.gov/nchs/data/vsrr/vsrr023.pdf.
Inflation adjustment: By authors using Gross Domestic Product Implicit Deflator, Bureau of Economic Analysis, National Income and Product Accounts, Table 1.2.4. Price Indexes for Gross Domestic Product by Major Type of Product.

[52] National Institutes of Health, "Appropriations History by Institute/Center (1938 to Present)." Inflation adjustment by authors using Gross Domestic Product Implicit Deflator, Bureau of Economic Analysis, National Income and Product Accounts, Table 1.2.4. Price Indexes for Gross Domestic Product by Major Type of Product.

Just as ARPA (later DARPA) began with the mission model of scientific research but soon moved to the linear model, in the days of the Marine Hospital Service, the Hygienic Laboratory had been focused on the mission of meeting the needs of hospitals and patients and preventing the spread of communicable diseases from returning sailors. But after World War II, it sought to embed itself in a university ecosystem of pure science. Its initial efforts were modest, but they were supercharged by the accelerating government science spending following Sputnik, with a quadrupling of its spending in four years. American universities were then primarily liberal arts colleges, so the NIH first had to convince them to take the NIH's money, but convince them it did, as Fred Stone of the NIH recounted, post-war "it wasn't anything to travel 200,000 miles a year" to solicit and extract research grants from the universities.[53]

4.1 Is bigger better?

Since 1960, NIH has since grown into a large and complex organization with 27 institutes, centers, and offices, each with its own Congressional budget submission. It employs approximately 18,500 people in government positions. In addition, 84 percent of its budget goes to more than 50,000 "extramural research" grants that fund more than 300,000 recipients at more than 2,500 universities and other institutions annually.[54]

In summary, NIH operates with two fundamental weaknesses that it shares with other government research institutions such as DARPA and NSF.[55] It has adopted a linear or pipeline model of science that has never been shown to yield results of as much value as the alternative mission model. It has not undertaken systematic efforts to audit its results to demonstrate their value to the health of America's population. In this white paper we draw attention to some of the specific issues of planning, budgeting, and execution that NIH leadership that the Office of Management and Budget, and the Congressional appropriations committees should address in their ongoing budget reviews.

Our documentation of the failures of NIH and its funding is not to deny that some research conducted or funded by NIH has produced identifiable achievements in detecting, treating, and curing disease. Many scientists funded by NIH are remarkably talented and dedicated. But as this analysis shows, progress toward improving health would be more rapid and effective with less government spending and more decentralized research and

[53] Stephen Strickland, *The Story of the NIH Grants Foundation* (University Press of America, 1989), p. 38.
[54] National Institutes of Health, "Budget."
[55] This parallel between DARPA and NIH became especially ironic when NIH initiated its own Advanced Research Project Agency for Health (ARPA-H) in the very second sentence of its 2024 budget request. In budget documents, it often is simply referred to as ARPA, without the H. ARPA-H seems to be home for projects that cannot be shoehorned into one of the other 27 institutes, centers, and offices within NIH.

development with private funding and direction. The same scientists in a more open and more mission-driven environment could produce even more beneficial outcomes.

The NIH's spending is rarely challenged in the Congressional budget process because its stated purpose, "to enhance health, lengthen life, and reduce illness and disability," sounds so noble. But reducing runaway federal government spending requires an across-the-board look at how government spends the money it takes from taxpayers. Equally important for a focused review of NIH is that despite its putatively noble purpose, such large sums of government spending in health-related research can actually slow the progress in improving health.

With its vast budgets, one would expect some spectacular results from the NIH, but the evidence does not show that. Figure 4.1 shows the history of life expectancy at birth for the United States. The last two years, 2020 and 2021, were affected by the COVID-19 pandemic with additional mortality arising from the disease itself and from delays in treatment of other conditions as the result of lockdown regimes. To avoid any distortions from this unusual event, much of the following analysis uses data ending with 2019. Except for a few specific examples, this paper will not examine the role of NIH or other agencies in the COVID-19 pandemic, including funding of gain-of-function research, because those are large topics deserving their own analysis and requiring more post-pandemic experience.[56]

In the first 60 years on the graph from 1900 to 1960, American life expectancy at birth rose from 47.3 to 69.7 years, an increase of 22.4 years. From 1960 to 2019, life expectancy rose to 78.8 years, an additional 6.2 years of expected life. During the earlier 60-year period, on average, each calendar year added 0.37 years of life expectancy, but in the more recent 59-year period, each calendar year added only 0.15 years. In short, beginning in 1960, the rate of improvement in life expectancy was cut by more than half. What is more surprising is that this slowdown in trend was relatively sharp and sudden, not gradual. Furthermore, this slowdown coincided with a massive reduction in smoking. A 1950 research paper by the British physician Richard Doll, followed by additional research from him and others showing the same results based on the United States experience, demonstrated the causal tie between smoking and cancer. This new understanding of the health dangers of smoking first helped arrest the trend toward more smoking, which stopped rising after peaking in 1954, and then declined by more than 75 percent until 2022.[57] Substantially less smoking contributed to significant reductions in lung cancer and heart disease, but overall improvements in life expectancy actually slowed because there were fewer improvements in health from other sources.

[56] As of this writing, there is an emerging collection of studies on the COVID-19 experience "Pandemics and Policy," at Cato Institute, https://www.cato.org/pandemics-policy and https://www.cato.org/covid-19. Ryan A. Bourne, *Economics in One Virus: An Introduction to Economic Reasoning through COVID-19* (Cato Institute, 2021) provides economic analysis around the pandemic.

[57] Jeffrey M. Jones, "U.S. Cigarette Smoking Rate Steady Near Historical Low," *Gallup*, August 18, 2023.

4.2 Causes of slower improvement

What could explain this sharp slowing in trend? One might argue that the first 60 years, and in fact, the 100 years before that, posted significant improvement by dealing with the easy low-hanging fruit, and after that, progress would be slower. But advances like open heart surgery, which look straightforward and obvious with hindsight, did not appear that way at the time. During that earlier time, work that led to the elimination of serious threats from smallpox, tetanus, typhoid, whooping cough, diphtheria, and even polio was carried out almost exclusively by private enterprise, foundation funding, and universities using their own funds.

One could argue that there might be some theoretical upper limit to human longevity and that improvement in life expectancy would slow as the limit was approached. It has been suggested that such a limit might be approximately 122 years of age, which is the age for the oldest person on record.[58] There is evidence that this is not a real physical limit and that longer life spans are possible both from improved delivery of existing technology and emerging new technologies.[59] But even if there were such a limit, we are a long way from reaching it, and if we were approaching it, the slowdown would likely be gradual over a long period of time and not an observable sudden shift well short of the lowest proposed limit.

The 1962 Kefauver amendments to the Food, Drug, and Cosmetic Act mandated new requirements for the Food and Drug Administration's (FDA) approval of new drugs. The new regulations added extensive testing on efficacy in addition to the existing requirements of testing for safety. These new regulations substantially increased the time for approval of new drugs by the FDA from about two years to between 12 and 14 years.[60] To the extent that they added 12 or so years to the development cycle for new treatments, this could plausibly have slowed the improvement in life expectancy, and the slowed increase in life expectancy from 1963 to 1975 could reflect that effect. But after the additional time for approval became built into the process, improvement would have returned to its former rate as new drugs came out of the longer pipeline at the same rate, only delayed. But the longer and more expensive approval was also an impediment for starting a new line of development or carrying it to market completion. In those cases, the improvements in life expectancy would have been lost. Today, the annual

[58] For example, J. Vijg and E. Le Bourg "Aging and the Inevitable Limit to Human Life Span," *Gerontology* 63 (2017): 432–34.

[59] Mikhail V. Blagosklonny, "No Limit to Maximal Lifespan in Humans: How to Beat a 122-Year-Old Record," *Oncoscience* 8 (2021): 110-19; Michael F. Roizen et al., *The Great Age Reboot: Cracking the Longevity Code for a Younger Tomorrow* (National Geographic, 2022).

[60] Gail Van Norman, "Drugs, Devices, and the FDA: Part 1: An Overview of Approval Processes for Drugs," *JACC: Back to Translational Science* 1, no. 3 (April 2016); Charles Hooper, *Should the FDA Reject Itself?* (Chicago Park Press, 2001), p. 243; Charles L Hooper and David R. Henderson, "FDA Shouldn't Keep Safe Drugs off the Market," *Wall Street Journal*, March 25, 2020; Sam Peltzman, *Regulation of Pharmaceutical Innovation: The 1962 Amendments* (American Enterprise Institute, 1974), pp. 51–73, 81–82. Peltzman's results have been validated more recently and added other elements of delay from authorizing generic drugs and delays in the COVID-19 response by Casey B. Mulligan, "Peltzman Revisited: Quantify 21st Century Opportunity Costs of FDA Regulation," National Bureau of Economic Research Working Paper no. 29574, 2021, pp. 28–30.

number of new drug approvals has fallen by approximately 61 percent from the average number before 1962.[61] So some of the slower growth in life expectancy may well be from FDA's slower approvals, but as we will show in subsequent chapters, there would still be additional slowing that arose from the impact of the rapid rise in NIH expenditures, coupled with a shift from mission focus to a pipeline model and distraction resulting from activities that contributed nothing to improved health—such as, for example, diversity, equity inclusion initiatives, as well as projects to control human behavior, promote gun control, and evaluate climate change.

While it may not be possible to demonstrate definitively that the shift from private to government funding of medical research caused most or all of the slowdown in the increase in life expectancy, we must ask why the massive shift to government funding of medical research at least did not prevent it.

[61] For a fuller discussion the adverse effects of the Kefauver amendments and FDA effectiveness regulations see Jeffrey A. Singer, *Your Body, Your Health Care* (Cato Institute, 2025), pp. 65–72; and Charles Hooper, *Should the FDA Reject Itself?* (Chicago Park Press, 2001), p. 250.

5 Biomedical Context for NIH

There is no single comprehensive and consistent set of data on spending for biomedical research and development (R&D) in the United States, but such data as do exist show that NIH spends about 20 percent of the national total. Another 7 percent is spent by other government agencies, with the National Science Foundation accounting for the largest share. That brings total government spending on biomedical R&D to 28 percent of the total. Only 64 percent of the total is spent by private industry. Colleges and universities spend about 5 percent of the total from their own funds and private charitable institutions spend the remaining 3 percent.[62]

5.1 Biomedical research process

R&D is not a homogeneous activity. Most analysis of R&D in medicine and health divides the research part into three stages with a typical taxonomy being: discovery research, translational research, and clinical research.[63]

Discovery research is sometimes referred to as basic research. It focuses on proving the root causes of diseases and conditions and on understanding the underlying biological, chemical, and environmental processes in their progression.

Translational research builds on the discovery results to identify potential pathways for treatment. Translational research may involve laboratory testing, building and testing mathematical models, or using animals to model biological processes. While clinical records and human samples such as blood or tissue may be used in earlier phases of research, human testing of new interventions does not occur until the clinical research phase.

Clinical research consists of three phases and is more precisely defined by FDA regulation. Phase I determines the safety of the proposed product or treatment and typically employs a very small sample of individuals, about 20-80 people, usually healthy, but not always. Phase II provides preliminary tests of efficacy and tests dosage levels using a small sample of 100-300 people. Phase III tests a much larger sample of 1,000 to 3,000 subjects, and sometimes more.[64] Both Phase II and Phase III split the sample into a "control" group that unknowingly receives a placebo and the "treatment" group that receives the drug or other treatment being tested. For new treatments that target conditions that already have an approved treatment, Phase III may also require an even larger sample to

[62] Calculated by authors from Research!America and TEConomy Partners, LLC, *U.S. Investments in Medical and Health Research and Development, 2016-2020* (Research!America and TEConomy Partners, LLC, January 2022).

[63] Milken Institute, *Getting Started: The Medical Research and Development Primer* (Milken Institute, 2017), pp. 2–10. Slightly different names are used by different authors for each stage, and the lines between stages are not always precise, but this taxonomy is widely used.

[64] Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* (Congressional Budget Office, April 2021), p. 14; Milken Institute, *Getting Started: The Medical Research and Development Primer* (Milken Institute, 2017), p. 7.

support a second treatment group receiving the previously approved treatment. Sometimes a Phase IV is required after the initial approval to look for more rare side effects or measure efficacy over longer time periods.[65]

Drugs designated as "orphans" treat rare diseases, those typically affecting fewer than 200,000 people each in the United States. They receive special financial incentives from the federal government such as R&D tax credits, waivers of FDA fees, and up to seven years of marketing exclusivity. In 2020, almost half of all new FDA drug approvals were for orphan drugs.[66] It is more difficult to find and recruit subjects for trials of orphan drugs, so the FDA often allows smaller samples in phases II and III, typically substantially less than half the standard size.[67]

5.2 How NIH distorts biomedical research

NIH claims to focus on discovery research and, to a lesser degree, translational research. More NIH funding for clinical research is mostly for Phase I and Phase II activities and disproportionately for rare diseases. As a result, NIH spends about 52 percent of all resources dedicated to discovery and translational research in the United States, which means it decides which diseases and hypotheses about their causes will be explored by more than half of all biomedical research in the United States. If spending by NSF and other government agencies is added, government, as a whole, controls 74 percent of discovery and translational research in biopharmaceuticals. Private industry spends only 24 percent of discovery and translation research. The remainder is spent by not-for-profit foundations and universities from their own funds.[68]

Because government controls the initiation of the flow through the research pipeline, it, in effect, determines the overall direction of the much larger total expenditure from private investment. The FDA has approved 18 patented drugs that were derived, at least in part, from basic research funded by grants from NIH in the year 2000. But private investors provided, on average, 66 times more money to complete the translational and clinical research required to bring them to market.[69]

This dominance by government crowds out private financing for basic research on diseases that could be researched and lines of inquiry that could be pursued in seeking their cures and treatments. It also crowds out

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[65] Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* (Congressional Budget Office, April 2021), p. 15; Milken Institute, *Getting Started: The Medical Research and Development Primer* (Milken Institute, 2017), p. 10.

[66] Kathleen L. Miller et al., "Drugs and Biologics Receiving FDA Orphan Drug Designation: An Analysis of the Most Frequently Designated Products and Their Repositioning Strategies," *Expert Opinion Orphan Drugs* 9, no. 11–12 (March 1, 2022): 265–72.

[67] Kavisha Jayasundara et al., "Estimating the Clinical Cost of Drug Development for Orphan Versus Non-Orphan Drugs," *Orphanet Journal of Rare Diseases* 14 (2019): 12, 4–6.

[68] Calculated by authors from Kavisha Jayasundara et al., "Estimating the Clinical Cost of Drug Development for Orphan Versus Non-Orphan Drugs," *Orphanet Journal of Rare Diseases* 14 (2019): 12, 4; and Research!America and TEConomy Partners, LLC, *U.S. Investments in Medical and Health Research and Development, 2016-2020* (Research!America and TEConomy Partners, LLC, January 2022).

[69] "Biden Ambushes Pharma Patents: New Guidance Will Let the Feds Steal IP if Drug Prices Are Too High," *Wall Street Journal*, December 10, 2023.

scientific talent that might be more fruitfully employed in addressing other health topics. As discussed above, government sponsorship of science is inherently more centralized, and questions proposed for investigation are more constrained by orthodoxy. By controlling the vast majority of discovery and translational research, government also has outsized influence on the treatments that enter the clinical phase where private spending predominates. Choices by government are heavily influenced by politicians seeking to gain and retain power.

Furthermore, because government dominates the discovery research and heavily directs translational research, these political choices will necessarily suppress or slow the development of alternative views. Analysis of government-funded scientific research in all scientific fields has shown that funding of research from government sources is highly concentrated, with the top 200 entities funded by NIH and NSF receiving 80 percent of the total funding. In privately funded research, the top 200 recipients accounted for only 33 percent of total funding.[70] This means that alternative hypotheses and avenues of investigation are less likely in government funding than in private funding. This artificial narrowing of the theories and methods considered automatically reduces, or at least slows, the likelihood of success.

But government impediments to breakthrough research go beyond the consequential effects of crowding out private research to actually threaten private research successes. In early December 2023, the Department of Health and Human Services announced its intent to exercise "march-in" rights to seize private patent rights to drugs that it considered to be too expensive. This claimed power is pure fiction and contrary to the clear language to the contrary in the Bayh-Dole Act. That act was passed in 1980 to address the problem of companies acquiring patents for pharmaceuticals and medical devices developed in part via government-funded research and then not pursuing development and marketing of products based on the research. The act permits the federal government to reassign patent right to other companies that demonstrate the willingness and ability to produce and market the results. The act's clear language is to ensure that the patent is used to manufacture and sell the results of the research. There is no explicit or implied power of government to set or evaluate the price.[71] Even if this and similar regulatory efforts are eventually thrown out in court, the very act of attempting to convert profitable businesses into losses because of their cooperation with government research is a disincentive and a barrier to progress.

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[70] Emily Sohn, "How Philanthropy Can Nurture Your Research," *Nature*, January 13, 2023.

[71] "Biden Ambushes Pharma Patents: New Guidance Will Let the Feds Steal IP if Drug Prices Are Too High," *Wall Street Journal*, December 10, 2023; 35 U.S.C. § 203 (2018). States "Sec. 203. - March-in rights [a] With respect to any subject invention . . . the Federal agency under whose funding agreement the subject invention was made shall have the right . . . to require the contractor . . . to grant . . . license in any field of use to a responsible applicant . . . if the Federal agency determines that such - (1) action is necessary because the contractor or assignee has not taken . . . effective steps to achieve practical application of the subject invention in such field of use; . . . (2) action is necessary to alleviate health or safety needs . . . (3) action is necessary to meet requirements for public use."

Another recent government initiative also holds a likely threat of impeding progress. The Office of Research Integrity (ORI) in the Department of Health and Human Services investigates alleged misconduct by researchers funded by health-related grants at colleges and universities. It issued new regulations in September 2024 that describe how it intends investigate misconduct more vigorously and how it expects the institutions that receive the grants to conduct their own investigations of misconduct.[72] Many institutions have objected strongly to the changes, which they believe are "an infringement on institutional autonomy."[73] The objections to the original proposed rule led to some modifications, but the final result is still more overweening bureaucracy. In fact, these rule changes clearly illustrate some of the dynamics that cause government funding of research to be ineffective and inefficient.

Universities and their employees are given government money to conduct projects. It is not their money, so the money source has every right to provide oversight. But the money does not belong to ORI, or any government official. It has been taken from the taxpayers who earned it.

ORI's expansion of its investigatory powers under the new rules will lead to more appropriations to fund more investigators and more higher-grade positions to supervise them and write more regulations that universities will need to comply with, leading to a never-ending-cycle of more investigators and more regulations. This is typical public choice behavior that expands government while reducing effectiveness.

More power in central authority to select, fund, and discipline research not only leads to a loss of freedom; it also slows scientific progress. One cannot argue with ORI that misconduct should be rooted out, but are the institutional beneficiaries of government grants or bureaucrats who set the rules, prosecute the infringements, and deliver the judgment the right parties to deal with it?

In a free market, research is funded directly by those who seek the benefits of the research, and meeting their expectations is the criterion for acceptable research. The funders can step in at any time and discipline any misconduct or even deviations from the funding's purpose. But even more fundamental is the fact that the sort of collegial participatory research generated within a mission model is the best guarantor against misconduct, as it incentivizes dynamic testing of competing hypotheses without artificial enforcement of conformity. This is the model that works in many places, and it used to be the model that ensured rapid progress in health research.

Occasionally there will be breakouts from the rigid government orthodoxy such as the departure of scientists at Celera to start private financing of the alternative approach to the human genome and the private departure

[72] Public Health Service Policies on Research Misconduct, 89 Fed. Reg. 76,280 (Sept. 17, 2024) (to be codified at 42 C.F.R. pt. 93).
[73] Melissa Korn and Nidhi Subbaraman, "The Feds Want More Oversight of Scientific Research. Universities Are Fighting Back," *Wall Street Journal*, March 28, 2024.

from orthodoxy to create mRNA foundations for vaccines. But these efforts required unusual strength and dedication to fight the official headwinds, and there are many more such innovations that never happened because the barriers were too great.[74]

[74] The much-heralded breakthroughs in mRNA vaccine development resulted in the 2023 Nobel Prize in Medicine for Katalin Karikó and Drew Weissman. But the story of their success is one of perseverance against the prevailing orthodoxy that threw up roadblocks to their efforts for years. Dominique Mosbergen et al., "Pair Met with Doubts, Now Win Nobel Prize," *Wall Street Journal*, October 3, 2023. "Notable & Quotable: Nobel Prize," *Wall Street Journal*, October 3, 2023. The double irony in this story is, of course, that once government players found it convenient, the breakthrough itself became a new orthodoxy.

6 The NIH Budget Process

With its stated purpose "to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability,"[75] one would expect that the NIH budget submission would start with the improvements it proposes to deliver in health, life expectancy, and disease prevalence. Then it could justify the requested expenditures in terms of their contributions toward achieving those improvements. But with extremely rare exceptions, which we discuss below, its justifications are in terms of the number of grants made, initiatives started, the immutable physical characteristics of the staff and grantees, and dozens of other secondary and tertiary matters—such as reducing adults' anxiety about visits to the dentist, promoting untested herbal treatments, and motivating teenagers to engage in different behavior—that have no demonstrated connection to improved health outcomes.

The budget request is not an integrated plan for improving health outcomes but a collection of 28 separate budgets and accompanying justifications for individual institutes, centers, and offices, plus an overall summary. While most of the budget items have some general relationship to diseases, conditions, or human biological systems, some—such as one conducting international relations and training foreign functionaries to analyze health data and another focused on "complementary" treatments like Swedish massage—do not.[76]

6.1 A substitute for real planning: The RCDC System

This approach is so divorced from the legislated purpose of NIH that Congress asked NIH to categorize how the money is being spent by disease or condition being investigated and treated. The result was an additional supplementary document that NIH describes as follows:

> At the request of Congress, the NIH embarked on a process to provide better consistency and transparency in the reporting of its funded research. . . . [T]he Research, Condition, and Disease Categorization (RCDC) system, uses sophisticated text data mining (categorizing and clustering using words and multiword phrases) in conjunction with NIH-wide definitions used to match projects to categories. RCDC use of data mining improves consistency and eliminates the wide variability in defining the research categories reported. The definitions are a list of

[75] National Institutes of Health, "Overview of 2024 President's Budget," in *The National Institutes of Health Congressional Justification Fiscal Year 2024* (National Institutes of Health), p. 2.

[76] Fogarty International Center, *Fogarty International Center, Congressional Justification for Fiscal Year 2024* (Fogarty International Center, 2023).

terms and concepts selected by NIH scientific experts to define a research category. The research category levels represent the NIH's best estimates based on the category definitions. These definitions include all aspects of the topic, such as basic, pre-clinical, clinical, biomedical, health services, behavioral, and social research.

. . .

The NIH does not expressly budget by category. The data reflect amounts that change because of science, actual research projects funded, and the NIH budget. The research categories are not mutually exclusive. Individual research projects can be included in multiple categories so amounts depicted within each column of this table do not add up to 100 percent of NIH-funded research.[77]

This description of how NIH classifies its spending is so far from reasonable expectations as to defy credibility. The laboratories that purport to be leading scientific institutions cannot tell us directly how much they spend on research to prevent or treat ischemic heart attacks. NIH pays for the research, yet it only reports estimates, not actual sums. A privately owned company that behaved in this way would soon be out of business.

Even worse, the NIH description above proclaims: "NIH does not expressly budget by category." If the goal is to improve health outcomes, then we absolutely must know which diseases and conditions are the most severe threats to health and allocate our resources accordingly. Below we look at some examples of where NIH seriously fails in this regard. Within each disease or condition, the organization asking for our money should be able to tell us which avenues of inquiry offer the most promise and how it will go about applying the funds toward that inquiry.

Along with the RCDC estimates on spending by disease or condition, NIH provides data from the Centers for Disease Control and Prevention (CDC) on the mortality (number of deaths per year) and prevalence (percent of population with the condition) for the diseases and conditions in its tabulations. But it says that these are not adequate for evaluating the spending because "NIH believes that the best way to understand disease burdens is by examining patterns in the larger context of multiple methods and measurements, chosen on a case-by-case basis as appropriate for each disease or condition."[78] The claim that the relative importance of each condition for research needs to be chosen individually on a "case-by-case basis" fails the test of good scientific method. It

[77] National Institutes of Health, *Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)* (National Institutes of Health, March 3, 2023).

[78] National Institutes of Health, *Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)* (National Institutes of Health, March 3, 2023).

is perfectly plausible that a multi-dimensional set of measures needs to be assembled and integrated, but if one is going to compare different conditions for funding, each condition must be evaluated on a consistent basis; otherwise, the choice is purely arbitrary, reflecting the preferences of persons making the comparison.

NIH could resolve this conundrum easily by specifying which metrics, either simple or complex, are used to prioritize budgeting. Or does NIH not really have any? NIH has spent $1.3 billion since 2008 on research to measure "burden of illness," and it asked for another $131 million in 2024. In addition, it has spent $2.6 billion on "cost-effectiveness" research and $4.0 billion on "data science". If it can't figure out how to measure priorities with all those resources and share it with the taxpayers, then it is time to get somebody else to do the math. Free markets have been making these kinds of decisions effectively for centuries, and life expectancy improved faster when they did.

The NIH, in its "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)" offers the following caveat about its data: "The research categories are not mutually exclusive. Individual research projects can be included in multiple categories so amounts depicted within each column of this table do not add up to 100 percent of NIH-funded research."[79] That confusion is not an inherent feature of the underlying data, but the result of poor specification of how to aggregate and display it. The result makes budget and policy analysis much more difficult and less rigorous. NIH is asking us to trust it because it is either unable or unwilling to show specific justifications.

The 315 categories of spending from NIH's data mining efforts are a confusing mishmash. Some are broad classes of disease like cancer or cardiovascular disease. Others are sub-categories within the larger groups—for example, lung cancer or pediatric cardiomyopathy. In Chapter 7 we look at a few examples of how inconsistent and incomplete those classifications are. At a minimum, NIH should be able to present all spending classified consistently and arranged according to major categories and subcategories rather than in just random lists. Table 7.2 in the next chapter provides that kind of analysis for a small subset of categories.

To illustrate the failure of the RCDC, consider how it handles cancers. The RCDC classification identifies 15 specific cancers, but more than half of the total cancer spending is not associated with any of those specific cancer categories. So, what is that additional money spent on? We were able to compute the residual by adding up all the cancer categories scattered across the list and subtracting them from the "total cancer" amount. It is extremely disconcerting that more than half the "cancer" spending has not been identified specifically by

[79] National Institutes of Health, "Funding for Various Research, Condition, and Disease Categories (RCDC): Acquired Cognitive Impairment," June 17, 2025.

the activity it supports. One might conjecture that some projects deal with general elements of carcinogenesis, but there is only one cancer category in the NIH RCDC classification not related to a specific type of cancer, namely "Cancer Genomics," which accounts for about 16 percent of cancer spending. Because of the multiple classifications for each project, most of the Cancer Genomic projects are classified in a specific single cancer or class of cancers and already counted in the specific-cancer categories. But even if none of the genomic projects were not already counted in the specific cancer types, that would still leave more than a third of cancer-related spending unaccounted for.

In addition to classifying research spending by the disease or condition being studied, some classes are partially identified by demographic features. For instance, childhood leukemia is one of the categories, but there is no total for all leukemia or for adult leukemia and neither mortality nor prevalence is available for the category. Elsewhere, NIH publishes mortality for leukemia overall as 23,710 deaths per year.[80] That is higher mortality than for many of the cancers published with the budget justification. So why is only childhood leukemia spending published in the RCDC tables, and no mortality published with the budget for all leukemia?

Sixteen categories in the RCDC list relate to young patients using a wide variety of terms – 6 use "child or childhood," 4 "pediatric", 2 "youth", 1 "infant", 2 "underage", and 1 "teenage". There is no systematic definition of any of these age terms, and the categories available provide no indication as to whether pediatric includes infants, children, youth, or teenagers. Is youth a broader or narrower classification than teenager? As in the case of childhood leukemia, there are no complementary categories for affected populations that are older or younger than one of these 16 categories.

This sloppy incompleteness extends to other demographic categories. "Women's health" and "Violence against women" are identified separately without a total or the men complement. Eight of the RCDC conditions are possible only for one sex or the other, so stratification by sex would not be necessary, but otherwise, if something is stratified by one sex, both science and budgeting require data for the other sex or at least for the total. Failure to tie together the spending, mortality, and prevalence across the entire demographic universe makes the data less useful. If some conditions are identified by age or sex, why not all for which it is biologically possible? The same principle also applies to classifications by race and ethnicity.

[80] National Cancer Institute, "Surveillance, Epidemiology, and End Results Program, Cancer Facts: Leukemia."

6.2 NIH does not provide a "public good"

In addition to satisfying general budget requirements for government spending, any proposals for government spending on medical research "to enhance health, lengthen life, and reduce illness and disability" must also address specific questions. The proposal MUST show evidence that the proposed research is a "public good," as described in Chapter 3. This requires that NIH show with empirical analysis that private investment or charitable funds are inherently unable to provide that research—not merely that they do not conduct it but that it is inherently impossible for them to do so. This requires showing that the specific research is both "nonexcludable" or "nonrivalrous."[81]

In later analysis of specific NIH categories, we will discuss these criteria with respect to several of the research categories. But we can illustrate them here with a single example, research on human fertility. In the United Kingdom, the great advance of in vitro fertilization emerged from the private sector after the Medical Research Council, the UK equivalent of NIH, refused to fund its research on grounds of ethics and morality.[82] Today, couples who are unable to conceive often willingly pay handsomely for treatments that will enable conception, and clinics that offer these services will conduct research or hire others to conduct the research necessary to improve success. Some clinics may learn from others' efforts and build on them to improve their market appeal to couples. These copiers are not free riders because, as we showed in Chapter 3, research is a "contribution good" and copiers can successfully build on the discoveries of others only by investing themselves in the relevant discipline and becoming active members of the research discipline or college—in this case, the college of fertility research. The research is excludable. Those who do not invest in research are excluded from production. And those who choose not to purchase the service do not get access to it.

The capacity both for delivery of fertility services and for fertility research are inherently rivalrous. The time and resources used on one patient will reduce those available for another. And resources dedicated to improving fertility will take resources from other medical improvements.[83]

In general, current NIH research is not a public good, but rather an agglomeration of public resources being spent for specific private benefits. Spending for NIH should be greatly reduced to support only specific missions that support necessarily governmental activities consistent with Article I, Section 8 of the US Constitution. NIH

[81] For a discussion of multiple examples in other policy areas that claim to meet these criteria but, in fact, do not, see David Boaz, *The Libertarian Mind, A Manifesto for Freedom* (Simon & Schuster, 2015), pp. 325–56.

[82] Martin Johnson et al., "Why the Medical Research Council refused Robert Edwards and Patrick Steptoe support for research on human conception in 1971," *Human Reproduction* 25, no. 9 (July 24, 2010): 2157–74.

[83] These general principles across all scientific inquiry are laid out in detail by Terence Kealey, *Sex, Science, and Profits. How People Evolved to Make Money* (Vintage Books, 2008), pp. 380–414.

must be required to demonstrate that each research effort meets the rigorous requirements of being nonexcludable, nonrivalrous, and authorized by the Constitution.

To the extent that NIH continues with its broad remit to enhance health, lengthen life, and reduce illness and disability for the entire American population, Congress should require NIH to consider the full range of possible applications of taxpayer funds within that universe and propose specific research spending that promises the greatest increases in longevity and greatest reductions in illness and disability. This determination extends first to selecting the diseases and conditions that currently create the most reduction in longevity and greatest increase in disability to function in daily life. Then, within research on a particular disease, specific investigations should be funded that, based on available evidence, offer the greatest likelihood of increasing longevity and reducing disability. Specific strategic goals must be set for improvements to be achieved in mortality and/or morbidity. The goals should be measurable and have specific end dates and intermediate dated targets. NIH's annual budget submissions should measure progress against the goals, provide analysis of any failures to progress toward achieving intermediate targets, and adjust strategies to fix failures as needed.

6.3 No measurement of outcomes

NIH has spent $3.9 billion since 2008 on research to measure disease burden and conduct benefit cost analysis and another $4.0 billion on data science. Yet it seems unable to apply these results to selecting, justifying, and tracking the research it funds. Since the 1970s, the health research community outside of NIH has been combining the measure of longer life—mortality— with the measure of disability—morbidity. The most commonly used metric is Quality-Adjusted Life Years, although others, such as Disability-Adjusted Life Years, Healthy-Year Equivalents, or Person Trade-Offs have also been tested both inside and outside of NIH. But NIH shows no evidence of using these or other metrics to target its research funding, it merely spends money for people to write about the metrics or apply them within individual projects.

For example, in the 28 separate budget requests submitted to Congress by NIH and its component institutes, centers, and offices, there is only one mention of any of the disease burden metrics. The Director's overview budget justification says, "Mental illnesses are the fifth leading cause of disability in the United States, accounting for 6.6 percent of all disability-adjusted life years in 2019."[84] That statement merely comments on how important mental health is. But nowhere else is there any indication of using these or similar metrics to allocate funding among the diseases and conditions that account for the other 93.4 percent of disability-adjusted life years.

[84] National Institutes of Health, *Congressional Justification: Overview of FY 2024 President's Budget* (National Institutes of Health, 2023), p. 6.

There are limitations to each of the available metrics, although one would expect that for $3.9 billion NIH should have either eliminated most of the limitations or reached the conclusion that it is an activity impossible to centralize and best left to the private sector—where spending choices are made by the people actually affected by those choices.[85] Instead, NIH merely claims it uses data, but that it is too complex to be explained. If NIH can't explain the data, how are we to know that it, in fact, uses reliable data and made the right choices based on that data?

NIH budget submissions are almost entirely bereft of metrics related to health outcomes, measurable goals, root cause analysis, benefit-cost analysis, progress against goals, or similar justifications for the amounts and uses of the requested spending. In Chapters 10 through 13 we analyze specific issues that indicate opportunities to lower spending; available data suggest they are excessive, and NIH justifications are inadequate to support them.

[85] Tom Miller, "More Volume than Value in Health Quality Measures," *Regulation* 46, no. 4 (Winter 2023-2024): 16–20, elaborates on this argument with respect to government funding of treatment, but the same logic applies to research. Sean Sullivan et al., "Alternatives to the QALY For Comparative Effectiveness Research," *Health Affairs Forefront*, April 21, 2023, argues for the usefulness of multiple measures applied in concert, but in the process highlight the inherent limitations.

7 Specific Strategic Issues in NIH Spending

The data and analysis provided by NIH in support of its budget request do not provide confidence that the proposed budget has been designed to fund activity that will substantially reduce mortality and morbidity.

7.1 Absence of quantitative understanding

Consider Table 7.1, which was extracted from the NIH supporting material for its budget. The top 10 most deadly diseases account for 54.4 percent of mortality in the United States, and account for only 46.9 percent of NIH funded research. That may not seem like that great a disparity, but digging deeper reveals starker disparities. The five diseases with the highest mortality account for 42.9 percent of deaths, yet they receive only 31.9 percent of NIH research funding. For the individual disease groups, the differences are even more pronounced. For the two most fatal classes of disease, the priority for funding to reduce their mortality is completely reversed. Cardiovascular diseases are the deadliest, accounting for 20.0 percent of U.S. mortality, yet they receive only 6.8 percent of funding. Cancers, on the other hand, cause only 8.8 percent of mortality, but NIH spends 20.8 percent of its research funds on cancer.

While there may be good reasons for some differential in the funding, this difference in spending relative to mortality for cancer versus cardiovascular disease is a factor of seven.[86] A difference that large seems hard to justify because far more lives would be likely be saved from efforts on cardiovascular disease. With a discrepancy that large, one would think that NIH would rush to explain it, but it does not.

Table 7.1: Top ten diseases by mortality, percentage of 2024 NIH budget request and 2019 US mortality

Disease	Percent of NIH 2024 budget request	Percent of 2019 US mortality
Top ten diseases by mortality	46.9	54.4
Top five diseases by mortality	31.9	42.9
Cardiovascular	6.8	20.0
Cancer	20.8	8.8
Hypertension	1.0	6.6
Chronic Obstructive Pulmonary Disease	0.4	4.0
Diabetes	3.1	3.6
Sixth through tenth diseases by mortality	15.0	11.5
Cerebrovascular	2.5	3.3
Sepsis	0.4	2.6
Liver Disease	2.3	2.0
Pneumonia & Influenza	1.4	1.9
Alzheimer's Disease	8.3	1.9

Source: Selected from "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)," March 3, 2023.

[86] [(cancer share of budget/cardiovascular share of budget)/(cancer share of mortality/cardiovascular share of mortality)] = [(20.8%/6.8%)/(8.8%/20.0%)] = [(3.057)/(0.439)] = 6.971.

7.2 Cancer

In the absence of a scientific explanation for the disparity in spending, there is an obvious reason from the history of NIH spending—politics. The second and third paragraphs of the first page of the Director's Overview for the National Cancer Institute Congressional Justification FY 2024 tells us exactly what happened the last budget cycle:

> In February 2022, President Biden unveiled a series of bold, compelling goals to end cancer as we know it: cut America's age-adjusted death rate due to cancer by 50 percent over 25 years, improve the experience of patients and their families living with and surviving cancer, and ending cancer as we know it today.
>
> Flanked by First Lady Jill Biden and Vice President Kamala Harris, and surrounded by patients, caregivers, advocates, cancer researchers, health care providers, and leaders in Congress and the Administration, the President outlined steps necessary to reach the ambitious, but achievable goals he set for the Cancer Moonshot[SM]. Since then, the President has kept a bright spotlight on initiatives to advance Cancer Moonshot goals.[87]

On the same page, NIH reports that "Since 1991, U.S. deaths from cancer have fallen by one-third." NIH's goal calls for an annual rate of improvement in the next 25 years that is twice as fast as the rate of improvement in the previous 31, and yet there is no hint of what will be done differently to accelerate that progress. Instead, NIH simply announces "30 new federal programs, policies, and resources." This is counting activity, not targeting results.

Where is a plan that will improve longevity and reduce disability? How does NIH measure the experience of living with and surviving cancer? How does it propose to measure steps to "end cancer as we know it"? How will we know we got there? And when will it happen—25 years from now, or some other time? What will be the research strategy? More of the same? The use of a service mark (SM) for Cancer Moonshot flashes a warning signal that this is mostly a marketing initiative.

The budget document lists only a few of NIH's touted 30 activities. Since the budget document is intended to sell the program, it should be safe to assume that the examples selected are at least representative of, if not the

[87] Monica Bertagnolli, M.D., "Director's Overview," in *National Cancer Institute: Congressional Justification FY2024* (National Institutes of Health, 2023), p. NCI-3.

most consequential among, the full 30. The few examples NIH chose to highlight are: (1) a trial to evaluate multi-cancer detection tests, (2) the Cancer Moonshot Scholars program to improve the diversity of the applicant pool for NCI grants, (3) the NCI Telehealth Research Centers of Excellence (TRACE) program to determine ways that telehealth can improve cancer-related care and outcomes, (4) a Department of Veterans Affairs clinical trial to improve diagnosis of liver cancer in veterans, and (5) accelerating cleanup at Superfund sites. Although some of these may contribute to some reduction in mortality from cancer, none are searches for fundamental medical breakthroughs that might double the rate of improvement as required to reach the goal. Numbers 1 and 4 are merely the next phases of existing projects; number 2 is useless for reducing cancer, as we will demonstrate in detail shortly; number 3 proposes to test a solution before identifying the root cause it is expected to eliminate; and number 5 has been around for decades, with no specifics on why it should contribute to an accelerated reduction in mortality.

The inherently political rather than scientific nature of this initiative is further accentuated by a White House press release on October 28, 2024, just 8 days before the Presidential election. It proclaimed, "Biden Cancer Moonshot Announces New Pilot to Mitigate Pediatric Cancer Drug Shortages."[88] It was followed by favorable pieces in the press.[89] But no data were offered as to the size of this shortage or its effects on health. Even an anecdotal story in the *Wall Street Journal* was only about parents worrying whether the drug would continue to be available for their child, who nevertheless received the proper drug at the right time and was progressing as expected.

A "White Paper" was referenced in the White House release for details about the steps taken to alleviate the putative shortages, but it was about drugs generally, not for the featured pediatric cancer drugs.[90] The paper provided some data on the number of shortages overall but only for the year 2011 – 13 years prior. It provided no counts of treatments that were delayed owing to shortages, not to mention any counts of adverse health effects. Because a "shortage" is merely a measure of when the supplies drop below some targeted level, not the actual absence of any supply, which would be a stock-out, the number of failures to meet scheduled treatments could be vanishingly small, even zero, and the White Paper had zero information on any outcomes.

The White Paper outlines efforts to mitigate drug shortages, beginning with appointing a "Supply Chain Resilience and Shortage Coordinator." Human history is replete with spectacular failures of such efforts at central planning, from the Soviet Union to Venezuela. A private company has a specialized staff to manage its

[88] "Biden Cancer Moonshot Announces New Pilot to Mitigate Pediatric Cancer Drug Shortages," *OSTP, News & Updates, Press Releases*, October 28, 2024.
[89] Brianna Abbott, "Biden's Cancer Moonshot's Last Acts: Easing Pediatric Drug Shortages," *Wall Street Journal*, October 29, 2024.
[90] U.S Department of Health and Human Services, *Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States* (U.S Department of Health and Human Services, n. d.).

supply chain, but no one outside of government has the hubris to try to manage all the supply chains in an entire major industry. Markets respond to shortages far faster when the information gathering and decision making is decentralized to the actual location of the transactions.

Centralization is a recipe for failure. In this instance, centralization is demanding more data from the manufacturers, distributors, and caregivers. This reporting burden increases costs and reduces the supply chain's flexibility as it becomes focused on responding to government demands rather than on meeting customer needs.

As part of this effort, HHS has developed "a manufacturing resilience assessment" and a Quality Management Maturity (QMM) assessment for drug manufacturing establishments. These assessment efforts are superfluous at best. There is already a vast literature on the subject, and dozens of renowned organizations provide training and consulting in the field. Every year since 1988 the Malcolm Baldridge National Quality Award has been bestowed by the National Institute of Standards and Technology[91] and the Baldridge Foundation[92] to organizations that have demonstrated outstanding success from quality management as demonstrated based on an extensive set of principles and standards that have been applied and validated regularly over the last 37 years. Recipients include 38 organizations that manufacture, build, and deliver healthcare.[93] Many of the existing principles are incorporated into the standards for the National Committee for Quality Assurance (NCQA) and most health care organizations must hold certification of conformance with those standards. They already have staff that are far more experienced in effective quality management methods, including Kanban methods, than the HHS bureaucrats writing their own assessment.[94]

Do government officials really think that they can react more quickly with a better understanding of the process than the people closest to the product in the producing companies, distribution networks, and their customers? That kind of assumption has produced baby formula shortages, gasoline shortages, and dozens of shortages in farm products at different times. Remember that this is the same cabinet department that failed to successfully launch the Affordable Care Act Marketplace website after having more than three and one-half years to develop it (as well as the experience of dozens of successfully launched private sector health insurance sites). That failure forced HHS to extend formally the enrollment period for four and one-half months with extensions up to six months in special cases.[95] Even in subsequent years, delays in the annual enrollment process were required owing to system failures.[96]

[91] National Institute of Standards and Technology, Baldrige Performance Excellence Program.
[92] Baldridge Foundation.
[93] Baldridge Foundation, "Baldridge Award Recipients."
[94] Wallace J. Hopp and Mark L. Spearman, *Factory Physics*, 3rd ed. (Waveland Press, 2011); *Value Stream Management Green Belt* (Juran Institute, 2013), pp. 146–151.
[95] "Health Insurance Marketplace," Wikimedia Foundation, last modified October 20, 2025, at 06:50 (UTC): Centers for Medicare & Medicaid Services, HealthCare.gov, "A Quick Guide to the Health Insurance Marketplace."
[96] Stephanie Armour, "Trump Administration Extends Deadline for Affordable Care Act Enrollment," *Wall Street Journal*,

One symptom of government ignorance about supply chains is a recent HHS administrative rule to pay hospitals for maintaining buffer stocks of critical medications. The rule fails to recognize the important factors of HHS' own making that have caused the shortages.

First, government reimbursement for Medicare and Medicaid are 44 percent below market prices, and often below operating costs.[97] Specifically, HHS seems to be unaware that it is paying to establish buffer stocks of drugs with one hand, while "negotiating" to lower drug prices that providers may charge (under the misleadingly named Inflation Reduction Act). Government regulation and interference like these make normal buffer stocks wasteful and sometimes even contrary to government regulation. By contrast, under market prices that encourage responses to customer demand, private parties maintain buffer stocks as a matter of course.

Second, HHS explicitly says it is working with the Federal Trade Commission to investigate concentration, contracting, and negotiations within the wholesale drug industry. That announced hostility to normal management practices that encourage and assure adequate stocks can only make the proposals counterproductive. The White House press release of October 28, 2024, says that all these initiatives were a "pilot"? Testing a radical change in a pilot may be a good idea, but the schedule for the pilot (which is buried in the HHS White Paper) says it will last for five years! Any CEO of a private company that could not fix this entire problem, not just run a pilot, in under two years would be seriously underperforming the competition and would soon be seeking other employment opportunities.

7.3 Elevating secondary characteristics of researchers above health results

The second item in the list of major initiatives provided by the Director's Overview for the National Cancer Institute Congressional Justification FY 2024 is to increase the diversity of the grant applicant pool. This objective is repeated throughout all NIH budget submissions without any evidence that it will increase longevity or reduce morbidity. For example, as we will describe in more detail, the National Heart, Lung, and Blood Institute (NHLBI), which has responsibility for cardiovascular disease, the number one killer of Americans, lists as its top six strategic priorities various initiatives dealing with the diversity of secondary physical characteristics

December 16, 2019.

[97] The overall average was calculated from service-specific percentages in Trudy Millard Krause et al., "Private Carriers' Physician Payment Rates Compared with Medicare and Medicaid," *Texas Medicine* 112, no. 6 (June 2016): 1. The Medicare–private fee differences vary widely by the particular service and also vary by geography and carrier. The differences have also grown over the last two decades. Compare S. Norton and S. Zuckerman, "Trends in Medicaid Physician Fees, 1993–1998," *Health Affairs* 19, no. 4 (2000): 222–32; M. E. Miller et al., "How Do Medicare Physician Fees Compare with Private Payers?" *Health Care Finance Review* 14, no. 3 (1993): 25–39; W. Fox and J. Pickering, "Hospital and Physician Cost Shift: Payment Level Comparison of Medicare, Medicaid and Commercial Payers," *Milliman Client Report* (December 2008); J. Clemens and J. Gottlieb, "Bargaining in the Shadow of a Giant: Medicare's Influence on Private Payment Systems," National Bureau of Economic Research Working Paper no. 19503, October 2013.

of researchers and patients. Particularly astounding in this list is the claim: "This fundamentally changes the meaning of a multidisciplinary research team; it now includes not only a diversity of scientific expertise and skills, but, equally as important, the viewpoints and inputs of people in and across diverse communities, whose differing life experiences add crucial insights into how to tackle complex health conditions."[98] The budget request offers no evidence as to just how the "life experiences" of "diverse communities" would help deliver superior research on cardiovascular disease. The history of great scientific debates have often been among folks with similar "life experiences" but creatively different ways of looking at the data and theory. The debates between the geocentric and heliocentric views of the solar system, the reconciliation of quantum mechanics with relativity, and the reality of string theory compared with quantum mechanics, were all among individuals of European extraction with radically different views, but hardly significantly different "life experiences" or genetics – Italians Galileo and the Roman Curia, German Albert Einstein and Dane Niels Bohr, Englishman Stephen Hawking and Polish-American Leonard Susskind.

The frequency of these budgetary requests based on the physical characteristics and genealogical origins of researchers is never justified with data, a serious omission for people claiming to be scientists and managing the largest pool of resources that we are asked to believe are being devoted to the scientific improvement of health. What is the basis for their belief that the amount of melanin in a body, the presence or absence of a Y chromosome, or the geographic origin of one's great-great grandparents has any effect whatsoever on one's skill in scientific research? We searched for an example of NIH-funded research that might address that question. We found one: "The Science and Value of Diversity: Closing the Gaps in Our Understanding of Inclusion and Diversity" by Talia H. Swartz and others published in *The Journal of Infectious Diseases* in 2019.[99] The publication confirms that "This work was supported by the National Institute of Allergy and Infectious Diseases (grant K08AI120806 to T. H. S)." When we accessed this project in the NIH database to gain more background, we discovered that this grant, a total of $877,755 over five years, was awarded to the lead author of "The Science and Value of Diversity" article for "Purinergic signaling in HIV-1 infection and inflammation."[100] The project authorization makes no mention of studying the effects of secondary genetic characteristics and geographic origins of researchers on their ability to do biomedical research. Of the published papers claimed by this grant,

[98] National Heart, Lung, And Blood Institute, *Congressional Justification, FY 2024* (National Institutes of Health, 2023), p. NHLBI-4.

[99] Talia H Swartz et al., "The Science and Value of Diversity: Closing the Gaps in Our Understanding of Inclusion and Diversity," *The Journal of Infectious Diseases* 220, suppl. 2 (2019): 33–41.

[100] "Purinergic Signaling in HIV-1 Infection and Inflammation," *NIH RePORTER*, Project Details, Project Number 5K08AI120806-05 (the last two digits are the sequential years of the grant).

almost one-quarter (23%) were on various similar "diversity" topics and totally unrelated to the subject for which the grant was paid out. This diversion of research funds from their authorized topics as reported to Congress and the public to hyper political advocacy may explain at least some of the slowing in the results of medical research results from NIH. The study's authors state, "Our goal should be to foster a culture of prioritizing and sustaining diversity at all levels of the biomedical workforce, including the trainee pipeline, trainees, faculty, institutional leadership, committees, national organizations, and government."[101]

The paper is organized into four major sections: (1) Why is Diversity Beneficial to Science? (2) What are the Barriers to Increasing Diversity? (3) How Can Our Field Foster a Culture of Diversity? (4) What Should Institutions Do to Foster Diversity and Inclusion? The first section is the most consequential because without evidence that more diversity and inclusion (as the authors and NIH define them) would improve the mortality and morbidity of Americans, the remainder of the paper, with its recommended actions, would be useless or even harmful. There is no original research in this paper; it simply summarizes other published papers. So, evaluation of the paper's claims can be evaluated solely based on the sources cited.

The paper's first source is *The Diversity Bonus: How Great Teams Pay Off in the Knowledge Economy*.[102] This book repeats and illustrates well-known best practices in team building from business and other environments. These best practices call for building teams from people with different thinking toolboxes of information, knowledge, heuristics, representations, and mental models. The book explicitly states that this is not a roadmap for social justice, but a way of successful working and is not the same as diversity of gender, race, sexual orientation, or other demographic features, although it speculates (but does not demonstrate) that there may be some relationship between the two meanings. There are no data even hinting at better scientific outcomes from research conducted by researchers with diverse demographics.

The second and third sources both show that when a multi-author academic paper has a more "diverse" sets of authors, it is more likely to be cited by other papers and more likely to be published in the more widely read journals.[103] This is not a measure of the effectiveness of the science generally, not to mention effectiveness in reducing mortality and morbidity. If anything, it could be considered a measure of "within-put"—that is, of researchers talking among themselves. Measuring and managing a "within-put" rather than the real

[101] Talia H Swartz et al., "The Science and Value of Diversity: Closing the Gaps in Our Understanding of Inclusion and Diversity," *The Journal of Infectious Diseases* 220, suppl. 2 (2019): 33–41.

[102] Scott E. Page et al., *The Diversity Bonus: How Great Teams Pay Off in the Knowledge Economy* (Princeton University Press, 2017).

[103] Richard B. Freeman and Wei Huang, "Collaboration: Strength in Diversity," *Nature* 513 (September 16, 2014): 305. Bedoor K. AlShebli, Talal Rahwan and Wei Lee Woon, "The Preeminence of Ethnic Diversity in Scientific Collaboration," *Nature Communications* 9 (2018): 5163.

"output" of research is a major mistake that has led to failures for all sorts of activities in healthcare, business, government, and civil society. These failures range from nosocomial infections to billing errors to automobile designs rejected by consumers, and they all occurred because the researchers and designers substituted their preferences for the real needs of the ultimate consumer.[104] This error is highlighted by the author's mislabeling this counting of paper citations as "scientific impact." How many lives were saved or how much suffering was averted would be real scientific impact.

Counts of journal citation and publication are not only irrelevant for measuring scientific impact. They are also inherently biased even as a measure of scientific readership. Many journals explicitly endorse the diversity agenda, and they are in a position, either explicitly or unconsciously, to promote that agenda in their selection of articles to publish. We know some journals behave that way from the perverse behavior of some that refused to publish research demonstrating that COVID likely originated in a biological laboratory run by China's Communist government or showing that school closures in the face of COVID were both unnecessary and harmful. Subsequent evidence showed many of these rejected papers were correct.[105] But whether the rejected papers were correct or not, the refusal to publish was an assault on the scientific process of considering competing theories and data.

Adverse selection of papers based on the diversity of the authors is harder to detect than obvious cases of refusing papers based on their topic because there is far more variation in author characteristics than the simple dichotomy of conformance to the official version of some COVID story. Nevertheless, if the authors of these papers choose to claim that greater diversity of authorship leads to more journal publication, then, at a minimum, they need to caution that the apparent correlation might arise from journals using diversity in their selection of papers for publication or, better yet, demonstrate that there is no such bias. They did neither.

The second and third sources make similar claims. Freeman-Huang confine their analysis to scientists with United States addresses and the AlShebli paper uses a larger global sample. Both seem to use the same data

[104] Building research and development on a quantitative measurement of the real customer needs was first identified by Joseph M. Juran. His updated principles were presented in J. M. Juran, *Juran on Quality by Design: The New Steps for Planning Quality into Goods and Services* (The Free Press, 1992). Shorter summaries with updates can be found in John F. Early and Joseph A. DeFeo, "Quality Planning and Design for New Goods and Services," in *Juran's Quality Handbook: The Complete Guide to Performance Excellence*, 7th ed., ed. Joseph A. DeFeo (McGraw Hill, 2017), pp. 101–54; Joseph A. DeFeo and John F. Early, "Continuous Innovation Using Design for Six Sigma," in *Juran's Quality Handbook: The Complete Guide to Performance Excellence*, 7th ed., ed. Joseph A. DeFeo, (McGraw Hill, 2017), pp. 477–508. The Food and Drug Administration (FDA) has mandated this approach for the development of pharmaceuticals and medical devices. For details on that implementation see Anurag S. Rathore, Rohin Mhatre, eds., *Quality by Design for Biopharmaceuticals: Principles and Case Studies*, (John Wiley & Sons, Inc, 2009).

[105] For example, Jonas Herby et al., "A Literature Review and Meta-Analysis of the Effects of Lockdowns, on COVID-19 Mortality," *Studies in Applied Economics*, no. 200, January 2022; Johan Norberg, "Sweden Avoided Covid Lockdowns, and Now Reaps the Benefits," *National Review*, August 30, 2023; Jeff M. Smith, "The Lie of the Century: The Origin of COVID-19," *Heritage Foundation Commentary: Public Health*, May 2, 2024.

source, namely the Microsoft Academic Graph dataset.[106] That source does not identify individual researchers' ethnicity, so the studies used software to assign ethnicity based on the researcher's surname. The Freeman-Huang paper mentions explicitly only English, Chinese, Russian, and Korean names, while indicating there were five other classifications. Their discussion gives no indication of how one would classify Galileo, Albert Einstein, or Niels Bohr under such a scheme. AlShebli's international sample may have had a wider set of languages, but the paper does not list any. What neither paper mentions is the African American ethnicity. By the surname standard, most African Americans would be classified as "English."

The analytical bias of surname proxies for ethnicity of African Americans was demonstrated when the Consumer Finance Protection Board (CFPB) attempted to punish auto-loan lenders for discriminating against African Americans with worse loan terms, even though the lenders had no information on ethnicity for the loan applicant. The CFPB assigned ethnicity to each loan based on a modified surname proxy method. When they checked the results, they discovered that 46 percent of African Americans were classified wrong.[107] Whether these two empirical studies cited by the NIH diversity paper exclude African Americans or whether they include them with nearly a 50 percent error rate is largely immaterial. In either scenario, they fail to produce reliable data for the largest and most discussed "underrepresented" ethnicity in the United States.

A similar data failure exists for America's other large ethnicity—Hispanics. Among recently married Hispanics, 27 percent married a spouse of a different ethnicity. Among those with a bachelor's degree or higher, the group relevant for research scientists, 46 percent have a spouse of different ethnicity. Even for older Hispanics married 44 years ago—who would be parents of young people entering the workforce in the last 20 years—26 percent were married to a person of a different ethnicity.[108] Especially, among couples married 44 years ago, most women would have changed their surname to their husbands', and children from those marriages would mostly carry their fathers' surnames. We cannot compute a precise proportion with mixed ethnicity from these data; nevertheless, we can reasonably expect that 20 percent or more of Hispanic surnames originate from an inter-ethnic marriage. How should these inter-ethnic folks be counted? Possibly they should be counted as "Americans"? More importantly, why should we be counting them at all? If large proportions of the most intimate relationship among humans are created without reference to one's ethnicity, why should

[106] The link provided to that data set URL leads to a general page including the notice: "Editor's note, May 4, 2021 – In a recent blog post (opens in new tab), it was announced the Microsoft Academic website and underlying APIs will be retired on Dec. 31, 2021."

[107] The *Wall Street Journal*, December 19, 2015, A14. The real scandal in this episode is that the CFPB covered up their audit result and attempted to levy fines on the lenders based on the false data. As recorded in their internal documents, "our internal methodological deliberations will not be discoverable."

[108] Gretchen Livingston and Anna Brown, "Intermarriage in the U.S. 50 Years After Loving v. Virginia," *Pew Research Center*, May 18, 2017.

government classify them by that rubric? In short, disparities by the two largest and most discussed ethnicities in the United States are either not measured at all by the studies cited in the NIH paper, or they are measured with extremely large error rates that make them unreliable.

Freeman-Huang do briefly caution about the limitations of using surname as a proxy for ethnicity, and, at least in the article cited by the NIH paper, they begin their data interpretation with, "To the extent that surnames can be a proxy for ethnicity."[109] However, as we have shown, this caution is too timid. Data limitations make the results highly suspect. This paper is also the only one that warns that the observed citation results can be the result of the "network" effect, a possibility that the NIH paper ignores. If the authors come from different demographic groups it is more likely that, on average, they will be part of different networks of other researchers, which will increase the likelihood that personal familiarity will increase the readership and citation just because there is more exposure, not because there is better science.

Yet another limitation on using these two studies in support of the NIH diversity agenda is that they measure "diversity" by the degree to which the set of authors for a single published article differ among themselves by ethnicity, gender, discipline, affiliation, or academic age. This is in diametric opposition to the concept used both in the NIH paper and the NIH budget documents, namely that "diversity" in researchers means adding more individuals from underrepresented diverse backgrounds to the pool of researchers. This distinction is especially important because the AlShebli paper provides some additional detail that the NIH summary completely ignores. AlShebli reports that while the ethnic differences among the set of authors on individual papers have not changed much in the last 40 years, the ethnic differences in the total pool of authors across all papers has grown substantially, completely destroying the NIH claim of a need to increase the pool diversity.

The NIH paper's fourth source is Jonathan Adams, who uses a different international data set of papers published by academics. He concludes that the number of papers with authors from multiple developed nations is generally growing faster than the number with authors from only a single developed nation. Among developing nations, however, the increase in the total number of papers generally comes primarily from authors who share work in a single developing nation. He also concludes that for developed nations, those papers with authors from multiple nations are more likely to be cited by other papers.[110] Of course, this result shares the same fundamental weakness as others that count the number of papers and the number of citations as indicators of effectiveness rather than the effect on mortality and morbidity. But the NIH paper's abuse of this source is far more serious,

[109] Richard B. Freeman and Wei Huang, "Collaboration: Strength in Diversity," *Nature* 513 (September 16, 2014): 305.
[110] Jonathan Adams, "Collaborations: The Fourth Age of Research," *Nature* 497 (2013): 557–60.

because it claims Adams shows: "Diverse groups published higher numbers of articles, and these receive more citations per article"[111] The NIH paper uses "diversity" to mean primarily differences in ethnicity or gender, and occasionally adds one or more other types of diversity including culture, religion, disability, socioeconomic, and others. It never uses it to mean the country where the author works. Its one-sentence summary of Adams misleads the reader to believe that his research shows the effect of some broad class of differences among people, at least including ethnicity and gender, when all Adams claims is the effect on publication from having people from different nations on the author line.

The fifth source cited by the NIH paper consists of anecdotal claims by an individual at the Okinawa Institute of Science and Technology Graduate University based on his hiring of 10 researchers globally.[112] The claim the NIH paper cites is "researchers from large world-class universities tend to have a more global perspective, while those from countries with less developed infrastructure tend to be more detail oriented. Working together, individuals with both perspectives can complement each other and inform new approaches."[113] These broad generalizations are not measured, just asserted. Moreover, this diversity is only about differences in where the individual researchers attended college, not to their ethnicity or gender or other sort of diversity. And there is no data, even for this small set, on whether the research results contributed to reducing mortality and morbidity.

The NIH paper's sixth source introduces a new element of diversity called "intersectionality," which it defines as "the interconnected nature of social categories, such as race, class, disability, and gender, as they apply to a given individual or group, regarded as creating overlapping and interdependent systems of discrimination or disadvantage."[114] This source merely discusses this concept, weaving an intricate web of terms and speculation focused on "surrounding inequities experienced by marginalized and underrepresented communities in the United States. . . This Commentary will describe strategies that can be used to integrate intersectional approaches into academic medicine to encompass multidimensionality."[115] There are no data in this piece to show any relationship between diversity broadly or intersectionality specifically in contributing to better scientific research or health outcomes.

These six sources are the only evidence cited by the NIH paper to support its claim that the quality of health and medical science research is improved by diversity, equity, or inclusiveness applied to the researchers

[111] Talia H Swartz et al., "The Science and Value of Diversity: Closing the Gaps in Our Understanding of Inclusion and Diversity," *The Journal of Infectious Diseases* 220, suppl. 2 (2019): 33.
[112] Kendall Powell, "These Labs Are Remarkably Diverse - Here's Why They're Winning at Science," *Nature* 558 (2018): 19–22.
[113] Talia H Swartz et al., "The Science and Value of Diversity: Closing the Gaps in Our Understanding of Inclusion and Diversity," *The Journal of Infectious Diseases* 220, suppl. 2 (2019): 34.
[114] Talia H Swartz et al., "The Science and Value of Diversity: Closing the Gaps in Our Understanding of Inclusion and Diversity," *The Journal of Infectious Diseases* 220, suppl. 2 (2019): 34.
[115] Kristen Eckstrand et al., "The Priority of Intersectionality in Academic Medicine," *Academic Medicine* 91 (2016): 904–7.

conducting the research. None of the studies demonstrated any improvement in mortality, morbidity, or any other outcome from applying diversity concepts or methods.

Near the end of its first section, the NIH diversity paper claims: "Diverse clinical and scientific teams may be better at addressing the disparities in health outcomes observed among patients of certain racial and ethnic groups."[116] The sources it cites in that paragraph say no such thing, either directly or by implication. That would be damaging enough to the argument, but the paper goes on to say, "They may be able to do so because they are interested in examining the role that nonscientific factors have in health and well being [sic], such as adverse social determinants of health." Once again, the sources offer no such evidence or even speculation. This is a dangerous statement, explicitly saying that "nonscientific factors" can be found by increasing diversity. Such an approach is problematic and can lead to all sorts of damage. Unless researchers can demonstrate scientifically with a high level of probability that a factor is a true cause of illness or death, then any resulting care will be ineffective or even dangerous.

After failing to prove any relationship between diversity and research outcomes, the paper continues with a section on remedies to solve the non-problem. First it urges research institutions to recruit preferentially from underrepresented diverse groups. Of course, that ignores the root cause of the underrepresentation: namely the failure of the government owned and run "public" schools that feed the universities to deliver qualified graduates.[117] The solution to these school failures has been shown to be requiring that government funding follow the children, letting their parents use the funding to select the charter, private, or other education option that best meets their child's needs and not default to government and union monopolies.[118]

Next, the paper urges widespread use of "The Implicit Association Test" (IAT) as "a good way to gauge individual biases because it measures the automaticity with which our brain makes associations." This recommendation is not only inconsistent with the evidence from the first part of the paper, it also fails to consider the significant literature that shows The Implicit Association Test is not science. The results from the IAT fail the most basic tests of validity for psychometrics, namely reliability and validity. Reliability requires that if an individual takes the test more than once, the results will be approximately consistent with each other. The IAT fails that test. Validity requires that

[116] Talia H. Swartz, "The Science and Value of Diversity: Closing the Gaps in Our Understanding of Inclusion and Diversity," *The Journal of Infectious Diseases* 220, suppl. 2 (August 20, 2019): S33–S41.

[117] Phil Gramm et al., *The Myth of American Inequality: How Government Biases Policy Debate*, (Rowman & Littlefield, 2022), pp. 153–56.

[118] Corey A. DeAngelis and Neal P. McCluskey, eds., *School Choice Myths: Setting the Record Straight on Education Reform* (Cato Institute, 2020); Thomas Sowell, "Charter Schools' Enemies Block Black Success," *Wall Street Journal*, June 19, 2020; Tim R. Sass et al., "Charter High Schools' Effects on Long-Term Attainment and Earnings," *Journal of Policy Analysis and Management* 35, no. 3 (Summer 2016): 683–706; "The 123s of School Choice," EdChoice, April 14, 2021; Michael Van Beek, "What Michigan's Charter Schools Can Teach the Country: The Secrets of Reform Success Include Liberal Chartering Rules and Freedom from Teacher Tenure," *Wall Street Journal*, May 18, 2013.

the metric measures what it claims to measure. Again, the IAT fails that test because one's score on the test does not correlate with the actual behavior of the individual.[119] The authors of the NIH diversity paper had available to them a study in the NIH National Library of Medicine that reports, "IATs were poor predictors of every criterion category other than brain activity, and the IATs performed no better than simple explicit measures."[120] The plural reference to "IATs" is indicative of a feature of the IAT approach, namely that the same basic structure is used to claim bias by race, ethnicity, gender, weight, and a long list of other secondary characteristics of people. None of these variants performed well. The only characteristic that performed acceptably was the generic metric of brain performance—which was the origin of the test in psychology but has been taken by ideologues and modified in a failed attempt to measure bias.

From this point to the end, the paper reads more like a flyer of grievances issued by a union before a strike, in this case a union representing holders of M.D.'s and Ph.D.'s in health and medical sciences – more specifically, those teaching or doing research in medical schools and graduate departments of universities. Because the empirical case for increased diversity, equity, and inclusion fails in the first section of the paper, these are all irrelevant. Nevertheless, NIH has continued to spend time and resources chasing these ephemera rather than on curing diseases, thereby slowing the improvement in our health.

7.4 The real consequences of anti-scientific thinking

A real-life story of a highly effective medical researcher highlights just how misguided the NIH policies on diversity, equity and inclusion are. Kevin Jon Williams, a physician conducting NIH-funded research related to the number one killer of Americans, cardiovascular disease, relates how this policy has placed him and his colleagues in a profound moral dilemma while threatening the effectiveness of the scientific method to improve health outcomes. He is proud of his African American heritage but has decided not to "check the box" of his "underrepresented" status in his grant application despite the NIH requirement "to recruit individuals from diverse backgrounds, including individuals from underrepresented groups for participation in the study team." His dilemma is that if he does not promote his ethnic origins, he reduces the chances of his research team receiving the grant, which he believes offers significant opportunity for reducing the risk of atherosclerosis at young ages. But if he does check the box, then his grant may be approved instead of it going to another applicant who offers even more opportunity for success. Plus checking the box can also place him in a difficult position when he works

[119] Heather MacDonald, "Are We All Unconscious Racists?" *City Journal*, Autumn 2017.
[120] Frederick L. Oswald et al., "Predicting Ethnic and Racial Discrimination: a Meta-Analysis of IAT Criterion Studies," *Journal of Personality and Social Psychology* 105, no. 2 (August 2013): 171–92.

with Asian American colleagues whom he says, "are at the bottom of the current racial caste system."[121] Congress should read this compelling report from the front lines of research and demand that NIH stop the immoral, and likely illegal, discrimination against researchers based on their physical or ethnic characteristics.

Complementing this deeply personal and scientifically compelling experience of a front-line researcher is the recent discovery and publication of extensive hiring discrimination in academic health research. Documents obtained under Freedom of Information Act filings by the National Association of Scholars show broad and deeply ingrained hiring discrimination by universities and medical schools against those not deemed URM (underrepresented minorities, sometimes underrepresented groups, or URG). This extensive and explicit discrimination occurs in the fulfillment of grants that schools receive from NIH through its one-quarter billion-dollar Faculty Institutional Recruitment for Sustainable Transformation (FIRST) program, which mandated diversity, equity, and inclusion (DEI) statements and criteria in hiring.[122]

While public statements from NIH claim that "Consistent with NIH practice and U.S. federal law, funded programs may not use the race, ethnicity, or sex . . . of a prospective candidate as an eligibility or selection criteria." Nevertheless, the school grant proposals that NIH funded frequently included explicit statements that funded hires would "focus on the cluster hiring of faculty from minoritized racial and ethnic groups, specifically Black, Latinx, American Indian, and Pacific Islander scientists." Notably, the term "cluster hiring" can conceal discriminatory intent against any one individual. This program's selection criteria for faculty usually include a requirement that the candidates write a DEI statement showing their commitment to the DEI ideological principles and documenting their efforts to implement them. These statements, in turn, could be used to justify selection of a candidate without making the selection explicitly about his or her URM status.[123]

The results showed that the discriminatory intent was achieved. For example, in one case, after a search committee determined that a South Asian man was not a URM, a search team member expressed excitement about interviewing the remaining two candidates because "their DEI statements are strong." In another case, a faculty member wrote in an email, "I don't want to hire white men for sure." But this explicit discrimination was not only in internal faculty communications, one medical school advertised jobs funded under this program saying, "Successful candidates will be early-stage investigators who are Black, Latinx, or from a disadvantaged background (as defined by NIH)."[124]

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[121] Kevin Jon Williams, "Why I'm Saying No to NIH's Racial Preferences," *Wall Street Journal*, March 28, 2024.
[122] John Sailer, "How DEI Becomes Discrimination," *Wall Street Journal*, July 6, 2024.
[123] John Sailer, "How DEI Becomes Discrimination," *Wall Street Journal*, July 6, 2024.
[124] John Sailer, "How DEI Becomes Discrimination," *Wall Street Journal*, July 6, 2024.

7.5 Strategic analysis is missing in action

True strategic planning and requests for investment spending would have identified where the improvements in reduced mortality or morbidity are planned, but there is no such discussion. In fact, the RCDC data on spending and mortality within the cancer category suggest that resources are not being deployed in a manner consistent with the strategic goal of reducing mortality. Table 7.2 shows that the largest source of mortality among cancers is lung cancer, which has almost three times the mortality of breast cancer yet gets one-third less spending on research. Now it is possible that this disproportionate allocation was selected because 80 percent or more of lung cancer is caused by smoking, which has declined sharply, causing a drop in the disease that is likely to continue into the near future without any additional research spending. But that is mere conjecture on our part because the budget documents do not even make that argument, much less show data to support it. Even if this difference were justified based on the expected continuing decline in smoking, NIH would still need to explain why it spends twice as much to research breast cancer as for colorectal cancer, which has the highest mortality of all cancers after lung cancer.

Table 7.2: NIH proposed 2022 expenditure on cancer research and associated 2019 mortality

NIH RCDCF funding categories	2022 expenditure ($ million)	2019 mortality
Cancer, total	$ 7,635	690,509
Breast Cancer	$ 738	52,938
Lung Cancer	$ 479	150,790
Brain Cancer	$ 401	17,862
Colo-Rectal Cancer	$ 346	61,368
Prostate Cancer	$ 278	44,395
Pancreatic Cancer	$ 265	48,250
Childhood Leukemia	$ 231	-
Ovarian Cancer	$ 178	14,620
Liver Cancer	$ 178	30,898
Cervical Cancer	$ 147	4,687
Esophageal Cancer	$ 54	1,181
Stomach Cancer	$ 44	12,030
Uterine Cancer	$ 37	13,036
Hodgkin's disease	$ 19	1,446
Vaginal Cancer	$ 3	-
Other Cancers or Cancer in General *	$ 4,237	237,008
* Computed from other lines		
How are these counted?		
Cancer Genomics	$ 1,232	n/a
Pediatric Cancer	$ 651	n/a
HPV and/or Cervical Cancer Vaccines	$ 61	n/a

Source: Selected from "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)," March 3, 2023.

But there is still a large gap in the disease-specific cancer data. Only 44.51 percent of cancer spending is assigned to specific-disease cancer research. Some of this remaining 55.49 percent may be on research on structures or processes common to several cancers. For example, research in the cancer genomics category may be relevant to multiple different cancers. Whether it duplicates spending in specific cancers is not documented. Childhood leukemia is listed as a category, but there is no category for either total leukemia cases or adult leukemia. The category "HPV and/or cervical cancer vaccines" may be included in the cancer total, but that is not clear. Even with these possible additions, more than 33 percent of NIH cancer spending is not identified with a specific research target. Furthermore, the budget documentation does not show progress to date and whether that is consistent with intermediate targets. With this lack of precision and clarity, how can Congress be confident that NIH knows how it will achieve a 50 percent reduction in cancer mortality?

One might expect that part of a strategic plan to reduce cancer deaths would include improving early detection, hence earlier treatment and increased chances of survival. Early onset cancer is not even mentioned in the NIH budget documents. But the business press has highlighted several companies that have developed such tests, including Grail's Galleri liquid biopsy test. There is active debate in the medical community about the value of these tests in their current state in view of their high cost of nearly $1,000 and significant, though small, false positives,[125] but published peer-reviewed research is encouraging about their potential.[126] So what is the NIH response? "Let's wait and see," says Lori Minasian, a deputy director at the National Cancer Institute (NCI). It is true that more experience will make the value clearer, and probably drive the price down. But instead of leading the charge to develop these tests, NIH has decided to play referee. That might be a reasonable choice, given that the private sector seemed to be making good progress, but at the same time NIH announced that it would wait another year and then duplicate the tests that were already being studied intensively in the private sector.[127]

Nowhere in the executive overview budget submissions from either the NIH Director or the Director of the National Cancer Institute is there even a single word about the 12.8 percent increase in early-onset cancer since 2000.[128] Colorectal cancer has shown the greatest resurgence among young people under age 55, with about 20 percent of all new cases discovered in patients under age 55, more than double the rate in 1995. While death rates

[125] Alex Janin, "New Test Says It Can Find Cancer, for $949," *Wall Street Journal*, October 26, 2023.

[126] Brian D. Nicholson et al., "Multi-Cancer Early Detection Test in Symptomatic Patients Referred for Cancer Investigation in England and Wales (SYMPLIFY): a Large-Scale, Observational Cohort Study," *The Lancet Oncology* 24, no. 7 (July 2023).

[127] Alex Janin, "New Test Says It Can Find Cancer, for $949," *Wall Street Journal*, October 26, 2023.

[128] National Institute of Health, *Overview of FY2024 President's Budget* (National Institutes of Health, 2023). National Cancer Institute, "Director's Overview," in *National Cancer Institute Congressional Justification Fiscal Year 2024* (National Institutes of Health, 2023). Brianna Abbott, "Cancer Is Striking More Young People, and Doctors Are Alarmed and Baffled," *Wall Street Journal*, January 11, 2024.

from colorectal cancer have steadily declined for patients over age 65, they have risen for those under 50.[129] So, the business press reports this trend which has been evident for more than a decade from the government's own data and experience at leading medical centers such as Memorial Sloan Kettering Cancer Center, but the NIH budget request for more than $50 billion ignores it.

Despite these many shortcomings, the National Cancer Institute is the only one of two NIH units that has even one measurable strategic goal for improving health. All major components of NIH should have similar goals, along with intermediate targets and reported progress against those targets. (The other strategic health goal, for HIV/AIDS, is discussed below.) The National Cancer Institute also has more meaningful details on how the money is spent than do many other NIH units, a level of detail that others would benefit from. Most units, including the National Cancer Institute, fail to demonstrate how progress can be made by identifying the most significant components of their relevant diseases and planning research that looks for its root causes. The National Eye Institute, National Institute of Mental Health, and National Institute on Aging do not include quantitative goals for health improvement, but their director overviews do demonstrate better-than-average analysis of what is needed to deliver better health care in each of their respective research areas.

7.6 Cardiovascular Disease

The National Heart, Lung, and Blood Institute (NHLBI) includes the highest mortality disease group, cardiovascular disease, in its portfolio. (See Table 7.1.) In the first paragraph of the NHLB 2024 budget submission, the institute's director acknowledges that the diseases covered by NHLBI are the "leading causes of death and disability in the United States." So, one would expect that the remaining 13 paragraphs (excluding the non-substantive final summary paragraph) in the "Director's Overview" for Congress should emphasize the strategy for reducing the mortality and morbidity of these most virulent diseases affecting Americans. But the descriptive paragraphs are completely discursive.[130]

7.7 Discursive rambling replaces strategy

Following are key extracts from each of the 13 paragraphs that describe the NHLBI strategy. Can you find an empirically based, clear strategy for reducing mortality and morbidity here?

[129] Brianna Abbott, "Cancer Is Striking More Young People, and Doctors Are Alarmed and Baffled," *Wall Street Journal*, January 11, 2024.

[130] National Heart, Lung, And Blood Institute, *Congressional Justification, FY 2024* (National Health Institutes, 2023), pp. NHLBI-3-NHLBI-6.

- Paragraph 1: "many of the diseases in NHLBI's portfolio have an inequitable effect upon people . . . [a list of "underserved" populations]."
- Paragraph 2: "a robust, comprehensive research platform that can be used by other researchers to address misinformation, foster trust in science and research, and ensure inclusive participation in NIH research."
- Paragraph 3: "Social determinants of health play a significant role in the effect of climate change, as low-income communities and communities of color will be disproportionately affected. NHLBI understands the important role it has to play in this massive challenge, and recognizes the value of leveraging community-engaged research platforms that evolved during the pandemic for other public issues. For this reason, NHLBI has provided significant funding to NIH's Alliance for Community Engagement-Climate and Health (ACE-CH) initiative."
- Paragraph 4: "Supporting Diversity, Equity, Inclusion, and Access Across the Research Enterprise . . . from the formulation of the research questions, through the planning, design, and implementation of research protocols, and to the interpretation and dissemination of findings."
- Paragraph 5: "This fundamentally changes the meaning of a multidisciplinary research team; it now includes not only a diversity of scientific expertise and skills, but, equally as important, the viewpoints and inputs of people in and across diverse communities, whose differing life experiences add crucial insights into how to tackle complex health conditions."
- Paragraph 6: "the NIH Researching COVID to Enhance Recovery (RECOVER) initiative has depended upon the input and support of those most affected by Long COVID: the people living with the condition."
- Paragraph 7: "The Mentored Career Development Award to Promote Faculty Diversity in Biomedical Research provides funding for mentoring opportunities to highly trained investigators from groups underrepresented in research areas of interest to NHLBI.
- Paragraph 8: "For example, more than 6.2 million adults in the United States have heart failure. Roughly half of them have heart failure with preserved ejection fraction (HFpEF). HFpEF is the result of the interplay of impairments in cardiac, pulmonary, renal, musculoskeletal, and vascular function."
- Paragraph 9: "HFpEF required a strategic, multidisciplinary approach to accelerate the development of treatments . . . It has established collaborative networks of researchers and given them a collection

and analysis hub that provides access to advanced data science tools and strategies that will help identify biological targets that could be used to develop therapeutic drugs or other interventions.

- Paragraph 10: "This new program, known as AMP Heart Failure, is forming working groups to systematically analyze data from HeartShare, Trans-Omics for Precision Medicine (TOPMed), and other NHLBI resources to turn discovery of novel therapeutic targets into safe and effective treatments.
- Paragraph 11: "Recent research shows that approximately half of all American women have at least one risk factor for heart disease before pregnancy. Members of certain racial and ethnic groups have disproportionately high rates of these risk factors. NHLBI's Chronic Hypertension and Pregnancy (CHAP) trial seeks to prevent adverse pregnancy. Recent results from this study have shown that treatment for mild chronic hypertension leads to better pregnancy outcomes and has no negative effect on fetal growth, a concern that had previously constrained interventions."
- Paragraph 12: "research to improve the lives of people with sickle cell disease (SCD), an inherited blood disorder that often leads to chronic pain, organ failure, and premature death. SCD affects 100,000 people in the United States and millions worldwide."
- Paragraph 13: "This year, the NHLBI-funded LungMAP Consortium, a group of researchers and experts in the pulmonary biology community, synthesized current data into a comprehensive and practical cellular census of the lung."

Of the 13 paragraphs, six of the top 7 are merely *au courant* political talking points that have nothing to do with lowering mortality and morbidity of the top health threat in the United States, cardiovascular disease (five concerned equity and diversity of the researchers and one talked about climate change). Only three paragraphs covered efforts on diseases with significant contribution to the overall disease burden. Two documented basic research initiatives that could plausibly be tied to the large disease threats, although no connections are described. Another two paragraphs address diseases with lesser impact, sickle cell disease and long COVID, each of which constitutes only 0.01 percent of all mortality. That does not mean that no research should be funded for those two conditions (although no evidence is provided that it should), but it does mean that leadership is distracted with political and second-order problems and is not focused on strategically important improvements in health.

This discussion does not demonstrate a case for increasing NIH spending on cardiovascular disease. But the disparate lower spending on major cardiovascular diseases is a clear indication that spending on other areas is

much too high. The budget narrative also indicates that the energy and direction of the agency is not focused on its prime purpose of reducing mortality and morbidity.

7.8 HIV/AIDS

The only other measurable strategic goal for a health outcome in the NIH budget submission besides the National Cancer Institute's 50 percent reduction in mortality from cancer is the project "Ending HIV Epidemic," which has a goal of reducing new HIV infection by 75 percent by 2025 and by 95 percent by 2030. The base year for the reduction is not specified in the budget documents.[131]

Like cancer, HIV/AIDS is another health condition for which the level of government spending is out of proportion to its mortality. NIH spends 7.3 percent of its budget on HIV/AIDS, even though it constitutes 0.1 percent of mortality among the US population.[132] In the words of the director of the NIH Office of Aids Research, research and development, 40 years of research and treatment have "turned HIV into a manageable chronic condition such that a person with HIV has a near-normal life expectancy."[133] There are dozens of commercially available medications for antiretroviral HIV therapy that reduce the viral load below detectable levels, which are also below the levels that will infect others. Both pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) medications are available in multiple brands for uninfected individuals who may become exposed. Some of these medications are widely promoted through multiple marketing channels. While HIV/AIDS continues to be a serious disease and individuals with the infection still must adjust their lives to continuing treatment, NIH's own assessment is that tremendous progress has been made. It is no longer the mysterious and threatening disease it was 40 years ago, and other diseases pose far greater health burdens on the population. This is another clear example where more moderate government spending would likely generate private investment and solutions. If there are good reasons for disproportionate government effort in the area, then NIH should make the data and analysis publicly available.

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[131] The NIH Director's "Overview of the FY2024 Presidents Budget" states this goal in slightly different form, saying that 2030 will be the end of the HIV epidemic. Maybe a 95 percent reduction is seen as the end of the epidemic, but the budget submittal does not indicate the equivalence and the apparent conflict between the two documents is not explained. National Institutes of Health, *NIH Congressional Justification Fiscal Year 2024*, NIH Director's "Overview of the FY 2024 President's Budget" (National Institutes of Health, 2023).

[132] National Institutes of Health, "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)," March 3, 2023. A footnote to the AIDS estimates says, "HIV/AIDS is unlike any other RCDC category. The funding for HIV/AIDS includes the entire HIV/AIDS budget which encompasses scientific and administrative overhead as well as intramural and extramural construction funding. As a result, the reported total for AIDS related research is not comparable to annual levels that would be produced using standard RCDC process that would exclude administrative or other general scientific support costs. More information on HIV/AIDS and HIV/AIDS-related research is available at https://www.oar.nih.gov/hiv-policy-and-research." While this may overstate HIV/AIDS spending by 10 percent or so, that does not affect the disproportionality materially.

[133] Maureen M. Goodenow, Ph. D., *Office of AIDS research, Congressional Justification FY 2024* (National Institutes of Health, 2023), p. OAR-3.

7.9 What Does NIH Prioritize?

The NIH budget justifications are filled with counts of projects, counts of researchers supported, meetings held, plans written, activities that have little or nothing to do with health, and working relationships formed among government agencies and foreign governments. There is very little about results that have or will prevent deaths or diseases, cure conditions, or ameliorate those that are not yet curable. These omissions are especially glaring for such conditions as the rapid increase in early onset cancers, in particular colorectal cancer discussed above.

The very first paragraph of the budget submission should grab our attention with either amazing breakthroughs in health or a plan to achieve those breakthroughs, but the NIH acting director chose to emphasize only two inconsequential maters – (1) the formation of "the new Advanced Research Projects Agency for Health (ARPA-H), [which] furthers NIH's critical mission to seek fundamental knowledge" and (2) "efforts to cultivate the diverse and inclusive workforce."[134] As already discussed, the ARPA-H initiative was launched blindly without any apparent awareness of the failure of its namesake when it departed from the mission approach to research. And the diversity comment is worthless, offering, as we describe above, no promise of better health.

Moving on to the second paragraph of the leader's request for spending money, he tries to claim the lion's share of credit for the mRNA COVID-19 vaccines. But the technology that enables these vaccines was developed despite NIH, not because of it. The successful development of the technology was begun by Katalin Karikó, who, focused her research after earning her doctorate. on uses of mRNA in medical treatments. She submitted more than 20 grant applications to NIH and other organizations, but they were all turned down. She moved to three different universities, but without grants, they would not support her work. Finally, the third university retained her, but demoted her to a non-faculty position. By accident at the copying machine one day she met the immunologist Drew Weissman, who was intrigued by her work, and they began collaborating. Because he already had grants for different work, he was able to support their exploration of mRNA-based vaccines.

While many projects had conducted research on using mRNA in treatments of various kinds, they all ultimately failed because the mRNA molecule created an immune response that either destroyed the therapy before it could enter the cells or generated serious negative side effects. Karikó and Weissman discovered that the immune reaction was caused by the uridine nucleoside in mRNA. They then developed a technique for replacing the uridine nucleoside with pseudouridine, a naturally occurring component within mRNA

[134] National Institutes of Health, "Overview of 2024 President's Budget," in *The National Institutes of Health Congressional Justification Fiscal Year 2024* (National Institutes of Health), p. 1.

that caused no adverse immune system reaction while preserving the functionality of mRNA. They are the inventors on the patent for this method and result.

Even then, they had to submit their results to several journals before one accepted it, and more applications to NIH for continuing the research were summarily dismissed. Karikó left academia and became CEO of a small startup company to continue her work and then moved to senior vice president at BioNTech, which subsequently joined Pfizer in a technical and financial partnership, just in time for the partnership to be the first to develop a COVID-19 vaccine. Karikó and Weissman, of course, won the 2023 Nobel Prize in Physiology or Medicine, with virtually no support from NIH.[135]

The NIH leadership's claim also ignores the fact that Pfizer, the first company to produce the vaccine, was the one company that refused to participate in the government's Operation Warp Speed and committed to spending at least $1.5 billion of its own money for research and development of the vaccine. It ultimately spent more than $2 billion.[136] Pfizer's partner, BioNTech, did receive €375 million ($451 million) from the German government, but that was for implementation and delivery capabilities after the vaccine has already been developed and was in the late stages of testing. As BioNTech explained, the funds were "to advance the clinical evaluation and potential marketing authorsation as soon as possible. Pfizer will continue to independently fund its share of development costs."[137] Pfizer's chief executive explained his choice for self-financing as his wanting to "liberate our scientists from any bureaucracy" and that by spending their own money they created incentives to succeed. Six other large biotech companies participated in the government program and received large grants to support their research, but in the end, they were also-rans.[138]

The third paragraph extols the virtues of the NIH staff – yes, "staff" is the word he uses – the paid bureaucrats, not the researchers outside of NIH that competed for grants, but the permanent staff in Civil Service positions from which they cannot be removed except for the most egregious offenses, requiring an interminable sequence of bureaucratic procedures. As usual, no metrics are supplied as to exactly how effective they have been. The second half of the paragraph would appear to provide a metric: "With that said, it remains tremendously important to continue to build our workforce, a process which will include supporting early-stage investigators (ESIs). Currently, NIH has reached an all-time record for number of ESI." The first four sentences of this paragraph talk exclusively about

[135] Chiara Franzoni et al., "Funding Risky Research," *Entrepreneurship and Innovation Policy and the Economy* 1 (2022): 105-108.
[136] Albert Bourla, interview by *Face the Nation*, CBS News, September 13,2020, transcript; Pfizer, "2021 Annual Review: Expanding COVID Manufacturing Efforts."
[137] "BioNTech to Receive up to €375M in Funding from German Federal Ministry of Education and Research to Support COVID-19 Vaccine Program BNT162," BioNTech, September 2020.
[138] Terence Kealey and Caleb Brown, "Pfizer, Operation Warp Speed, and the Race for a Vaccine," *Cato Daily Podcast*, November 12, 2020.

the employees at NIH, but ESIs also include outside researchers with less than 10 years of experience following completion of their doctorate degree. There is no clear connection between the two halves of the paragraph.

Even as a metric related to ESI, the budget request tells us very little about building research capability. Just how is this measure important? ESI participants may have as much as ten years of experience after completing their PhD, so this is a very imprecise indicator for the rate of growth for new researchers. Furthermore, what is the goal for the number of ESI? How was that goal determined? Did the "all-time record" meet the goal, or was it a "record" that nevertheless fell short of the goal, or maybe it exceeded the optimal need? A little exploration of the NIH website, however, shows just how inconsequential the all-time record claim is. This 2024 budget request was written in early 2023 for funding to begin in October 2023. The number of ESI individuals had increased by less than one-half of one percent in 2022 but then declined by four times that amount in 2023.[139] And, of course, NIH fails to tell us what is really important – just which diseases were conquered or alleviated as a result?

The fourth paragraph speaks for itself: "Meanwhile, NIH has pivoted in real-time through the creation of several programs and initiatives and is working to lay the groundwork for a robust and diverse biomedical research enterprise for years to come." This is a wonder of high-sounding words strung together without meaning or data in what might be called "ideological hogwash."[140]

As if the focus on a "diverse and inclusive workforce" in the fourth paragraph weren't enough off topic, the director spends the entirety of paragraph five embroidering on that theme and concluding, "I am deeply appreciative of the continuing efforts at NIH and across the broader biomedical community to further enable diversity, equity, inclusion, and accessibility within the biomedical research workforce," without a word on any evidence that this will hasten the reduction of mortality or morbidity.

The leadership introduction to the Congressional budget request continues in much the same vein for 245 pages, but one section title caught our attention, "Scientific breakthroughs ushered by NIH."[141] Surely here were some major medical breakthroughs to justify the expenditures. The NIH leadership chose to highlight four items in this section.

1. An early clinical trial showed a single injection of a monoclonal antibody was highly effective in protecting adults exposed to malaria.
2. Creation of 3-D tissue chips that modeled two serious rare neuromuscular diseases (demyelinating

[139] "NIH Data Book," Report 304, 2024.
[140] John Gridley III, Washington High School, Sioux Falls, South Dakota, February 1960. In that small city in the American agricultural belt, hogwash was a well-known, repulsive slurry.
[141] National Institutes of Health. *Overview of FY 2024 President's Budget*, 64-65.

polyneuropathy and multifocal motor neuropathy) and enabled authorization of clinical trials.

3. A new definition of recovery from alcohol use disorder (AUD).
4. A catalog of more species of microorganisms residing on human skin than ever before.

Now one can always quibble over a few examples, but these presumably are cases that NIH leadership believes are indicative of why their work is important and deserving of $51 billion in taxpayer dollars. The first one is certainly important in a global context, but malaria is not a major threat in the United States, and if Americans are being taxed billions of dollars for the enterprise, that expenditure should be justified for them. Furthermore, private organizations such as the Gates Foundation fund malaria work.

The second highlighted item is scientifically interesting, but these are two very small diseases, clearly important to those who suffer from them, but why pick them as examples rather than the diseases from which millions die or suffer – maybe there is no meaningful activity addressing the diseases most threatening to the population?

The third item is one that only an isolated bureaucrat with no sense of proportion would think was important. Who cares about the definition? What progress is being made in saving lives or reducing morbidity from alcohol use disorder?

Finally, the catalog of skin microorganisms is at least potentially a scientific building block, but how about waiting until they actually identify an organism that is a cause for a significant disease, not just an added item on a list? Not one thing in these four examples should move us to want more. The real threat is that this is not just a failure of marketing, but that there is nothing more consequential to report.

This chapter has highlighted some of the failures of strategy at NIH. Strategic planning and execution. These capabilities are well-established disciplines among successful private and government managers, but NIH has shown virtually no capability in them. It starts with a reasonable vision to enhance health, lengthen life, and reduce illness for Americans. The next step would be to set specific quantitative goals for results that would realize that vision. It has failed to do that except for two disease categories – cancer and AIDS, which together account for only 8.9 percent of all mortality in the United States. There are no strategic goals related to more than 90 percent of the deaths that Americans will experience.

Even the two existing strategic goals are poorly conceived and incoherently articulated. The cancer goal implicitly requires a doubling of the rate of improvement over the next ten years, but the plan offers only more of the same approach and no analysis to show that we should expect a doubling in the rate of improvement. The

AIDS goal is imprecise, articulated as a percentage of reduction without specifying what the base year is from which the reduction is computed. Both fail to report tracking of intermediate progress against those goals.

The budget is focused on building a bureaucracy and not on eliminating disease. As shown above, the spending by disease is highly disproportionate to the disease incidence and mortality. While there could be good reasons for some of these differences, NIH offers none and makes no effort to report progress in reducing disease. The budgetary and planning documents are focused on spending that is if no or only minor importance for reducing mortality and morbidity – diversity, equity, inclusion, recruiting more bureaucrats, and building an overhead infrastructure. Subsequent chapters will document the consequences of these failures at the tactical research level.

8 Overreach

The "Overview of FY 2024 President's Budget" for NIH describes some important neuroscience research but wraps up the discussion with a sentence that emphasizes: "The BRAIN Initiative® will also continue to work to shift the research culture within neuroscience through its emphasis on neuroethics, diversity and inclusion in the research community, and data sharing practices to enable and enhance the scientific and technological advances from this initiative."[142] Almost identical wording appears in the National Institute of Neurological Disorders and Stroke Congressional Justification FY 2024.[143]

8.1 Government excess and threats

This statement raises several important concerns. First, it uses the ® symbol with "BRAIN Initiative." This implies the name is a registered trademark that cannot be used by others. In free markets, innovators may well create new trademarks for their products and register them to protect their work from unauthorized use. This step by a government agency is indicative of the kind of crowding out that government can exert directly over private efforts. The work flagged with this symbol was funded by taxpayers and therefore all taxpayers "own" it. When government tries to assert its ownership and exclusion of taxpaying individuals or companies, it is moving beyond mere crowding out when it uses both its overwhelming size and its monopoly on coercive power to assert exclusive registered trademarks over the work. This type of interference undermines companies' freedom to develop intellectual property rights and slows scientific progress.

This aggressive assertion of government dominance shows up in the same Institute with the National Institute for Neurological Diseases and Stroke's Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs, which support research by small businesses on therapies, diagnostics, and research tools relevant to the NINDS mission.[144] These programs—which have been dubbed "America's Seed Fund"—limit research to a politically selected pool of firms and promote favored research at those firms.

The list of priorities for the BRAIN Initiative begins with "neuroethics." While one would expect government-funded research to observe medical ethical norms, it should be concerning that NIH has a Department of Bioethics and a Neuroethics Working Group, composed of NIH staff and academics selected by NIH, that "provide ethics

[142] National Institutes of Health. *Overview of FY 2024 President's Budget*, 12.
[143] National Institute of Neurological Disorders and Stroke. *NINDS FY 2024 Congressional Justification Chapter 508C*, 17.
[144] National Institute of Neurological Disorders and Stroke. *NINDS FY 2024 Congressional Justification Chapter 508C*, 19.

consultation to researchers," "identify neuroethics research questions" for NIH funding, and "publish guidance on key ethical challenges."[145] When government is issuing ethical guidelines rather than focusing on observing medical community standards, we should worry.

The history of government telling people what is right and what is wrong has a troubled history when it goes beyond the basics of public order and protecting individuals from infringement on their rights. NIH is authorized to conduct and fund medical research to enhance health, lengthen life, and reduce illness and disability, not decide what is right and what is wrong. Ethics is not a natural science. Ethics are personal, societal, and religious. As soon as a branch of government starts defining ethical standards rather than merely adhering to those established more broadly, we have started down the slippery slope of totalitarian rule. Unfortunately, America's experience with government and medical ethics is not encouraging. Consider the following three serious ethical failures:

- The US Public Health Service Untreated Syphilis Study at Tuskegee began in 1932 and continued until 1972. It involved 600 Black men; 399 had syphilis at the time, and 201 did not. The study failed on many ethical grounds, the two most serious being that the participants provided no informed consent and that once penicillin became the established, proven treatment for syphilis in 1943, the study participants were not treated and continued to be followed to observe the "natural history" of the disease.[146] Although the project has since been repudiated, the fact that government created it and then continued to fund it for 40 years should be a strong caution to avoid government dictating moral values.
- Half the states continue to have "eugenics" laws on their books that have allowed the state to force the sterilization without consent of thousands of "morons," "promiscuous," "feebleminded," and other "unfit" individuals. A 1927 Supreme Court decision *Buick v. Bell* upheld these laws and has never been overturned or vacated.[147] We are not aware of any interventions brought under these statutes in recent years, but the fact that government created them in the first place is troubling. That they remain on the books and have not met judicial repudiation even today is a clear warning of moral failure by government.

[145] National Institute of Neurological Disorders and Stroke. *NINDS FY 2024 Congressional Justification Chapter 508C*, 6. And National Institutes of Health. *Neuroethics Working Group*.

[146] Tuskegee Syphilis Study Ad Hoc Advisory Panel, *Final Report of the Tuskegee Syphilis Study Ad Hoc Advisory Panel* (Department of Health Education and Welfare, April 28, 1973).

[147] Rose Pacatte, "Documentary tells chilling history of US 'Eugenics Crusade,'" *National Catholic Reporter*, October 16, 2018.

- Dr. Anthony Fauci, at the time Director of National Institute of Allergy and Infectious Diseases, and other health officials, systematically and aggressively denied that NIH had funded any gain of function research at China's Wuhan Institute of Virology. They also denied that the COVID19 virus could have come from that laboratory. Hard documentation has since emerged that neither of these contentions were true, that Fauci knew that at the time, and that he worked with others to conceal both facts.[148]

There are at least partial summary minutes of the Neuroethics Working Group available online, and Congressional review should include careful examination and questioning of some of work conducted under its auspices.[149] While our review of a small sample of these minutes shows no cases as outrageous as the three failures above, they still point to ethical approaches that should be of concern to Congress and the public at large. For example, the meeting summary for February 12, 2024, included the following from a discussion of neurostimulation research on children[150]:

- "Meeting participants also expressed interest in allowing risk/benefit analyses to inform whether a trial should be initiated in younger populations and reconsidering the traditional approach of first testing devices in adults." There is no evidence in the meeting summary that any data were supplied to show that the current process of testing on adults first was harmful or of no value. It does note the observation by a participant that caution should be observed when extrapolating adult results to pediatric patients. That is a reasonable caution, but it does not follow that the practice of testing adults first, which can allow for any adverse results to be detected first in an older population, should be abandoned. That is fundamental ethics because a child is not as well prepared to give assent for any testing and the adverse reactions will reduce the quality of life for the patient for much longer periods of time. In the case of brain research, this caution should be doubly important because the young brain is less developed and a negative reaction is far more likely to create larger and longer-lasting dysfunction. In the absence of compelling data on the point, considering such a move puts the child at unnecessary increased risk.

[148] David Zimmermann, "Fauci Knew NIH Funded Wuhan's Gain-of-Function Research as Pandemic Began, Email Reveals," *National Review*, September 5, 2023.

[149] National Institutes of Health, *Neuroethics Working Group*.

[150] The seventeenth meeting of the Neuroethics Working Group occurred virtually on Monday, February 12th, 2024. National Institutes of Health, *Neuroethics Working Group Meeting Summary*, February 12, 2024.

- "A core theme of this session, while not necessarily unique to pediatric neurostimulation research, was to protect children through research, rather than from research." On its face, and in the context immediately following the consideration to drop the adult-testing-first standard, this implies that the researchers think their work is so important for protecting children that it takes priority over the safety of the research for the individual child. One would hope that if the researchers were to be confronted with this implication, they would retreat in their claim, but the fact that no one raised that objection—or at least it was not recorded—is both startling and deeply troubling.
- In a similar vein, the summary includes as an objective "improving the assent process to better engage pediatric patients in clinical research, as well as the importance of early and sustained community engagement." Once again, the priority seems to be getting engagement from the patient and the community so the researchers can get more subjects, not so much that the patient is protected. Perhaps most disturbing is that only children and the community at large are mentioned, with seemingly no concern for the parents' rights and responsibilities.
- The summary also notes "prioritizing the protection of vulnerable patient populations by encouraging their participation in clinical trials rather than excluding them, and addressing challenges related to cost (e.g., traveling to clinic, post-trial care) and social support." Vulnerable populations would include those with diminished physical or mental capacity, those with limited education, children in general and especially those without parents, and others with limited capacity to protect themselves. The discussion, however, was not about whether the results from non-vulnerable populations could be reliably transferred to vulnerable populations, but about how to increase the numbers of vulnerable individuals enrolled, and the record did not report any counter consideration of the potential negative effects on the patient.[151]

Asserting government control over ethics is particularly concerning in studies of the brain, but the Neuroethics Working Group is not the only NIH initiative asserting control over ethical decisions. Government employees should observe the law and norms of civil society. They are not empowered to set those norms.

Consider the following ELSI projects funded by the National Human Genome Research Institute (NHGRI) Ethical, Legal, and Societal Implications (ELSI) Research Program. The program, notes NHGRI's description, "fosters basic and applied research on the ethical, legal and social implications of genetic and genomic research for individuals, families and communities," and "is often at the forefront of newly arising

[151] "Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN) Neuroethics Working Group (NEWG) Meeting," February 12, 2024.

issues such as the appropriate use and implementation of genomics in diverse communities or the ELSI concerns of citizen science."[152]

The continuing project "Investigating ELSI issues that may facilitate or impede clinical translation of epigenomic research" has so far spent $1,758,527 over three years.[153] Its stated objective is to "facilitate the translation process by developing epigenetic communication strategies that are understandable and meaningful to socio-demographically diverse audiences, and that minimize harmful beliefs (e.g., determinism)." (Epigenomic is the study of how some environmental factors may modify how genes are expressed.) More specifically, the project proposes the following results:

> (1) Determine how people come to understand and interpret epigenetics information; (2) Examine the ethical, legal, and social implications (ELSI) of epigenetics for (a) creating or minimizing harmful beliefs and (b) promoting or discouraging acceptance of using epigenetics in clinical settings; (3) identify strategies for communicating information about epigenetics in a way that fosters understanding of epigenetic concepts, minimizes harmful beliefs, and increases acceptance of using epigenetics in clinical settings; and (4) Determine how race, ethnicity, and formal education shape the results of Aims 1-3.

The statistical methods proposed are identical to methods used in commercial marketing campaigns—somewhat dated, but still common. A government medical research group has no business engaging in marketing its ideas with methods designed to change people's minds or influence their behavior. Substitute laundry detergent or beer for epigenetic concepts, and this is a typical commercial market research project for an advertising campaign. Moreover, the project's objective to "minimize harmful beliefs" should serve as a serious warning. We all remember government efforts to suppress "harmful," "misinformation,' and "false" views about the origins, effects, and prevention of COVID-19. How did that workout?

Medical research, like all scientific research, should be reported in clear, precise language that accurately reflects the facts. Report results with accuracy, clarity, and precision, then let physicians translate those for their patients. That last word is important. "Patients" are individuals with specific conditions, needs, backgrounds, and beliefs. They are not averages of heterogenous groups. Yet, this project aims to differentiate the messaging by six different racial and ethnic groups, but a patient consulting a physician is not a group average. If we

[152] "Overview of FY 2024 President's Budget," 64–65, 157.

[153] "Investigating ELSI Issues That May Facilitate or Impede Clinical Translation of Epigenomic Research," *NIH RePORTER*, Project Details, Project Number 5R01ES033743-03.

have learned anything about attempts to differentiate among racial groups, it is that on most dimensions, the differences within a group are larger than the differences between them. It would be the ultimate malpractice to treat a patient according to his or her race.

"Education Modules to Boost DiveRsity And InCrease Equity in Genomics (EMBRACE Genomics)" an NHGRI-funded project coded as ethics, spent $226,036 in its first year of operation to "correct the demographic makeup of the research workforce, to more nearly represent the diversity of the general population." This will do nothing to complete effective research to improve health. It will merely develop an introductory training class in genomics, claiming that "these steps are necessary to reduce health inequities and rebuild trust with historically underserved populations so that we may boost their enrollment in research and incorporate genetics and genomics into their healthcare."

"To achieve this goal, we will develop genomics educational modules (GEMs) for the entry-level medical and research workforce." By workforce, they do not mean scientists, but "laboratory associates, medical assistants, and community health workers." These folks are important for our healthcare system and may require such training, but this is not research. The faculty at these institutions should be providing the training their students need. The proposed training is for delivery at three local Baltimore institutions that the proposal characterizes as demonstrating "their support and enrollment of students that come from demographics that are underrepresented in science."[154]

The project "Eastern Nigeria Research Ethics Training (ENRICH) Program," has spent $1,152,517 to date training people in eastern Nigeria in research ethics.[155] The project, conducted by the University of Maryland, proposes to "provide forty master's degrees, two hundred short- and twenty-five medium-term trainings in research ethics training to faculty members, members of ethics committees and individuals who are identified as potential leaders in bioethics by their institutions in eastern Nigeria at the newly established bioethics degree program at UNN [University of Nigeria, Nsukka]." The project is in its third year and does not specify when and how much more money will be required to reach these target numbers. NHGRI followed this up with the project "Vanderbilt-Nigeria Research Ethics Training Program (V-NET)," which has spent $498,505 to date on "an innovative research ethics training program that involves the creation of a Master of Science (MSc) in Research Ethics degree program" in eastern Nigeria.[156]

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[154] "Education Modules to Boost DiveRsity And InCrease Equity in Genomics (EMBRACE Genomics)," *NIH RePORTer*, Project Details, Project Number 1R25HG013492-01.

[155] "Eastern Nigeria Research Ethics Training (ENRICH) Program," *NIH RePORTER*, Project Details, Project Number 5R25TW011811-04.

[156] "Vanderbilt-Nigeria Research Ethics Training Program (V-NET)," *NIH RePORTER*, Project Details, Project Number

8.2 Diversity again and failure to recognize fundamentals

The second item in the list of priorities for shifting the culture within the neuroscience community is a focus on "diversity and inclusion in the research community." This agency was established to conduct research that improves health and reduces mortality. As discussed above, this diversity and inclusion focus does neither.

Finally, only the third item in the focus list is even moderately relevant to the purpose of NIH, namely, data sharing practices. While this is a reasonable principle for managing research, it should have been fundamental from the very beginning. Fixing it now is a no-brainer, but hardly a major achievement.

5R25TW012715-02.

9 Tactical Details

The preceding discussion has demonstrated the extensive strategic failures of NIH funding. Budgets are justified in terms of dollars spent, projects completed, meetings held, grants made, numbers of people hired, and ideological objectives unrelated to the agency's purpose. With two exceptions, objectives and goals are not set in measurable terms of reduced mortality, reduced disability, lower prevalence, or even mitigated symptoms. But even the two exceptions, reduced mortality from cancer and fewer new HIV infections, are weak because the progress against those goals has not been documented in quantitative terms and there is no plan in the budget documents for achieving those goals.

The allocation of resources within NIH seems problematic and requires a more thorough explanation. Both cancer and HIV appear to have overallocated resources compared to other diseases with higher mortality. It may be possible to explain the reasons for these and other counterintuitive choices, but the budget submission would be the place to do that, and NIH declines to provide such explanations.

The lack of clear, strategic direction built on sound data analysis is also demonstrated in extensive spending and effort on activities that do not yield improved longevity or reduced morbidity and may even slow or prevent scientific progress. Bureaucratic spending on developing guidance on bioethics is not only a waste of money, it sets a dangerous precedent for government to insert itself into decisions that belong to individual choice and civil society. The extensive and expansive attention to "diversity and inclusion in the research community" is detrimental to the scientific enterprise because it values immutable characteristics of individuals that are not directly related to the purpose of the organization.

Our discussion so far has illustrated these types of failures at the highest levels of planning and budgeting for NIH. In the next four chapters, we discuss 28 of the 315 major categories in the NIH program RCDC classification. These 28 categories consume 43.1 percent of NIH spending. See Table 9.1. Despite this huge share of spending, these categories represent only 3.9 percent of mortality and 18.8 percent of disease prevalence. They illustrate the types of requests for which Congress should insist on clear quantitative justification about how they will reduce mortality and morbidity of the population and on why only government can do the research required.

Table 9.1. Selected NIH funding categories from Fiscal year 2024 budget request, mortality, and prevalence, by chapters where analyzed

Chapters with NIH Funding Categories	2024 Budget Estimated $ millions	2019 US Mortality	2019 US Prevalence
Chapter 10: Projects that Reject Science			
Complementary and Integrative Health	$621	-	
Climate-Related Exposures and Conditions	$374	-	
Climate Change	$70	-	
Burden of Illness	$131	-	
Chapter 11: Projects that Endanger Liberty			
Child Abuse and Neglect Research	$43	-	
Violence Research	$194	-	
Youth Violence	$45	-	
Youth Violence Prevention	$26	-	
Violence Against Women	$60	-	
Firearms Research	$19	-	
Chapter 12: Projects Irrelevant to NIH Mission			
Behavioral and Social Science	$8,382	-	
Basic Behavioral and Social Science	$3,467	-	
Homelessness	$36	-	
Health Services	$3,068	-	
Obesity	$1,243	47,466	32.1%
Foodborne Illness	$157	-	
Screening and Brief Intervention for Substance Misuse	$37	-	
Chapter 13: Projects of Pure Waste			
Adolescent Sexual Activity	$87	-	
Cost Effectiveness Research	$368	-	
Smallpox	$39	-	
Allergic Rhinitis (Hay Fever)	$6	98	
Tobacco	$346	-	
Tobacco Smoke and Health	$304	-	14.0%
Contraception/Reproduction	$717	-	
Infertility	$199	-	
Pregnancy	$650	-	
Alcoholism, Alcohol Use and Health	$639	87,566	
Nutrition	$2,341	-	

Source: Selected from "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)," March 3, 2023. Note that in a few cases, such as in violence research, both an aggregate category and some of its components are listed. The total of 43.1 percent of NIH spending cited in the text for the 28 categories includes only the aggregated category and does not double-count the detailed categories within it.

This analysis is organized into the next four chapters (Chapters 10–13). Each chapter highlights one of four themes in the tactical failures of NIH projects:

1. Projects that reject science
2. Projects that endanger liberty
3. Projects that are irrelevant to the NIH mission
4. Projects that are pure waste

Each of these chapters reports on a sample of projects funded by NIH in several of the 28 categories listed in Table 9.1. A research category is assigned to one of the chapters based on the prevalence of the particular failure mode for projects within that category. Placing a research category in one of these chapters does not imply that all, or even most, of the project in that category suffer from the broad failure covered by a chapter, but many projects in the category do and are illustrated in the discussion. Individual projects often demonstrate multiple failure modes that are not the focus of the chapter, but are discussed in that chapter as part of the category discussed in that chapter. All issues relevant to a particular research category and its funded projects are discussed in only one chapter, not just those issues related to the chapter topic. A summary analysis of the failures across all projects is included in the final chapter.

The analysis of each of the 28 categories (in a few cases combining related categories) is based on specific projects funded by NIH and documented by NIH in its RePORTER database.[157] This database is the official record of the purpose of the project, the approach used within the project, the money spent, and the results obtained. This database contains reports on each of the 2,775,460 research grants funded by NIH since 2008, with updates through fiscal year 2023. Because of the enormity of the grant activity, the issues identified are only illustrative of underlying issues and other problems also undoubtedly exist. These categories consumed 43.1 percent of the NIH budget and highlight issues associated with both the broader objectives of the spending and the actual performance of the funded projects.

[157] *Active Projects by Institute/Center*, *NIH RePORTER*.

10 Projects That Reject Science

This chapter looks at four categories of NIH spending: Complementary and Integrative Health, Climate Change, Climate-related Exposures and Conditions, and Burden of Illness. The two climate-related categories are analyzed together. In addition, this chapter considers the disastrous initiative on hormone replacement therapy (HRT), which so far as we can tell, has been removed from the NIH database. We found 91 projects in the NIH project database that spent $26.8 million and seemed to relate to the topic based on keywords, but 70 of the 91 were never assigned an NIH Spending Category (or RCDC) classification, which means that they were never reported to Congress. Each of the four categories and the RHT initiative has significant projects that reject or ignore basic scientific research principles and suffer from other deficiencies.

10.1 Complementary and Integrative Health

The project "Meditation and Exercise for Preventing Acute Respiratory Infection" illustrates technical failings common in many NIH projects that should never occur. The project proposal says it will test the hypothesis that "8-week training programs in meditation and exercise lead to reductions in incidence, duration and severity of acute respiratory infection (ARI) illness."[158] The description says it would require five years to complete the research, testing only about 99 individuals in each of four years, with one third randomly assigned to meditation training, another third to an exercise program, and the remaining third to a waiting list that received neither and is used as a control group. All three groups would be tracked for seven months using a standardized self-reporting form to indicate whether they experienced ARI episodes. For those reporting an ARI episode, a nasal sample would be collected to identify the virus involved. The project published two reports – one for the first two years of data and a second for subsequent years.

The ARIs studied here are not major health threats. On average, across both reporting periods, only 58 percent of participants reported ARI symptoms and only 48 percent were confirmed with infecting viruses. The common cold virus Human Rhinovirus accounted for 55 percent of the tests, while other viruses with similar health effects accounted for 17 percent. Coronaviruses constituted 19 percent, but these were responsible for minor infections from globally circulating viruses present before 2016. They were from the same large family as COVID-19, but much less virulent and infectious. Finally, only 9 percent were seasonal

[158] "Meditation and Exercise for Preventing Acute Respiratory Infection," *NIH RePORTER*, Project Details, Project Number 4R01AT006970-05.

flu.[159] This project to test the effects of exercise classes and meditation classes on these minor infections cost $4,844,921 over seven years.

There are several indicators of failure around this project. The first was trouble with basic arithmetic. In the project description for the seventh year of grants, they were still calling it a five-year project and describing five years of work—four for collecting data and one for analyzing it. Activities for the other two years were not described, although the inference from subsequent published papers suggests that an additional fifth year of data was collected.

While indicative of general sloppiness, these descriptive failings are minor compared to more substantive problems. More serious failures include the fact that neither of the reports on the results from these grants provide any description of the biological processes that were hypothesized to cause either exercise or meditation to reduce infections. The reports merely cite other observational studies claiming relationships between either exercise or mediation and infections. The statistical tests merely provide a more systematic measurement of that relationship. The authors fail to provide evidence of causation. They do not even offer a plausible explanation of a potential biological or chemical pathway that might transmit causation from exercise or meditation to the immune system and counter the infection. The entire project is like the old joke in statistics that sunspots cause the business cycle because they are highly correlated.

Even beyond this foundational failure, the study design was seriously flawed on several dimensions. The so-called control group was not a true control because its members received no treatment whatsoever. There is a reason that placebo treatments are given to control groups in drug and other treatment trials. The very act of providing a treatment can change the subjects' perception of the trial and its outcomes, which is why control groups receive a placebo rather than nothing. In this project, members of the control were expecting nothing different from their usual experience because they received no intervention, whereas each of the treatment groups received some sort of treatment. This failure is especially serious in this design where the principal outcome measure was self-reported perceptions of contracting an ARI.

The full sample size for all three test groups in the first report was 149 and in the second was almost three times as large, at 413. In each report the samples were divided approximately evenly among the two treatment groups and the control group.[160] Those sample sizes are both inadequate and terribly inefficient at the cost of

[159] For the first report, Brue Barrett, et al., "Meditation or Exercise for Preventing Acute Respiratory Infection: A Randomized Controlled Trial," *Annals of Family Medicine* 10, no. 4 (July/August 2012,): Table 2, p. 343. For the second report, Bruce Barrett et al., "Meditation or exercise for preventing acute respiratory infection (MEPARI-2): A randomized controlled trial," *PLOS One*, June 22, 2018, Table 2, p. 10.

[160] Bruce Barrett et al., "Meditation or exercise for preventing acute respiratory infection (MEPARI-2): A randomized controlled trial," *PLOS One*, June 22, 2018.

$4.8 million. While the published papers described in detail how individuals were assigned to one of the three test groups, no attention was given at all to the overall sample selection design. Subjects appear to have been recruited at convenience, not randomly from the entire population. They were all from the Madison, Wisconsin, area and 76 percent were female. At least some wider geographic coverage and a balanced sex distribution would have been minimum requirements for the design, but they were not applied.

Table 10.1 summarizes the key result for the proportion of people in the study contracting an ARI. Although these data are contained in the published tables, the projects' analyses essentially ignore this primary question of what effect the two treatments had on the proportion of the participants in the study who contracted an ARI. That is the measurement of "incidence" of the infection, the first item listed for testing in the research proposal, but the report does not incorporate these incidence results in its analysis and summary of results.

Table 10.1 contains the results on the primary effects that the research proposal said it would test. In the first study, 55 percent of the control group reported an ARI, while 36 percent of the exercise group reported an ARI and the meditation group reported 41 percent. These differences—19 and 14 percentage points, respectively—suggest that there may be a small effect from exercise and meditation classes, but since these are very small samples, there is considerable uncertainty as to whether the differences between the control and treatment groups are meaningful. The confidence intervals in Table 10.1 are statistical statements of the range of values for which we can be 95 percent certain that the true value lies within that range. For example, in the first report, we can be 95 percent certain that the true value of the difference between the control and exercise treatment lies somewhere between -0.01 and 0.37 (or -1 percent and 37 percent). In other words, it is possible that the true difference is negative, and that the infection rate is slightly higher for the exercise group. Similarly, for the meditation group, it is possible that the infection rate is 6 percentage points higher than for the control.

Table 10.1. Key results from two project reports in testing effects of exercise and meditation classes on incidence of Acute Respiratory Infections

	Report	
	First	Second
Overall sample size	149	413
Percent of participants reporting ARI		
Exercise group	36%	61%
Meditation group	41%	54%
Control group	55%	59%
Differences from Control group		
Control minus Exercise	19%	-2%
Control minus Meditation	14%	5%
95% Confidence interval of difference		
Control minus Exercise	(-0.01, 0.37)	(-0.22, 0.16)
Control minus Meditation	(-0.06, 0.32)	(-0.10, 0.29)
p-value for difference		
Control minus Exercise	0.032	0.748
Control minus Meditation	0.083	0.331
Fisher Exact p-value for difference		
Control minus Exercise	0.071	0.806
Control minus Meditation	0.234	0.395

Sources: First Report, Brue Barrett, et alia, "Meditation or Exercise for Preventing Acute Respiratory Infection: A Randomized Controlled Trial," Annals of Family Medicine, 10 no. 4, July/August 2012, Table 2, p. 343. Second Report, Bruce Barrett et alia, "Meditation or exercise for preventing acute respiratory infection (MEPARI-2): A randomized controlled trial," PLOS ONE, June 22, 2018, Table 2, p. 9. Fisher Exact p-value calculation by authors from data in this table.

In Table 10.1, the p-value of 0.032 for the difference between control and exercise groups in the first report means that if we accept the hypothesis that the difference is greater than zero, then there is a 3.2 percent chance that we will be wrong. In most business applications, the critical value for p is usually 0.050, or 5 percent because a 5 percent risk for spending time and money to achieve some business end is usually an acceptable risk. But for healthcare (as well as for safety and other critical applications) a much lower risk is usually adopted, such as 0.025, 0.01, or even 0.005 because the consequences for failure are generally viewed as more severe.

The researchers in this study adopted 0.025, the highest risk level applied in health and medical research. By that standard, they should reject both hypotheses that either the exercise or meditation groups have lower infection rates than the control group. In fact, even with the less stringent general business standard, they should reject the hypothesis that the mediation group has a lower infection rate; nevertheless, they publish as their conclusion, "Training in meditation or exercise may be effective in reducing ARI illness burden." They might demur that by saying "may" they are hedging their bets, but the rules of statistical inference are clear. The results in the first report are not statistically significant. We could just as well say that chicken soup, mothers' chest rubs, and drinking water "may" help. In their conclusions they claimed, "We observed substantive reductions in ARI illness among those randomized to exercise training, and even greater benefits among those receiving mindfulness meditation training."

This statement ignores the most basic statistical standards. The effects of either exercise or mediation on ARI is not statistically significant. The term "substantive reductions" has no scientific or statistical meaning in this context. The researchers appear to be trying to suggest statistical significance to the reader where there is none.

The results are even weaker than presented in the article because the grantees use the wrong statistical test calculation. Most of us are at least casually acquainted with the so-called bell curve that shows the distribution of data values. In statistics, this is called a normal distribution. Normal distributions apply only to "continuous" data, which can take on any value within a range—for example, length, mass, or temperature. But this project uses "categorical" data, which can take on only a few discrete values, in this case either infected or not infected. The measure that follows is the percentage infected in each group. That measure is also discrete. Each of the samples has 50 observations, so the percent infected can only take on the values 0, 2, 4, 6, . . .100 percent infected. It cannot be 3 percent, much less 3.14156 percent. This is called a binomial distribution. The calculation of the p-value for assessing significance, is different for continuous normal-distribution and discrete binomial distributions. Back before computers, researchers would sometimes use the normal distribution as a reasonable approximation of the underlying binomial distribution and use it to calculate the p-value. This approximation is reasonably accurate for differences close to 50 percent and with samples of 2,000 or greater. But for these differences of 19 percent and 14 percent with samples in each group of only about 50, the error in the approximation is large. The exact calculations, a method developed by Ronald Fisher almost 100 years ago and used by trained statisticians for data like these, are displayed in Table 10.1. They show that on an exact basis, if one accepts the hypothesis that the differences are greater than zero between the control group and exercise and the meditation groups, the probability of being wrong equals 7.1 percent and 23.4 percent respectively.

The research team is almost correct at one point when they note: "Even with the large effect sizes observed, our sample size was only marginal for statistical significance." In fact, both hypotheses fail the significance test, but they are right in noting that the small sample size may be the reason for failure. They then almost triple the sample size with the follow-on tranche of funding and a second report. The increased sample size between the two papers was large enough that if the new larger sample had shown the same percentages contracting ARI for all three groups as shown for the first, smaller sample, then the differences between the control and the treatments would have been significant using the normal-distribution approximation, although the meditation treatment would have still been insignificant using the exact Fisher calculation.

The second data column in Table 10.1 contains the results for the second study with a sample that was 2.8 times larger and would have registered significant differences between the control and the two treatments

using the normal-distribution approximation if it also yielded about the same infection rates as the first sample, but the larger sample shows much smaller effects. In fact, the larger sample shows that the exercise group had a slightly higher infection rate than the control. In other words, the seemingly substantial reduction in infection rates by the treatments in the first, smaller sample were the result of random chance. The larger sample showed that if one accepted the hypothesis of reduced infection from exercise, there would be a 75 percent chance of being wrong—81 percent chance using the exact Fisher calculation. The chance of being wrong when accepting a reduction from meditation would be 33 percent—40 percent with the exact Fisher calculation. This is overwhelming evidence to stop. Neither treatment showed any reasonable indication of improvement. Yet, the final paper concludes, "Training in mindfulness meditation or exercise may help protect against ARI illness."[161] That is a perfect example of confirmation bias, the inclination of researchers to hold onto their prior beliefs even when the data say otherwise. While the conclusion of the first paper was excessive, at least it was followed by a larger sample to establish whether the observed differences were significant. But this conclusion in the second paper is in direct contradiction of the data.

Instead of addressing this primary metric, the reports emphasize two secondary metrics – the number of times each individual contracted an ARI during the study and the amount of absenteeism from work. Both secondary metrics could be affected by many uncontrolled exogenous variables for sampled individuals such as the degree of interaction with other people, the type of work they performed, the location of their work, the sick-leave policy at their workplace, and the amount of sick leave balance in the individual's benefits. These uncontrolled variables make the modeling of these secondary variables inherently unreliable. These secondary metrics might be interesting to look at, but when one does research, the proposed hypotheses must be tested, but these reports largely ignore the primary metric of the proportion of people who acquire the disease. The reports also ignore the other two metrics in the research proposal, namely "duration and severity." The reports also wander into multiple minor metrics and issues, such as mental attitudes and depression, that were not part of the original proposal. Sometimes a research project will generate additional hypotheses for testing, but good research never does so at the expense of ignoring tests of the original hypotheses.

Three high-dollar projects typical of this complementary and integrative health spending category illustrate a prevalent disturbing trend and the inherent failure of the NIH model. The project "Conservation and Sustainable Use of Biodiversity in PNG [Papua New Guinea]" has spent $11,558,527 over 6 years "to improve human health

[161] Bruce Barrett et al., "Meditation or Exercise for Preventing Acute Respiratory Infection (MEPARI-2): A Randomized Controlled Trial," *PLOS One*, June 22, 2018, p. 2.

and well-being through . . . utilization of the flora and fauna of Papua New Guinea (PNG). . . . Understanding of the full range of biological resources resident in PNG is essential for their management and the preservation of species critical to indigenous cultures, ... It is a central hypothesis of this work that effective new therapeutics can be derived from the natural products of PNG flora and fauna. . . . [providing] needed revenue to local stakeholders and responsible PNG institutions."[162]

A set of projects associated with "Arizona Complementary and Alternative Medicine Research Training Program" have spent $1,464,699 "to prepare qualified fellows to perform rigorous and innovative research on whole systems of CAM [complementary and alternative medicine]."

Another project has spent $600,000 in Suriname focused on "1) gold mining-related Hg [mercury] contamination of indigenous food sources . . . 2) access and use of pesticides in large and small-scale agriculture; and 3) environmental contamination of nutraceuticals and indigenous medicinal plants." They further highlight: "An important aspect . . . will be engaging the indigenous and other health disparate communities in characterizing, protecting and preserving the nutraceutical assets indigenous to this region . . . while preserving the unique assets, health and cultural traditions of indigenous- and other health disparate populations." There is no scientific research involved here, just cultural anthropology about foreign cultures. And while the project description mentions preventing contamination of "indigenous medicinal plants," there is no mention of verifying that the plants claimed to be medicinal were of any medical or other scientific value.

A common structural weakness in all three of these projects is that each is a hammer in search of a nail. They have ideological hammers such as indigenous medicinal plants, alternative medicine, or disparate populations. Now they are spending millions of dollars in search of a nail on which to use them. In more specific scientific terms, they are doing pipeline research on indigenous treatments, alternative medical procedures, and disparate populations in hopes that something useful will pop out. But as shown earlier, this approach is far less effective than the "mission" approach, where the focus is on a specific outcome like reducing deaths from a particular variety of cardiovascular disease. That search may include looking at populations with low incidence of the disease to see if there are clues as to cause or treatment. Scientific inquiry may also include testing herbal or other alternative treatments, but those investigations must apply the same rigorous scientific testing as any theory.

One of these authors (Early) recalls an instance in 2017 where he was invited to facilitate development of a strategic plan for an office in the National Science Foundation. At one point, as the group completed a set

[162] "Conservation and Sustainable Use of Biodiversity in PNG," *NIH RePORTER*, Project Details, Project Number, 3U01TW006671-05S1. $11,558,527 over 6 years is the sum of payments in the project data base, although the "History" table in the project report shows $8,791,611 over 12 years. Discrepancy is not explained.

of measurable strategic goals, one member objected that using measurement was only one "way of knowing" that was culturally biased. The rest of the group, fortunately, ignored him and moved on, but it appears that this unscientific way of thinking has moved from the idiosyncratic fringe into everyday projects in scientific agencies. In fact, the Department of Health and Human Services, the parent agency for NIH, issued a draft "Scientific Integrity Policy in July 2023,"[163] It endorsed the use of "indigenous knowledge" in scientific research. That policy was approved[164] and then incorporated verbatim into a final NIH Scientific Integrity Policy, effective December 30, 2024, as follows:

> NIH also works to apply scientific integrity practices in ways that are inclusive of non-traditional modes of science, such as citizen science, community-engaged research, participatory science, and crowdsourcing. . . . and inclusion of multiple forms of evidence, such as Indigenous Knowledge.[165]

Yet it was by discarding long-held "evidence" from indigenous "knowledge" such as the earth being flat, physical reality being constructed of only four elements—earth, water, air, and fire—and the sun traveling around the earth, that the Renaissance, Enlightenment, and Industrial Revolution brought us greatly enhanced prosperity and health. If all NIH meant was that people living in unstudied biomes may have observed some effects that might be theories worth testing, they could have said so, but they made the anti-scientific claim that these observations are evidence.

The NIH policy also proclaimed, "It is the policy of NIH to . . . Promote diversity, equity, inclusion, and accessibility in the scientific workforce."[166] Making the immutable physical features of a person into qualifying characteristics for employment and promotion is inconsistent with the goal of maintaining high scientific standards by selecting individual to conduct research based solely on their ability to contribute to scientific knowledge.

While NIH rushed finalization of this policy change into effect just before the change in administration, the new leadership spotted and at least partially fixed some of these failings immediately. The entire Scientific Integrity Policy for the National Institutes of Health of 2024 was rescinded March 28, 2025, although separate

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[163] "Request for Comments on the Draft HHS Scientific Integrity Policy," *Federal Register* 88, no. 138 (July 20, 2023): 46802–46803.

[164] "The Scientific Integrity Policy of the U.S. Department of Health and Human Services," *Federal Register* 89, no. 203 (October 21, 2024): 84166–84180.

[165] "Scientific Integrity Policy of the National Institutes of Health, Federal Register," *Federal Register* 89, no. 203 (October 21, 2024): 84173.

[166] "Scientific Integrity Policy of the National Institutes of Health, Federal Register." *Federal Register* 89, no. 203 (October 21, 2024): 84176.

related policies remained in force and the umbrella HHS policy still applied.[167] The HHS policy made two important improvements on March 21, 2025. First, the entire advocacy promoting diversity, equity, and inclusion policies was eliminated. Second, the anti-scientific advocacy for indigenous knowledge was removed but that paragraph still retains vague references that could be interpreted as undermining scientific rigor, such as:

> HHS also works to apply scientific integrity practices to non-traditional modes of science, such as citizen science, community-engaged research, participatory science, and crowdsourcing.[168]

The project "Motor Activity Research Consortium for Health (mMarch)" has been funded for seven years and spent $6,218,307.[169] Its principal focus is to reconcile and aggregate the large number of studies of "the environmental, biologic, and genetic correlates of the components of motor activity as well as the relationships between motor activity with sleep, exercise, mood, and cognitive functioning." The objective—to compare, contrast, reconcile and aggregate different studies on the same topic—is laudable and some of the results look like they would be valuable for those working in the field. The most startling feature of this study is not the objective, method, results, or obvious high cost, but the fact that it was needed at all. As the research team notes: "Aggregation of the findings across studies is challenged by the substantial differences in the study goals, procedures, and statistical methods." If there were any value at all for a centralized direction of health research, we would expect it to include requiring that the funded projects are coordinated and when their data, methods, and results differ from earlier projects, they be compared and reconciled as a necessary part of the grant. But in projects we have examined, with few exceptions such as this one, we have seen no such requirements, and often complete disregard for the need. Rather, we observed a pattern of providing research grants to people based on all sorts of political considerations, physical characteristics of the researchers, and structural preferences.

These kinds of allocations are inherent in the public choice environment of government grants, which primarily benefit officials and bureaucrats. Civil servants progress in their careers, gain promotions, and benefit from additional financial and non-financial rewards largely based on the size and scope of their assignments. These assignments, in turn, grow from the budgetary process, which often rewards politicians' demands, such as DEI requirements, grants to hometown universities, or projects favored by donors to politicians, rather than scientific rigor. We would not expect this issue to arise in a free interchange of ideas stimulated in a research

[167] "Rescission of the Final Scientific Integrity Policy of the National Institutes of Health," Notice Number NOT-OD-25-080, March 28, 2025.
[168] "The Scientific Integrity Policy of the U.S. Department of Health and Human Services," March 21, 2025.
[169] "Motor Activity Research Consortium for Health (mMarch)," *NIH RePORTER*, Project Number 1ZIAMH002954.

college that grows cooperatively around a key research topic in the private sector. Researchers would expect, provide, and, if necessary, demand such reconciliations among research results.

We cannot leave this spending category without mentioning two examples that did nothing to advance medical science. One NIH grant spent $18,259,801 over the last 16 years, most recently $1,430,685 in 2022, to identify and eliminate microbiological and/or chemical contamination from the microenvironment of lab rats, such as their feed, caging, bedding, and water, to preserve the animal's health and prevent adverse effects on the experiments.[170] These expenditures are not for the general maintenance, feeding, breeding, etc. of the rodents. It is only for chasing down and removing new contaminants that routine maintenance of the rat facility failed to do. This seems excessive.

A second project that looks like a make-work program for a lone statistician. "Statistical methods in collaborative research" was a $169,458 project in 2022 that funded a statistician to give advice and assistance to other projects.[171] These other projects ranged from the describing community-based testing sites for COVID 19 to analyzing data on dermatomyositis (a rare inflammatory disease), measuring the relationship between blood molecular measurements (ND1, cell free DNA and GAPDH) and autoimmune diseases, and a study in Nigeria of exposure to biomass fuel and birth weight. The term "collaborative research" is pointless here. The cost of this activity should have been rolled into the cost of the base projects. It appears that NIH simply funded this person to go hunting for existing projects to work on.

10.2 A Highly Harmful False Report on Hormone Replacement Therapy

As wasteful and harmful as the project was that tested whether mediation reduced respiratory illnesses, another major NIH initiative made some of the same errors that caused far more significant medical harm. The Women's Health Initiative (WHI) was a massive set of studies that spent nearly $1 billion from the early 1990's until 2005. Part of the initiative was a study of hormone replacement therapy (HRT) for post-menopausal women. It followed 16,608 women. Approximately half were assigned to the treatment group that received the previously standard treatment of estrogen and progesterone, and the rest received a placebo. The study was funded and promoted by NIH and included an experienced principal investigator from each of 40 medical research facilities. Marty Makary, MD, has written a highly accessible summary of this failure, documenting the initial false report, the highly unusual tactics to avoid normal peer review, the reaction of NIH and other traditional medical organizations to suppress

[170] "Physiological Effects of Natural or Contaminating Compounds in a Rodent's Microenvironment," *NIH RePORTER*, Project Number 1ZIGES022120-25.
[171] "Statistical Methods in Collaborative Research," *NIH RePORTER*, Project Number 1ZIAES103360-02.

dissenting views, and the slow reaction of medical schools and others to correct the errors in their recommendations and practices. Except as noted otherwise, the following description relies on Dr. Makary's research.[172]

The fundamental failure in scientific method was to ignore mathematical results for testing whether the observed difference in some variable between two samples is statistically significant— the same failure described in detail above for the test of mediation and respiratory infections. Midway through the HRT study, the difference between the treatment and control groups showed a slightly (less than one in a thousand) higher incidence of breast cancer in the treatment group. That small difference was not significant, but three of the principal investigators prepared a paper that called for the trial to be stopped because of this small increased incidence and made the recommendation to cease HRT. The lead investigator, Dr. Jacques Rossouw, had previously published his opinion before the study began that HRT should be abandoned.[173]

The three authors showed up at the regularly scheduled meeting of the 40 principal investigators involved in the massive study with their three-person paper already written, along with a draft NIH press release announcing the results and recommendations. They replaced the previous agenda with their paper and the press release. When the other principal investigators asked about providing comments, they were told that the paper had already been accepted for publication and that the press release was approved by NIH. That was at 10:00 AM and they were given until noon that day to make any comments. Most saw the futility of the effort, but several quickly prepared extensive edits to misleading and false elements in the article. The comments were delivered by noon, but they were not accepted because the journal was already printed and in the warehouse. The next day, NIH issued a press release summarizing the article.[174]

One of the dissenters, Dr. Robert Langer, was removed from his former position as chair of one of the WHI committees and banned work on any WHI publication with respect to HRT. WHI leadership responded to his request for an explanation with an email: "The PIs have reached a consensus on interpretation of our data and prefer that our publications not be contradictory."[175] That is just about as anti-scientific as it gets.

The NIH leadership of the WHI refused to release the raw data from the study, despite the scientific principle to do so, and the NIH directives requiring it. Whether that continues to be the case, we could not determine,

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[172] Marty Makary, *Blind Spots: When Medicine Gets It Wrong, and What It Means for Our Health* (Bloomsbury Publishing, 2024), pp. 17–37. A more extensive technical critique is provided by three of the dissenting principal investigators at A.Z. Bluming, H.N. Hodis, and R.D. Langer, "'Tis But a Scratch: A Critical Review of the Women's Health Initiative Evidence Associating Menopausal Hormone Therapy with the Risk of Breast Cancer," *Menopause* 30, no. 12 (December 1, 2023): 1241–45.

[173] J.E. Rossouw, "Estrogens for Prevention of Coronary Heart Disease: Putting the Brakes on the Bandwagon," *Circulation* 94 (December 1996): 2982–85.

[174] NIH News Release, "NIHLBI Stops Trial of Estrogen Plus Progestin Due to Increased Breast Cancer Ris, Lack of Overall Benefit," National Institutes of Health Tuesday, July 9, 2002.

[175] Marty Makary, *Blind Spots: When Medicine Gets It Wrong, and What It Means for Our Health* (Bloomsbury Publishing, 2024), p. 21.

but even from the published results, it is possible to compute that there is at least a 10 percent chance that the conclusions are wrong—what is called a type I error.[176]

When members of the group that pushed through the tainted publication were questioned about the lack of statistical significance, their responses were astonishing. One of them replied, "Yeah, yeah, you know, that's right. And you know what happens? You know what happens is, if it's an important question and you can't do it again because it costs too much money, then they'll say that's the best data there is and then . . . the statistical police have to leave the room."[177] The study's statistician then asserted, "When it's an issue as important to women as breast cancer, we intentionally set the bar low."[178] Another lead author claimed that the test "approached" statistical significance.[179] Had a student in one of our classes made such claims, they would have failed.

The failures in these reactions are many. First, if a lesser standard for a type I error is to be applied for an investigation, it must be specified and agreed to by all involved—the sponsor, funder, researcher, and possibly others, and the study design must be consistent with that target. Second, if the test is especially important (as the investigators asserted in this case), then a higher standard, not a lower one, would be called for. Third, the statistical tests include consideration of the sample size. If the sample is large, then the test has been calculated for that large size; one never adjusts decision based on the sample size, which is already baked into the statistical result. Finally, to claim that the result "approached" significance would be discarded by any valid peer or publication review. Statistical testing is real life. In basketball (or any other sport other than horseshoes) you don't get half a point for almost making the basket; the customer either buys the product or not; the patient survives or does not. If the statistical test comes close, that might be grounds for further investigation such as calculating the type II error for indications of whether further testing would likely be successful. And their combined results might be grounds for a new, improved study, but it is never grounds for accepting a hypothesis that fails the established tests.

In addition to being wrong based on the standard statistical tests, the adoption of the resulting incorrect recommendations to cease HRT has had widespread repercussions. Dr. Macary reports that when the new HRT

[176] The published 95% confidence interval around the risk ratio is (0.83-1.92). From this the authors calculate that there is at least a 10% chance that the ratio is less than 1.00, which would indicate a reduced chance of cancer, rather than an increased risk. That risk of being wrong is widely required to be smaller than 5% for making most business decisions, smaller than 1% for critical business decisions and most health decisions, and even lower for especially critical choices. The paper that was pushed through in the face of significant peer opposition ignored this heightened risk of being wrong.

[177] Transcript of lecture by Dr. Rowan Chlebowski, recorded by Dr. A Bluming, and reported by Marty Makary, *Blind Spots: When Medicine Gets It Wrong, and What It Means for Our Health* (Bloomsbury Publishing, 2024), p. 23.

[178] Marty Makary, *Blind Spots: When Medicine Gets It Wrong, and What It Means for Our Health* (Bloomsbury Publishing, 2024), p. 23. Citing A. Bluming and C. Travis, *Estrogen Matters* (Little, Brown Spark, 2018).

[179] Marty Makary, *Blind Spots: When Medicine Gets It Wrong, and What It Means for Our Health* (Bloomsbury Publishing, 2024), p. 23, from his personal conversation with a study lead author.

recommendation became the standard, many women not only began suffering again from the readily observable effects of menopause, such as hot flashes, brain fog, depression, and sleep disruption, but they also lost many other medical benefits that far outweighed any small increased risk of breast cancer, even if the increase had been real and not insignificant. These health benefits include: a 50 percent lower risk from heart attack, lower incidence of Alzheimer's diseases, fewer bone fractures, and greater longevity. Here we have a specific NIH failure that directly caused some of the slowdown in American longevity.[180]

The NIH leadership violated fundamental, widely recognized, and sound scientific and moral principles in the published interpretation of the HRT project reports' data. If the authors of that alternative interpretation wanted to make the case that the usual statistical rules did not apply, they could have done so and engaged in robust debate with the defenders of the established principles. But the bureaucratic leaders strongarmed and threatened those who uphold the established principles with removal from their positions and prohibitions on publishing conclusions that differed from those of the bureaucratic heads.

In addition to failings like those in the HRT case, a critical failing in other cases is outright fraud that publishes fake data. One example of outright fraud is illustrated by the case of Hoau-Yan Wang of City University of New York, along with a number of coauthors. They published a series of papers, many funded by NIH, that built the case for the compound simufilam being a potential treatment for Alzheimer's disease. Many were funded by NIH, with the most recent three-year grant totaling $1,855,233 through August 2021.[181] The papers then served as a basis for funding two clinical trials in which live patients were receiving the proposed treatment.[182] It took nine years,[183] but NIH eventually uncovered evidence that images used to justify the findings were likely manipulated. NIH reported its findings to the Office of Research Integrity (ORI) in the Department of Health and Human Services, which then requested on September 13, 2021, that CUNY conduct an investigation. The ORI information documented 31 allegations of misconduct over 20 years in 30 publications, primarily falsification of "western blot images."[184] Because Wang refused to supply any of the underlying raw data and images, the

[180] Marty Makary, *Blind Spots: When Medicine Gets It Wrong, and What It Means for Our Health* (Bloomsbury Publishing, 2024), p. 23, citing A. Bluming and C. Travis, *Estrogen Matters* (Little, Brown Spark, 2018).

[181] "Development of PTI-125-DX, a Blood-Based Diagnostic for Alzheimer's Disease," *NIH RePORTer*, Project Details, Project Number 5R44AG057329-03, with funding for fiscal year 2020, https://reporter.nih.gov/search/lfLeyYk97UO-hx3O-FPVvA/project-details/9850182. When accessed May 28, 2025, most of the information about this project had been removed from the website, but the budget and outcomes summary remained. Among the items removed were the principal investigator names, the project title, and the proposed research description. All the information had been present when first accessed in mid-2024.

[182] Charles Piller, "Co-developer of Cassava's Potential Alzheimer's Drug Cited for 'Egregious Misconduct'," *Science Insider*, October 12, 2023, updated October 30, 2023.

[183] Hoau-Yan Wang, Kalindi Bakshi, Maya Frankfurt, Andres Stucky, Marissa Goberdhan, Sanket M. Shah, and Lindsay H. Burns, "Reducing Amyloid-Related Alzheimer's Disease Pathogenesis by a Small Molecule Targeting Filamin A," *Journal of Neuroscience* 32, (July 18, 2012): 9773–9784.

[184] City University of New York, *Final Investigation Report of Associate Professor Hoau-Yan Wang, Ph.D.*, no date (report says it extended over approximately ten months, which would place it in approximately July 2022).

CUNY investigation report about ten months later was somewhat tentative but still damning. Eventually, CUNY sent notices to the publishers of the offending papers, and most complied with the request.[185] While the relevant fraud investigation office eventually identified the fraud, and no new grants were awarded after that, the remedy was long after serious damage had been done, Not only had the funds been wasted, but volunteer patients were subjected to a test treatment developed from fraudulent research. The internal investigations eventually led to the Department of Justice obtaining criminal indictment on four felony fraud counts by a federal grand jury, on June 28, 2024, with the trial still pending.[186]

10.3 Climate-Related Exposures and Conditions

NIH proposes to spend $444 million on climate change research. (See Table 9.1.) The mere existence of these categories reflects NIH leadership obsession with *au courant* political talking points rather than important matters for reducing mortality and morbidity. The most extreme claims about global warming are that by the end of the current century, average global temperatures may rise by as much as 2°C or 3.6°F, from the beginning of the industrial age, with the current temperature readings already accounting for 1.15°C (2.07°F) of the total rise.[187] The latest United Nations report, which has a history of overstating its forecast of the amount of warming, recently shifted to claiming that even a more moderate increase (still labeled "serious") of 1.5°C (2.7°F) would cause more serious damage than previously advertised.[188]

So how much could the change in global temperature possibly affect health? From the current level of warming the climate lobby is warning of serious consequences for another 0.63°F rise and catastrophe for adding 1.53°F. Thousands of people willingly, even eagerly, move from New York to Florida and experience an increase in average daily temperature that is 34 times greater than the "serious" level and 14 time greater than the "catastrophic." Yet we see no evidence of health differences, and the population flow is consistently from colder to warmer. Basic common sense and simple arithmetic tells us there is little or no health threat from such small changes in temperature.

If there were some scientific foundation for a claim of deteriorating health from the suggested changes in global temperature, then NIH owes Congress and the American people a clear data-based explanation. But instead , advocates of a threat to health from climate change prefer to use complicated models to conclude, "Using a generalized [sic] exposure–response function to provide an estimate of heat-related deaths globally,

[185] Charles Piller, "Co-developer of Cassava's Potential Alzheimer's Drug Cited for 'Egregious Misconduct'," *Science Insider*, October 12, 2023, updated October 30, 2023 .
[186] Office of Public Affairs, U.S. Department of Justice, "Professor Charged in Operating Multimillion-Dollar Grant Fraud Scheme," June 28, 2024.
[187] World Meteorological Organization, *State of the Global Climate 2022*, WMO-No. 1316, 3,
[188] United Nations, "Climate Change."

this indicator finds that annual heat-related mortality of people older than 65 years increased by an estimated 68 percent between 2000–04 and 2017–21."[189] This claim was published by the medical journal the *Lancet*, but the underlying failure of the claim was immediately spotted by multiple readers. The authors counted the number of aged people dying from conditions attributed to heat, but the underlying population 65 years and older increased by 60 percent. Almost all that increase was the result of a growth in the older population. At most, only 5 percent of the increase could have been associated with rising temperatures.[190]

A second flaw in the claim is only slightly less obvious. If the average temperatures are rising, then the exposure of people to lower temperatures and their associated mortality would likely be falling. In the United States and Canada, from 2000 to 2019, on average between 8 and 9 times as many people died from exposure to cold as died from exposure to heat. The same models that attribute 17,000 additional deaths annually among the over-65 population from exposure to heat also show more than 500,000 *fewer* deaths from cold.[191] That latter number is almost never reported. Such censorship of data—a standard statistical term for ignoring some subset of the data being analyzed—is clearly, and effectively anti-scientific.

In a sense, the good news about this category is also bad news. Only 7 of the 174 projects classified in this category dealt even remotely with climate change. While that result may reduce the harm from misdirected research dollars, it also reveals serious flaws in the NIH classification system for projects.

Many of these misclassified projects are about pollutants, which means that the people to whom we pay billions of dollars are not able to distinguish between (1) greenhouse gases that have been assigned as causes of climate change, such as carbon dioxide, which is beneficial for plant growth and (2) pollutant gases like sulfur dioxide that are inherently harmful to both plants and people, but so far have not been attributed to contribute to climate change. Another large group of projects relates to melanoma and carcinoma. None of these offer any reason why they are related to climate change (one is left with the impression that they must follow the reasoning that warmer temperatures encourage people to go out in the sun where they get more UV radiation and thus more skin cancer).

The one project that is at least explicit about its proposed connection to climate change is "A Causal Analysis of the Complex Mental Health Impacts of the Climate Crisis in Young People."[192] Unfortunately, this project is like the man who murdered his parents in cold blood and then begged for mercy because he was an orphan.

[189] Marina Romanello, Claudia Di Napoli, Paul Drummond, Carole Green, et alia, "The 2022 Report of the Lancet Countdown on Health and Climate Change: Health at the Mercy of Fossil Fuels," *Lancet* 400 (2022): 1625.

[190] Bjorn Lomborg, "Climate Change and the Lancet's 'Heat Death' Deception," *Wall Street Journal*, November 5, 2022. More extensive analysis in Bjorn Lomborg, *False Alarm: How Climate Change Panic Costs Us Trillions, Hurts the Poor, and Fails to Fix the Planet* (Basic Books, 2020).

[191] Bjorn Lomborg, "Climate Change and the Lancet's 'Heat Death' Deception," *Wall Street Journal*, November 5, 2022.

[192] "A Causal Analysis of the Complex Mental Health Impacts of the Climate Crisis in Young People," *NIH RePORTER*, Project Details, Project Number 1R15ES033817-01.

The project proposal begins by noting it will study, "the role that environmental factors sensitive to climate change and variability (e.g., increasing temperatures, heat waves) may play in the complex pathway linking environmental exposures and negative mental health and well-being outcomes." In other words, the researchers begin by positing a looming disaster and then cite one of the familiar surveys that shows "7 out of 10 young people are worried about their future in the context of these planetary changes."

The actual warming increase on average is less than would accompany a short trip down the highway and less than the average daily temperature variation in a typical week. The project proposal is to measure "local spatiotemporal patterns of help-seeking for mental health in response to three extreme climate events—hurricanes, wildfires, and heatwaves" by young people. This is treating the symptoms not the cause of youth anxiety. The root cause is more likely the constant drumbeat about some coming climate disaster, rather than any actual disastrous climate-change outcomes. If we stop being alarmists, the anxiety problem likely goes away.

The project proposal assumes increasing hurricanes, wildfires, and heatwaves, but the data show otherwise. Hurricane prevalence and intensity are highly variable, and the claim for their increase is made on the basis of an increase from 1980 to 2009. But the narrative supporting that claim is based on a data set from 1920 to 2014. The claim of increased prevalence and intensity can be made only by deliberately and deceitfully deleting the data from 1920 to 1979 and from 2010-2014. The full data set shows no trend over the entire period. It also shows that the 1980 starting point used by political activists promoting climate-inspired policies, was a randomly low point that gave a false impression of rising prevalence. The false story is further enhanced by deleting the more recent data for 2010 – 2014, which declined sharply to the lowest levels in 30 years.[193]

Although data on other weather-related destruction such as floods, wildfires, tornados, and droughts do not all have equally long or complete records as hurricanes, they all partly reflect our rising wealth and population. If a hurricane hits Miami (or some other event in some other city) today, there will be more property and people in its path than 100 years ago. Independent academic research has shown that, adjusted for GDP, global economic losses from weather events has not increased since the series began in 1990; rather, it has fallen by 25 percent. Insured losses have not risen since the series began in 1960.[194] More generally, Environmental Protection Agency (EPA) data show that in the 1930s heat waves were almost an order of magnitude greater than those in the more recent decades.[195]

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[193] Patrick J. Michaels and Paul C. Knappenberger, *Lukewarming, The New Climate Science that Changes Everything* (Cato Institute, 2016), pp. 171–173. Data from Ryan Maue.

[194] Roger Pielke Jr., "Statement of Dr. Roger Pielke, Jr. to the Committee on Environment and Public Works of the United States Senate Hearing on Climate Change: It's Happening Now," July 18, 2013.

[195] Patrick Micheals et al., *Addendum: Global Climate Change Impacts in the United States* (Washington, D.C., 2012).

This project illustrates a common problem with many NIH projects. They do not define and measure the problem they propose to solve. This study proposes to find the causes of "complex mental health impacts of the climate crisis," but it does no such thing. First, it looks only at hurricanes, wildfires, and heat waves. The proposal offers no data to back up the claim that those phenomena constitute a climate crisis. And how big are the mental health impacts? Saying 7 of 10 young people in an unvalidated survey are worried about future climate changes is irrelevant. How many have an actual mental-health failure as the direct result of actual hurricanes, wildfires, and heat waves? The principal investigator wants $413,598 of our money to find the causes of "complex mental health impacts of the climate crisis on young people." Before we buy, we should know just how big the problem is.

The failure to define and measure the problem is even more puzzling because the proposal is to "leverage our longstanding partnership with Crisis Text Line (CTL), a global not-for-profit organization that provides free, 24/7, and confidential text-based crisis response service. CTL currently has the largest repository of mental health data in the world." If they really have access to this data, then it would have been a straightforward exercise to at least come up with the counts of the number of CLT interventions with youth by type of intervention associated with a large sample of hurricanes, wildfires, and heatwaves at a variety of time frames prior to any awareness of the event, immediately before the event, during the event, and at several points in time after the event. If the data already exist, any second-year student in a quantitative discipline could figure this out in a few days. Failure at least to measure the problem before begging for money to pay for further analysis shows a complete misunderstanding of the nature of research. Measure the problem and be explicit about the theories to be tested and the methods to be used.

The project fails to get the basics right, but it has mastered the politics. It promises to identify "mediating underlying disparities driving" patterns in "mental health conditions related to climate disasters," . . . "enhance the research and learning infrastructure at Appalachian State University" and "engage undergraduate students, primarily represented by rural 'first generation' college students in research." It also claims it will supply "[t]raditionally underrepresented students" with mentorship and research experience and introduce "primarily rural college students in geography, public health, and mental health sciences to transdisciplinary research." None of these features of the project apply the scientific method to reduce mortality or morbidity, but they do check all the political boxes—climate disaster, disparate outcomes, disadvantaged populations, underrepresented demographics, etc.

In case you were wondering, as were we, what the difference is between "transdisciplinary" research that will motivate this project and the usual "interdisciplinary" research that has been productive for more than a century, NIH explains: "Interdisciplinarity analyzes, synthesizes and harmonizes links between disciplines into

a coordinated and coherent whole. Transdisciplinarity integrates the natural, social and health sciences in a humanities context, and transcends their traditional boundaries." There. One more box is checked, but is our health any better? Does this mean that any conclusions from the data must be confirmed by a panel of blank verse poets and abstract painters? The proposal offers no example of a transdisciplinary research project that was even attempted, not to mention one that produced significant improvements in health.

The other six projects that might be at least tangentially related to climate change tell us more about the grant-making process than anything else.

1. "Effects of climate change on prevalence and environmental niches of clinically important vibrios in the Chesapeak [sic] Bay" has spent $546,833 over five years presumably assessing whether climate change might encourage the growth of different species of vibrio bacteria in the Chesapeake Bay.[196] But NIH fails to provide any description of the projects, simply noting, "No abstract provided." We know from other sources that only about 100 deaths occur nationwide from these bacteria every year, and illness from them can be avoided by cooking seafood adequately.[197]
2. "Evidence to improve heat warning effectiveness in reducing morbidity and mortality."[198] The project proposes "to identify the optimal health-based and location-specific metrics for issuing heat alerts, to estimate the causal benefits of heat alerts, and to identify characteristics of individuals or communities associated with the greatest reductions in morbidity or mortality following heat alerts." But the project has been dragging on for four years and spent $2,509,245 and is still not complete.
3. "Increased Risk of Chronic Disease Due to Domoic Acid Exposure with Age." has spent $652,343 over five years.[199] The prevalence of domoic acid exposure has not yet been documented and is limited to older individuals consuming seafood from recreational catches. The project per se might be useful, but the time and expense seem excessive for any possible beneficial outcome from spending money on a very rare occurrence with well-known etiology and simple prevention.
4. "Mapping impact and developing mitigation strategies for climate change-mental health nexus in the context of vulnerable adolescent populations in Kenya" has run for five years with seven grants totaling

[196] "Effects of Climate Change on Prevalence and Environmental Niches of Clinically Important Vibrios in the Chesapeake Bay," *NIH RePORTER*, project number 5R01ES030317-05.
[197] Centers for Disease Control, "Vibrio Infection (Vibriosis)."
[198] "Evidence to Improve Heat Warning Effectiveness in Reducing Morbidity and Mortality," *NIH RePORTER*, Project Details, Project Number 5R01ES029950-05.
[199] "Increased Risk of Chronic Disease Due to Domoic Acid Exposure with Age," *NIH RePORTER*, Project Details, Project Number 5R01ES030319-05.

$647,845.[200] This is an example of substantial NIH grants in other countries with no possibility of beneficial effects on the agency's purpose of improving health in the United States. This project is focused on pregnant "adolescents" up to age 24 in Kenya. After five years, the investigators should have been able to document the existence and magnitude of any climate effects that are occurring. They also should have measured any current change in mental health on their sample of only 200 subjects. One reason they have no results may be that there are none. Under "Outcomes" in the NIH project database project-details, it reads "No Outcomes available."

5. "NOLA HEAT-MAP: New Orleans Home, Environment, and Ambient Temperature: Measurements and Analysis for Preparedness," has spent $1,988,557 over four years, with no outcomes reported.[201] The proposal is built on the claim that "In the United States, heat is responsible for more fatalities than any other type of weather and the burden of morbidity and mortality attributable to heat is growing. . . . New Orleans, Louisiana, with over a quarter of its population living in poverty, is uniquely sensitive to the health risks from rising temperatures." That is speculation without any data cited. As documented above, cold weather events cause at least 8 times more mortality than heat. The project's claim is for the nation as a whole, not just for extra-warm New Orleans, which suggests, if anything, that it would be a poor site for the study because any results could not be applied to the vast majority of the country. Furthermore, their undocumented claim that anybody, much less the poor, are "uniquely sensitive to the health risks from rising temperatures" is unfounded. Comprehensive data from the Department of Energy show that 88 percent of the poorest families today live in airconditioned homes, compared with only 12 percent of *all* families 50 years earlier.[202] Any exposure to natural heat will have been cut substantially, so where are the data to show otherwise?
6. "The confluence of extreme heat cold on the health and longevity of an Aging Population with Alzheimers [sic] and related Dementia," has spent $2,615,789 over two years with no reported outcomes.[203] The investigators propose to count the number of healthcare encounters and deaths of Medicare patients from an existing data file of cases and classify them by whether they occurred

[200] "Mapping Impact and Developing Mitigation Strategies for Climate Change-Mental Health Nexus in the Context of Vulnerable Adolescent Populations in Kenya," *NIH RePORTer*, Project Details, Project Number 3K43TW010716-05S1.

[201] "NOLA HEAT-MAP: New Orleans Home, Environment, and Ambient Temperature: Measurements and Analysis for Preparedness," *NIH RePORTer*, Project Details, Project Number 7R01ES031955-02.

[202] Physical amenities in poor households are calculated from the US Department of Energy, Residential Energy Consumption Survey (RECS), 2009, as summarized and reported by Robert Rector, "How the War on Poverty Was Lost," *Wall Street Journal*, January 8, 2014; and Robert Rector and Rachel Sheffield, "The War on Poverty after 50 Years," *Backgrounder* no. 2955, Heritage Foundation, September 15, 2014.

[203] "The Confluence of Extreme Heat and Cold on the Health and Longevity of an Aging Population with Alzheimers [sic] and Related Dementia," *NIH RePORTer*, Project Details, Project Number 1RF1AG074372-01A1.

> during or following an extreme hot or extreme cold event. The computations required are trivial and any undergraduate student in a quantitative discipline should be able to do the job in a few days. Moreover, exposure to extreme temperature in the United States is avoidable. Just stay in a temperature-controlled structure. Almost all homes, including 88 percent of homes among the poor, are air conditioned, with most unconditioned homes located in temperate zones. All homes have heat, and the government pays the heating bills for the poor, so the theoretical exposure is infinitesimal, and preventing any exposure would be trivial.

One set of related projects illustrates the essence of funding bureaucratic activity in perpetuity without demanding outcomes. The project "Genetically Engineered Mouse Models to Study Melanoma Genesis and Progression" is a 2022 project in a long line of 27 projects stretching over 23 years and spending $18.7 million to nurture and perpetuate a strain of mice that have been genetically modified to mimic at least some elements of the development and progression of melanoma in humans.[204] Although, on the surface, it may be useful for finding better treatments for melanoma and some interesting results are reported, why does it need to continue for 23 years at a cost of $18.7 million? At a minimum, the justification should at least attempt to explain why so much money is needed over such a long time for such limited results. Better yet would be to assign these costs to project seeking treatments for melanoma.

Many projects have nothing to do with advancing scientific knowledge in support of reducing mortality and morbidity. They simply apply well-known methods and remedies to the benefit of small, politically influential groups. "Environmental Exposures of the Northern Arapaho Tribe: An Exploratory Study" spent $422,344 to "measure indoor/outdoor particulate matter (PM), indoor radon, and heavy metals in soil, plants, and water." It applied techniques widely available commercially for decades in only 36 households.[205] There is no advancement of science. In fact, the proposal is distinctly anti-scientific, declaring, "This community-engaged project represents a holistic assessment incorporating traditional ecological knowledge (TEK)." The first "discovery" of this project was that their attempt at "citizen science" to have the 18 affected residents install their own monitoring equipment was only "moderately successful" because people needed help to succeed. The second discovery was the importance of having a "Community Advisory Board" to make the project successful, after noting in the proposal that the Board "consists of members of the N. Arapaho community . . . all of whom are eager to see this work succeed." Spend

[204] "Genetically Engineered Mouse Models to Study Melanoma Genesis and Progression," *NIH RePORTer*, Project Details, Project Number 1ZIABC008756-35.

[205] "Environmental Exposures of the Northern Arapaho Tribe: An Exploratory Study," *NIH RePORTer*, Project Details, Project Number 5R21ES032137-02.

this kind of money at the direction of its political leaders in a tiny community with only 9,862 residents and you get access.[206] The third result was for the only health measures, self-reported asthma and cancer incidence. These indicators showed no statistically significant difference between the residents who received air quality measures and those who did not. Of course, with a sample size of 36, any epidemiologist would have told the project team that their chances of getting a significant result would be very low because only huge differences of more than doubling the incidence would be detected. The final reported result was fully predictable, namely, "Further study is needed to evaluate these findings in a larger sample size."[207] Also noteworthy is a missing result. After claiming the project would incorporate "traditional ecological knowledge (TEK)," no TEK effect was even mentioned, much less incorporated. The project team could not even invent a *pro forma* result related to it. It is not clear how much NIH paid to a public relations consultant to come up with a title and associated TEK acronym pronounced "tech."

In addition to manipulation of political influence with "scientific" grants that are nothing but paying for the application of known science for the benefit of limited populations, there are also simple, clear examples of grants to promote the commercial success of the investigators' earlier discoveries, activities that are inherently part of private sector investment, not government activity authorized by the Constitution.

In one case, development of "microslit filters" to filter out tiny specs of plastic from water led the NIH grant recipients to create a new company, which then entered a joint venture with an unspecified "large instrument vendor" to market and produce these filters. The stated purpose of the grant was: "This Phase II project will advance the manufacturing of microslit filters, automate their packaging into 13 mm discs for compatibility with existing vacuum filtration devices, and develop peripherals for rapid MP screening and filter analysis. We will scale our nanomembrane production to multi-wafer batches to reach cost-of-good targets in lined with identified pricing levels. We will develop a process for combining injection-molded 13 mm disc blanks and nanomembrane chips using pick-and-place robotics, precision glueing [sic], and thermal curing. We will also develop two peripheral products." This is not science, but mere product promotion through changes in packaging to benefit a particular firm.

Examples of wasteful spending at NIH are legion, and projects coded as related to climate are no exception.

NIH has spent $412,928 in the last two years, with no end in sight, to study how cooking dinner with gas stoves may increase asthma.[208] Large segments of the world cook with wood, coal, and even dung, but NIH

[206] Norther Arapaho Tribe, "About Us."

[207] "Outcomes: in "Environmental Exposures of the Northern Arapaho Tribe: An Exploratory Study," *NIH RePORTer*, Project Details, Project Number 5R21ES032137-02.

[208] "AIM to Improve Asthma: Airflow Improvements during Meal-prep," *NIH RePORTer*, Project Details, Project Number 5R21ES030173-02.

wastes effort on one of the cleanest, most advanced methods of cooking rather than chasing down the causes of cardiovascular and cancer fatalities that are the greatest threat to American health—a perfect example of the linear-model failure in funding science.

The common fruit fly Drosophila melanogaster is used in many research projects studying biological processes at the cellular and molecular level. One project says this is a limitation because Drosophila melanogaster naturally dwells in moderate conditions favorable to humans. The project proposes to develop a different strain of fruit fly to use as a model in research, namely Drosophila mojavensis, which naturally developed in dry, hot climates, to see if we get different answers from this subspecies.[209] That is an interesting intellectual question, and, so far, "only" $44,896 has been spent, but why is it really important for reducing morbidity and mortality? The principal investigator doesn't provide any data. Perhaps he should try getting some venture capital for this effort.

NIH spent $40,000 to send people to the "2021 Central and Eastern European Conference on Health and the Environment" in Vytautas Magnus University, Kaunas, Lithuania.[210] Especially in this day of extensive electronic communication, why is this travel important for reducing mortality and morbidity in the United States?

The project "Disparate Exposures, Disparate Outcomes: The Effect of Cumulative Disadvantage" spent nearly $1 million ($979,277), over six years.[211] It reported no specific health outcomes. It proposed to use existing data to look at "whether disparities in adverse pregnancy outcomes are related to prenatal air pollution exposure, and to what extent combined exposures to adverse pregnancy outcomes, lead, and neighborhood environment contribute to disparities in early childhood educational outcomes. Both adverse pregnancy outcomes and lead exposure are patterned by race/ethnicity and SES [socioeconomic status]." The explicit first objective of the project was "During the training phase of this grant, [the principal investigator] will use sibling models to investigate relationships between prenatal air pollution exposure and adverse pregnancy outcomes in maternal siblings." When the grant sequence began, the principal investigator already held a Ph.D. in epidemiology from Yale University and had held a research appointment at Rice University for two years. The proposed research would be barely adequate for a dissertation topic, so why characterize it as more training for a full Ph.D. with two years of post-graduate experience? And why doesn't she have the results after six years and nearly a million dollars spent?

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[209] "Comparative Approaches for the Study of Somatosensory Processing in Drosophila," *NIH RePORTer*, Project Details, Project Number 1F31NS129270-01.

[210] "2021 Central and Eastern European Conference on Health and the Environment," *NIH RePORTer*, Project Details, Project Number 1R13ES032658-01.

[211] "Disparate Exposures, Disparate Outcomes: The Effect of Cumulative Disadvantage." *NIH RePORTer*, Project Details, Project Number 7R00MD011304-06.

Here, and in other projects, NIH gets its mission backward. It must start with the health outcomes to be achieved through research and then assemble the resources needed to reach that end—which may include some staff with basic preparation who are ready to learn more, but also still ready to contribute. Junior participants in a project are part of the means of acquiring the results, not the result itself.

The "training" approach to defining projects is also detrimental to both the project itself and to the young participants. The project will lose by focusing on socializing young researchers into the "we've always done it that way" of doing things—while veteran researchers risk losing the opportunity to benefit from new researchers' fresh insights. Young researchers may also lose their spark for challenging thinking, further entrenching bureaucratic inertia at NIH. Remember that Einstein's Nobel Prize work was written when he was 26. By age 48, he was trying to refute the next innovations of quantum physics in public but collegial debates with the young Niels Bohr. This and dozens of other historical examples demonstrate the importance of contributions from young researchers, the critical role of debate, and the significance of a lifetime of learning. Large projects will usually have room for one or more less-experienced researchers to contribute and to learn. That not only gives them experience, but also sets an important example of approaching research with a mission focus in mind.

Furthermore, private charitable foundations regularly provide support to freshly minted researchers, making government projects justified primarily for the development of new researchers of questionable value. For example, the Gates foundation funds a wide range of disciplines but is perhaps best known for its work in malaria and a variety of vaccines.[212] The ZOLL foundation specializes in research related to cardiopulmonary and respiratory conditions, including emergency medicine, critical care, and trauma.[213] The Robert Wood Johnson Foundation, perhaps best known for its work in HEALTH policy, also funds a broad range of medical research, especially in disease prevention and health promotion, such as childhood obesity.[214] There are also many specialty foundations and hospitals and medical centers that sponsor research as part of their mission, such as Children's Cancer Research Fund and St. Jude Children's Research Hospital.[215]

The remaining objectives of the project were to identify the effects on early childhood educational outcomes from adverse pregnancy outcomes, early childhood lead exposure, neighborhood environment, residential instability, and changing neighborhood environment, both individually and in combination on early childhood educational outcomes. What this project is trying to explain is not health effects, but educational effects, which

[212] More information available at the Gates Foundation website, https://www.gatesfoundation.org/.
[213] Early State Research Funding, The Zoll Foundation.
[214] More information available at the Robert Wood Johnson Foundation website, https://www.rwjf.org/.
[215] More information available at the Children's Cancer Research Fund website, https://childrenscancer.org/ and "St. Jude Children's Hospital, Childhood Cancer Treatment."

are outside the scope of NIH's work. Furthermore, the adverse educational outcomes for disadvantaged students in the public school system are well known and the remedies well-tested.[216] Establishing and expanding school-choice options in disadvantaged neighborhoods in which the money follows the student almost invariably improves student performance.

10.4 Burden of Illness

Projects in this category seem to constitute a potpourri of different research about the burdens that different conditions may create. None appear to address comprehensive measurement of the components of the overall burden of illness, which would presumably be important for assigning resources for health research if one were relying on bureaucrats to do the job. One project illustrates how fruitless such efforts might be.

"The long-term health effects of the New Deal: An 80-year follow-up of 4 cohorts" has spent $3,208,107 to analyze existing data from the decennial Census and some longitudinal demographic data sets collected by universities and government agencies. It proposes to "examine the effects of New Deal work-relief spending on the long-term health outcomes of children growing up during the Great Depression. Our central hypothesis, based on our prior research, is that employment from New Deal programs will be associated with lower levels of chronic disease and lower mortality for both the children in beneficiary households, but also for children in non-beneficiary households living in areas that received greater amounts of New Deal program funding."[217]

Even if it were true that the beneficiaries of New Deal subsidies had better health and other well-being outcomes than those who were unemployed without the New Deal benefits, the results would be irrelevant because in 1940, the reference year of the published research from the project, the affected households would have had less than $2,500 of income in constant 2017 dollars. In 2017, only 0.05 percent of all households (67,000 of the total 128,000,000) had income that low, so the results would be irrelevant to the current economy because almost all households today have far more real income than the poorest 20% in 1940.[218] Even if the proposing investigators were ignorant of these facts, the NIH grant reviewers should have caught the problem and refused to fund it.

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[216] The following contain empirical overviews of the literature: Herbert J. Walberg, *School Choice: The Findings*, (Cato Institute, 2007); *School Choice Myths: Setting the Record Straight on Education Freedom*, ed. Neal McCluskey and Corey A. DeAngelis (Cato Institute, 2020); "The 123s of School Choice," EdChoice, April 14, 2021; Tim R. Sass et al., "Charter High Schools' Effects on Long-Term Attainment and Earnings," *Journal of Policy Analysis and Management* 35, no. 3 (Summer 2016): 683–706.

[217] "The Long-Term Health Effects of the New Deal: An 80 Year Follow-Up of 4 Cohorts," *NIH RePORTer*, Project Details, Project Number 5R01AG059791-05.

[218] Phil Gramm et al., *The Myth of American Inequality: How Government Biases Policy Debate* (Roman & Littlefield, 2022), pp. 83–100, 141–64. Augmented with author calculations back to 1940 from Bureau of Economic Analysis, "National Income and Product Accounts," Table 2.1. Personal Income and Its Disposition.

One of the published papers from this $3.2 million project claimed to test whether health across the life history of people who were young children in 1940 was affected by the percentage of the labor force in their childhood Census "Enumeration District" that was enrolled in a New Deal "Emergency Employment" program in March 1940.[219]

The paper claims "Poverty reductions in communities with Emergency Employment activity could lead to a variety of positive outcomes for child development, especially for child cognitive development." The authors test both "direct" pathways that reduced poverty in households with persons paid by Emergency Employment activity and "indirect" pathways such as "increased circulating resources" from government transfer payments in the community and the improved environment from better sanitation, school building and recreation opportunities that might affect all children in the Enumeration District.

They test whether the percentage of Emergency Employment in young children's Enumeration District and whether the father's participation in Emergency Employment affected outcome measures across the individuals' life histories by comparing the amount of Emergency Employment in a geographic area with the following outcome measures:

Adolescent IQ

Rank in high school graduating class

Parents' income 17 to 20 years later

Earning a bachelor's or higher degree

Participation in the labor force in their mid-30s

Wages in mid-30s

Total earnings in mid-30s

Body mass index in early-50s

Whether ever smoked

Whether ever had alcohol problem

Average intelligence score across early-50s, early-60s, and early-70s

Longevity

Whether the father was paid under the Emergency Employment programs is a categorical variable. It can take on only two values, "yes" or "no." But the percentage of the labor force in the Enumeration District that was

[219] Sepideh Modrek et al., "Long-Term Effects of Local Area New Deal Work Relief in Childhood on Educational, Economic and Health Outcomes over the Life Course: Evidence from the Wisconsin Longitudinal Study," *Demography* 59, no. 4 (August 1, 2022): 1489–1516.

engaged in Emergency Employment is a continuous variable that can take on any value between 0.00 percent and 100.00 percent. In statistical analysis, continuous variables are much more reliable and powerful. One should never destroy a perfectly good continuous variable and replace it with a categorical conversion, but that is exactly what this project did.[220] It converted the proportion of labor force in Emergency Employment from a continuous proportion into just five quintiles as follows:[221]

Quintile	Range of Enumeration District percentage values
Q1	0%-0.93%
Q2	0.94%-2.4%
Q3	2.46%-4.4%
Q4	4.4%--7.7%
Q5	7.7%+

Percentages reproduced exactly from source, including the shifting number of significant figures and the ambiguous upper-lower limit relationships between adjacent quintiles.

The "recoding" of the actual percentage engaged in Emergency Employment to the quintiles of engagement destroys information. If two Enumeration Districts have percentage values of 0.01 percent and 0.93 percent, respectively, then analyzing them as continuous variables would use the information that the second district has 0.92 percent more of its labor force in an Emergency Employment program compared to the first Enumeration District. But using the categorical quintiles destroys that information and makes the percent engagement for both look identical. Now suppose a third Enumeration District had 0.94 percent of its labor force in the program. If the statistical analysis used the original continuous variable, the statistical calculations would treat it as having engagement only slightly larger than the second area and substantially larger than the first. But using the recoded categorical quintile variable would imply that the third area exceeds both the first and second areas in Emergency Employment by the same amount.

Such destruction of information may lead the analyst to miss meaningful relationships, but it can also create artificial evidence of statistical significance by hiding the significant random variation in the raw data that underlies the artificial groupings into quintiles.

[220] Survey data are often aggregated for publication purposes into quintiles as done here or other aggregate groups, but that is done only for economy and clarity of summary publication. Real statistical analysis would not use these groupings when the underlying continuous variables are available.

[221] Sepideh Modrek et al., "Long-Term Effects of Local Area New Deal Work Relief in Childhood on Educational, Economic and Health Outcomes over the Life Course: Evidence from the Wisconsin Longitudinal Study," *Demography* 59, no. 4 (August 1, 2022): 31, Table 1.

Given these deficiencies, the published research from the project contributes nothing to the NIH's mission to reduce mortality or morbidity. In its published abstract, the project claims to show that young children living in Enumeration Districts with "moderate work relief activity in 1940" (defined as quintiles 2 or 3 of Emergency Employment percentages of the labor force) had more favorable outcomes on four variables compared with those living in districts with low Emergency Employment percentages (less than 0.94 percent). These claims are weak, however.

The first claim is for higher adolescent IQ scores. This claim rests on measures of statistical significance. Tests of statistical significance are measures of the uncertainty in outcomes owing to random variation and limited information in the sample. As we have seen, most statistical tests of business performance usually accept that a relationship is statistically significant only if there is less than a 5 percent probability that the relationship would not exist in the full universe of data (if we had access to it). For medical and health outcomes, analysists usually require that this probability of being wrong be less than 1 percent.

The significance test for the effect of Emergency Employment on adolescent IQ is significant at the 5 percent level only for the difference between the third quintile and the first quintile. The second quintile is not significant. None of the quintiles for districts with more Emergency Employment show any significant relationship to adolescent IQ. Girls typically score slightly higher than boys on this IQ test, so a better estimate of the relationship would adjust for the gender of the child. The project added sex differentiation and found only "marginal" significance in the second and third quintiles and the same lack of significance for other quintiles. "Marginal" significance is not a statistical term. It is used by authors when they want to claim success despite failed standard tests.

The same equations that the report uses to justify a positive effect of Emergency Employment quintiles within the Enumeration District on adolescence IQ also show that there is a similarly significant *negative* effect from the child's own father participating in Emergency Employment. The project report includes the negative result in its Table 4 but fails to report it in the summary of findings. This is a much more direct relationship than the vague and dispersed community effects, and deserves at least as much attention, but it is simply ignored. The failure to mention this negative effect is, at best, sloppy analysis and likely arises from confirmation bias.

Statistical significance is different from importance. The relationship between two variables can be statistically significant but also totally unimportant. Significance means that two variables move more or less together, but that does not mean causation. And even if there is causation, the contribution of a statistically significant variable may be trivial, which is why regression models should always include the associated analysis of variance to

indicate just how much of the variation in the dependent variable such as adolescent IQ is explained by the independent variable (Emergency Employment in the Enumeration District in this case).

One metric that comes from the analysis of variance is the R-squared (R^2). It ranges from 0.000 to 1.000 and measures the proportion of the variance in the dependent variable (adolescent IQ in this case) that is explained by all the independent variables in an equation. An R^2 of 0.900 means that all the independent variables in the regression combined explain 90 percent of the dependent variable's variation, and an R^2 of 0.100 means that they explain only 10 percent. Although the New Deal paper does not provide the full analysis of variance, it does report the R^2 of 0.068. That means that only 6.8 percent of the variation in adolescent IQ is explained by the combined effects of all the independent variables in the equation—the individual's sex, father's work status, quintile of Emergency Employment in the Enumeration District, and the interaction between sex and Emergency Employment quintile. In addition to those four independent variables, the equation also incorporates 13 control variables – maternal education, paternal education, father born in the United States, family home ownership, family size, urban location, Enumeration District-level percent home ownership, Enumeration District-level percent foreign born, Enumeration District-level percent aged 25+ with high school education, Enumeration District-level percent white unemployed, Enumeration District-level average home value, county-level average farm size, and county-level retail sales change 1929-1933. That is a total of 16 independent variables that combined explain only 6.8 percent of the variation in IQ, an average of only 0.4 percent. That is less than one-half of one percent, or 4 parts in a thousand for each of the independent variables, which is extremely weak. There may be a statistically significant relationship between Enumeration District-level Emergency Employment and adolescent IQ, but its contribution is trivial at best.

An important result here, as well as in almost all the other variables, is that any significant positive effects are in the second and third quintiles. The effects become much smaller and even negative in the Enumeration Districts with greater Emergency Employment penetration. Although these results are implicit in the discussion, the consequence is never highlighted. There are no positive effects above the third quintile where a maximum of 4.4 percent of the households receive government subsidies. In the 21st century, more than 25 percent of households are receiving government subsidies, more than five times the maximum percentage above which there was no measured positive effect at all back in 1940. These facts mean, that even if we ignore the major flaws in the study, the authors' conclusions are irrelevant because the effects of the paper's model in 2025 would be zero. Moreover, the policy implications for the current state would be to reduce subsidies drastically, but the paper does not even consider that possibility.

The second claim is that children living in Enumeration Districts with Emergency Employment participation failing into the second and third quintiles graduated from high school with a higher-class rank. The results here are as statistically weak as the IQ measure, with a caveat stemming from a fundamental design failure. Consider two schools, both with the same level and distribution of performance by students on an achievement test that has scores ranging from 0 to 100. One school has 300 students and the other 900 students in their respective graduating classes. Student performance ranked 1, 2, and 3 in the smaller school would constitute the top 1 percent of that school, and might have test scores of 99, 95, and 91, but the top 1 percent in the larger school would be nine students. If they come from the same population distribution of capability, their test scores would likely be 100, 99, 98, 96, 95, 94, 92, 91, and 90. The average score is the same overall and for each third of the top cohort. But because the larger school has more students, its top three performing students have higher test scores, and thus higher capability than the top three in the smaller school. In other words, the position in the rankings is affected by school size and larger schools will have greater capability in their top three ranks. So, the measure is really one of school size, not better performance, which makes the metric meaningless in terms of outcomes.

The third claimed positive effect of Emergency Employment programs is making children more likely to obtain a bachelor's degree. This outcome exists only for the second quintile compared to the first, and it is not significant for any greater Emergency Employment penetration of the labor force, so it is of little consequence. The authors fail to include any analysis of variance information on this one, so the importance cannot be assessed.

The last outcome for which the paper makes claims of positive effects from Emergency Employment is late-life cognitive scores. It offers 32 different relationship scores, four different metrics by four different quintile comparisons, each presented both with and without sex adjustment. Only 4 of the 32 are statistically significant, and R^2 values for the estimated regression equations all lie within the range of 0.043 to 0.066, meaning that the importance of the effects is trivial at best.[222]

Even more consequential than the trivial effects of those four outcomes for which the report claims any positive Emergency Employment effects are factors that are tested but show either negative effects or no significant positive effects. The most important of these is mortality. The only outcome variable with even a weak significance at 10 percent probability of being wrong is the higher mortality for females in the second quintile compared with the first quintile. There is no effect for males, for females in any other quintile, or for any of the other variables tested. Here is the quintessential strategic metric for NIH showing no effect from New Deal

[222] Sepideh Modrek et al., "Long-Term Effects of Local Area New Deal Work Relief in Childhood on Educational, Economic and Health Outcomes over the Life Course: Evidence from the Wisconsin Longitudinal Study," *Demography* 59, no. 4, (August 1, 2022): 1489–1516. Appendix Table 5.

Emergency Employment. The full list of outcomes tested without finding any positive effects from Emergency Employment programs is as follows:

> Parents' income 17 to 20 years later
>
> Participation in the labor force in their mid-30s
>
> Wages in mid-30s
>
> Total earnings in mid-30s
>
> Body mass index in early-50s
>
> Whether ever smoked
>
> Whether ever had alcohol problem
>
> Male mortality
>
> Female Mortality

The essential health outcomes regarding body mass, smoking, excessive drinking, and mortality are not affected. The economic well-being measures of participation in the labor force, wages, and total earnings are likewise unaffected. An objective assessment of the total set of results can only conclude that there is nothing useful here. Nevertheless, the researchers, seeking still more money and unwilling to take "no" for an answer conclude:

> In future studies it is important to examine if benefits accrue differently by child age of exposure, gender and race. While this study is one of the first to examine long-term outcomes for children in New Deal work relief programs and examined outcomes by gender, there is a need to examine these associations in detail in a more geographical, socio-economic and racially diverse population of Americans. Furthermore, as new data sources emerge on the actual outcomes of the New Deal investments, future studies should examine possible mechanisms related to increased sanitation, better nutrition, or higher area-level consumption that New Deal expenditures supported.

11 Projects That Endanger Liberty

As described earlier, many medical research dollars are spent in accordance with the wishes of bureaucrats and politicians seeking to expand their power, influence, and budgets. When they do so, it erodes our liberty by exercising governmental force to take our money. But there are also projects that directly endanger other fundamental individual liberties. Many of these liberty-eroding projects are concentrated in the child-abuse and-neglect category and the violence research category, which are discussed below. There are other types of failures in these categories, and we discuss those as well.

11.1 Child Abuse and Neglect Research

Child abuse and neglect are crimes, not diseases. While they certainly harm the health of children, the actual abuse and neglect are the result of bad ethical choices by caregivers. As in the cases of research characterized as behavioral and social science or violence research in subsequent chapters, these are arguably not properly within the scope of NIH's purpose.

Many projects in the child abuse category have been used to remove children from their parents' care and convict parents of child abuse, sending them to prison and, at least in one case, condemning a father to execution, which continues to be postponed at this writing.[223] Yet, we could find no projects of the more-than 1,500 projects that have been funded in this category that even acknowledge that there are law enforcement and civil society dimensions to this problem.[224] But flawed NIH research as well as misuse of sound research has been used by law enforcement to intervene and in some cases accepted by courts to support conviction.

So-called shaken baby syndrome (SBS) is a particularly compelling illustration of the danger inherent in government controlling the research agenda. The syndrome was first described in the 1970s by Dr. A. Norman Guthkelch as the association of subdural hemorrhages, brain swelling, and retinal hemorrhages in babies who have been subjected to violent shaking. This set of three signs have since been named "the triad." NIH has funded multiple projects that largely assume the syndrome as a given and prescribe parental behaviors to avoid it.[225]

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[223] Jeffrey A. Singer, "Texas May Execute a Man Based on Flawed Science. Will Abbott Intervene?" *USA Today*, September 25, 2024.

[224] Since we were working from project summaries in the NIH database, it is possible that some projects may have considered these issues at some point, but the published summaries do not consider the topics important enough to include.

[225] "All Babies Cry: Shaken Baby Syndrome Parent Education Toolkit," *NIH RePORTer*, Project Details, Project Numbers 4R44HD061122-01, 4R44HD061122-02, 4R44HD061122-03. "Identifying Potential Therapeutic Targets for Abusive Head Trauma," *NIH RePORTer*, Project Details, Project Numbers 5R01HD099397-01A1, 5R01HD099397-02, 5R01HD099397-03, 1K01HD083759-01A1, 1K01HD083759-02, 1K01HD083759-03, 1K01HD083759-04, 1K01HD083759-05. "HIF-1/p38 MAPK pathway in rotational acceleration-deceleration neonatal brain injury," *NIH RePORTer*, Project Details, Project Numbers 1R21NS098170-01A1, 1R21NS098170-02.

At least partially backed by this NIH research, a group spearheaded by the Society for Pediatric Radiology has issued what it calls a "consensus" about parental abusive behavior in infant head trauma and began calling the syndrome "abusive head trauma" (AHT).226 NIH also began using the term "abusive head trauma," implying that that the constellation of symptoms was *ipso facto* evidence of abuse. But that is far from the case. The existing evidence only shows that sufficiently violent shaking might cause this triad cluster of signs, but there is significant evidence that other factors—genetic, accidental, or disease related—can also cause them. In the absence of any direct symptoms or physical signs of abuse, the triradial cluster of SBS is far too weak to infer abuse. The so-called consensus generated immediate rebuttals from several academic sources.[227]

In effect, reverse causation of the known facts has been used to send parents to prison. Even the originator of the syndrome description, Dr. Guthkelch, cautioned against using it for diagnosis and legal convictions. "SBS and AHT are hypotheses that have been advanced to explain findings that are not yet fully understood. There is nothing wrong with advancing such hypotheses; this is how medicine and science progress. It is wrong, however, to fail to advise parents and courts when these are simply hypotheses, not proven medical or scientific facts."[228]

Because of the powerful implicit backing of NIH-funded research and other government entities, it has been difficult for defense attorneys to even raise concerns about the limitations of the evidence against their clients. Groups such as the Innocence Project have succeeded in working with attorneys to overturn some of these unjust convictions on appeal, but it is hard work because the SBS orientation is so embedded in the legal conventional wisdom.[229]

Advocates for continuing the use of shaken baby syndrome as criminal evidence often point out that only 1 percent of the cases of people convicted of AHT/SBS were overturned on appeal on the grounds of faulty medical evidence.[230] Of course, 1 percent is 1 percent too many, but the advocates of SBS prosecution overlook the formidable barriers that appeals face in most cases. The appealing attorneys must be familiar with and competent in presenting the technical basis for rejecting the presumed proof of AHT/SBS. Because NIH has

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[226] Arabinda Kumar Choudhary, Sabah Servaes, Thomas L. Slovis, et al, "Consensus Statement on Abusive Head Trauma in Infants and Young Children," *Pediatric Radiology* 48 (2018): 1048–1065.

[227] Keith A. Findley et al., "Feigned Consensus: Usurping the Law in Shaken Baby Syndrome/ Abusive Head Trauma Prosecutions Abusive Head Trauma Prosecutions," *Wisconsin Law Review* 2019, no. 4 (2019): 1211–268; Randy Papetti et al., "Outside the Echo Chamber: A Response to the 'Consensus Statement on Abusive Head Trauma in Infants and Young Children,'" *Santa Clara Law Review* 59, no. 2 (May 15, 2019): 299; Wake Forest University Baptist Medical Center, "Researchers Say Criterion for Diagnosing Child Abuse Not Always Accurate," *Science Daily*, February 26, 2006.

[228] Jenna Little, "Shaken Baby Syndrome Hypothesis Has Never Been Scientifically Validated," California Innocence Project, May 3, 2019.

[229] For examples see "Washington Post In-Depth Investigation: Shaken Baby Syndrome," Innocence Project; John Grisham, "Texas May Execute a Man Based on a Scrapped Medical Theory, *Wall Street Journal*, September 7, 2023; Innocence Project, Shaken Baby Syndrome Archive.

[230] S. K. Narang et al., "Overturned Abusive Head Trauma and Shaken Baby Syndrome Convictions in the United States: Prevalence, Legal Basis, and Medical Evidence," *Child Abuse and Neglect*, December, 2021, 122:105380.

adopted the AHT/SBS hypotheses, its imprimatur creates an appearance of legitimacy that makes judges less inclined to challenge orthodoxy. This bias toward government agency preeminence makes the appeal process an uphill battle.

NIH also provides most of the project funding in this area, so researchers in the field depend on NIH for their career advancement, creating at least an unconscious bias in much of the published work.

A small number of projects tested methods for detecting abuse and differentiating it from accidental injury.[231] And only one of the 1,500 grants actually tested methods for treating symptoms of physical abuse, in this case head trauma.[232] A series of grants for career development in this category is indicative of the focus on supporting highly educated researchers rather than on conquering disease.

One project, "Using Clinical Design Support to Improve Child Physical Abuse Testing," appeared to be at least appropriate as a general matter of inquiry, though not for federal government funding. But the project abstract gives the game away: "This career development award supports the development of Daniel Lindberg MD into an independent investigator focused on the early recognition of child physical abuse. . . .The career development goals of this proposal are to allow Dr. Lindberg to develop skills in informatics and dissemination & implementation science. These skills will provide the foundation for an independent research career that will translate the best evidence within the field to the large community of physicians who care for abused children."[233] Four grants totaling $625,129 went to a single physician to develop his career. While there may be some benefits for some children included in the study, there are no metrics to track the actual improvements made. The priority goals for this project are in terms of career development for an existing physician, the highest paid occupation in the United States.

Another series of five grants were made to a single MD physician who also held an MSPH (Master of Science in Public Health) for a total of $627,830, again explicitly, "This career development award supports the development of Joanne Wood, MD, MSHP as an independent researcher focusing on child maltreatment research and improving the quality of care for victims of abuse.[234]

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[231] Two tested a method to automate radiology results to differentiate between accidental and non-accidental trauma: "Automatic Rib Fracture Detection in Pediatric Radiography to Identify Non-Accidental Trauma," *NIH RePORTer*, Project Details, Project Numbers 5R21HD097609-01 and 5R21HD097609-02.

[232] "Identifying Potential Therapeutic Targets for Abusive Head Trauma," *NIH RePORTer*, Project Details, Project Number 5K01HD083759-05.

[233] "Using Clinical Design Support to Improve Child Physical Abuse Testing," *NIH RePORTer*, Project Details, Project Number 5K23HD083559-01A1; "Using Clinical Design Support to Improve Child Physical Abuse Testing," *NIH RePORTer*, Project Details, Project Number 5K23HD083559-02; "Using Clinical Design Support to Improve Child Physical Abuse Testing," *NIH RePORTer*, Project Details, Project Number 5K23HD083559-03; "Using Clinical Design Support to Improve Child Physical Abuse Testing," *NIH RePORTer*, Project Details, Project Number 5K23HD083559-04.

[234] "Occult Injury Screening and the Detection of Physical Abuse in Young Children," *NIH RePORTer*, Project Details, Project Number 1K23HD071967-01.

NIH has reversed the desirable direction of causation here. Projects should be funded that will advance health, and then the appropriate staffing of those projects should deliver results while also giving less experienced, but highly capable individuals the opportunity to develop and show their growing capabilities.

Over the last five years, $6.6 million were granted to "The Center for Innovation in Child Maltreatment Policy Research and Training (CICM)." Less than half this total was allocated to specific projects. A majority of the money went to support activities such as "experts and activities supply material for dissemination products to policy stakeholders as well as education and training, . . . help train the future researchers to sustain scientific activities as well as engage the community in advising and prioritizing research and training efforts."[235] Once again, more money goes to building a bureaucracy than to improving health.

Even the two nominally health-related projects within this $6.6 million mega-project are of dubious value. The "Child Welfare Data S.M.A.R.T." subproject spent $1.8 million to build a data base that converts existing data on "CM" in each of five states into a standard common format to support "linked administrative data for screening and targeting services . . . to prevent CM [Child Maltreatment]" and then release the format for others to follow.[236] Aside from that being a very long time and a lot of money to reformat data from only five states into a common format, the whole concept of a single large data base of all child abuse cases in the United States should be a significant cause for concern. The opportunities to misuse those data to impinge on individual liberty are legion, especially since the few explicitly named identifiers include "race and culture."

The other sub-project is "Identification of Newborns at High Risk for the Occurrence of Preventable Child Maltreatment." It is described as follows: "The prospect of real-time identification of newborns at risk for CM on the basis of risk indicators available in obstetrical settings to be able to target prevention is exciting, but empirical testing of feasibility and predictive utility of methods are key to any systematic attempt to integrate this in U.S. obstetric or newborn clinical services . . . we contrast the predictive utility of three types of newborn screening for risk of future official-report of CM." The data included in the predictive model will include "retrieval and analysis of a set of medical record and insurance claims variables (for each family)."[237] This could be a violation of the Health Insurance Portability and Accountability Act (HIPAA). But even if it were marginally legal, using tax dollars to build a model of an entire family's medical history to predict whether a child may be subject to later abuse and then intervening to prevent or ameliorate that abuse should be viewed with deep suspicion by anybody who values individual liberty.

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[235] "The Center for Innovation in Child Maltreatment Policy Research and Training (CICM)," *NIH RePORTer*, Project Details, Project Number 1P50HD096719-01.

[236] "Child Welfare Data S.M.A.R.T.," *NIH RePORTer*, Project Details, Project Number 5P50HD096719-02, sub-project 8508.

[237] "Identification of Newborns at High Risk for the Occurrence of Preventable Child Maltreatment," *NIH RePORTer*, Project Details, Project Number 5P50HD096719-02.

Within the child abuse and neglect category, there are multiple projects targeted at specific racial or ethnic groups: Of the 574, recognized Native American tribes, NIH projects focus separately on 37: Sioux and Assiniboine,[238] Menominee,[239] and 34 tribes associated with the Great Lakes Native American Research Center for Health.[240]

Eleven different grants for a single project totaling $22.8 million over six years have been devoted to "Breaking the cycle of intergenerational disadvantage" by collecting data to study neurodevelopment among Puerto Rican children.[241] This is a lifetime research project collecting exhaustive data on a sample of 2,491 Puerto Ricans living in the South Bronx, New York, and San Juan, Puerto Rico. The researchers have published dozens of papers, but no specific health improvements have been documented.

Another series of nine grants totaling $4.2 million over five years used essentially the same data set of Puerto Rican children in the South Bronx and San Juan to study "Childhood Adversity and Cardiovascular Health among Puerto Rican Youth."[242] They claim Latinos are "are vulnerable to the health-related consequences of living in poverty; 32 percent are obese and 22 percent have hypertension. Puerto Rican women have the highest rate of obesity, hypertension and hypercholesterolemia than any other Latino subgroup." The claim that 32 percent obesity and 22 percent hypertension constitute a vulnerability from poverty is incorrect. According to NIH's own data that accompany its budget request, 33.1 percent of the entire US population is obese and 27.1 percent have hypertension.[243] In other words, obesity in the Hispanic population has the same prevalence as in the population as a whole and hypertension has much lower prevalence than in the total population. So, by NIH's own measure, Hispanic poverty is unrelated to the prevalence of either of these indicators for cardiovascular disease. Furthermore, while the official poverty rate for Hispanics is higher than for the population as a whole, the Hispanic population is strongly middle class: underrepresented in both the bottom and highest quintiles of households by income and overrepresented in the middle 60 percent.[244]

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[238] "Wa'Kan Ye'Zah: Enhancing Caregivers' and Children's Well-Being Through an Evidence-Based and Culturally Informed Prevention Intervention," *NIH RePORTer*, Project Details, Project Number 5R01MH115840-02.

[239] "Building a Menominee-Centric Trauma Resilience Model," *NIH RePORTer*, Project Details, Project Number 1S06GM127793-01, 1S06GM127793-02, 1S06GM127793-03, 1S06GM127793-04.

[240] "Great Lakes NARCH - Expanding Community and Academic Partnerships," *NIH RePORTer*, Project Details, Project Number 1S06GM127793-01.

[241] "Breaking the Cycle of Intergenerational Disadvantage: Neurodevelopment Among Puerto Rican Children," *NIH RePORTer*, Project Details, Project Numbers 1UG3OD023328-01, 5UG3OD023328-02, 4UH3OD023328-03, 3UH3OD023328-03S1, 5UH3OD023328-04, 5UH3OD023328-05, 3UH3OD023328-05S1, 5UH3OD023328-06, 3UH3OD023328-06S1, 5UH3OD023328-07, 3UH3OD023328-07S1.

[242] "Childhood Adversity and Cardiovascular Health among Puerto Rican Youth," *NIH RePORTer*, Project Details, Project Numbers 1R01HL125761-01, 5R01HL125761-02, 3R01HL125761-02S1, 7R01HL125761-03, 5R01HL125761-04, 3R01HL125761-04S1, 3R01HL125761-04S2, 5R01HL125761-05, 3R01HL125761-05S1.

[243] National Institutes of Health, "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)," RCDC Funding Summary 05112023.

[244] Phil Gramm et al., *The Myth of American Inequality: How Government Biases Policy Debate* (Rowman & Littlefield, 2022),

As with most similar projects in this category, the authors' train of thought appears to be: "Being raised in lower-income households predisposes children to cardiovascular disease in adulthood." They never give any indication that they considered and tested the alternative that the cardiovascular disease is not related to the household income, but that household income and unhealthy living patterns that lead to disease are both caused by the series of well-known factors that affect income: (in order of importance) the work effort by prime work-age adults in the household, their level of education, their choice of occupation, postponing having children until after completing school, holding a full-time job, and marrying before having children.[245]

The project "Family Violence in Older African American Women" gave more than half a million taxpayer dollars over four years to a highly compensated professional not only to advance her career goals, but also to enable the researcher to apply for yet another grant. The project's abstract simply concludes, "The research and training activities proposed herein will allow Dr. Paranjape to submit an R01 grant towards the end of the award period, providing a timely catalyst for her as she progresses towards attaining her career goal of being a leader in FV [family violence] research."[246] With the focus on building a research bureaucracy, the substance of the project is unclear. In some years it is coded in the "Violence against women" classification and in other years, "Child abuse and neglect." Whether the women are victims or perpetrators, or some combination that is not defined, is also unclear.

In addition to projects that are directly harmful, the child abuse and neglect category also includes projects that are clear cases of waste, fraud, and abuse. They waste taxpayer money on activities that are not research focused on improving mortality and morbidity. They fraudulently claim to be working on such research when they are not. And they abuse the trust that Americans placed in NIH by growing and enriching individuals and companies rather than improving health.

Especially wasteful, and irrelevant to improving Americans' health, are projects that focus on behavioral phenomena in other countries: for example, a half-million-dollar, three-year feasibility study in Zambia on sexual abuse;[247] a third-of-a-million-dollar, four-year assessment of parenting in Kenya;[248] a quarter-million-dollar study of early psychosocial deprivation in Romania;[249] a two-year, nearly-half-million-dollar implementation (not research)

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pp. 150–53.

[245] Phil Gramm et al., *The Myth of American Inequality: How Government Biases Policy Debate* (Rowman & Littlefield, 2022), pp. 59–81.

[246] "Family Violence in Older African American Women," *NIH RePORTer*, Project Details, Project Number 5K23RR023364-05.

[247] "HIV and Child Sexual Abuse in Zambia: An Intervention Feasibility Study," *NIH RePORTer*, Project Details, Project Numbers 7K23MH077532-03, 5K23MH077532-04, 5K23MH077532-05.

[248] "Assessing Parenting Practices and Service System to Adapted a Prevention Program to Promote Child Wellbeing in Kenya," *NIH RePORTer*, Project Details, Project Numbers 1R21HD094227-01A1, 5R21HD094227-02.

[249] "Early Psychosocial Deprivation and Risk Taking Among Adolescents in Romania," *NIH RePORTer*, Project Details, Project Number 1R21DA031357-01A1.

of a child mental health prevention program in Uganda;[250] a third-of-a-million-dollar intervention to prevent family violence in Sierra Leone;[251] and a half-million-dollar project to study "Social Inequality and Children's Mental Health" by using a sample of 2,232 children who were twins born in England and Wales.[252] (There may be other projects funded in foreign locations, as these examples were retrieved from high-level summaries that may have omitted the geography.)

Perhaps the most egregious examples of wasteful, abusive, and even fraudulent are NIH grants that fund existing commercial activity while calling it research in child abuse. One example was a series of four grants totaling $1.9 million to a project leader at Washington University in St. Louis for "Preventing Conduct Disorder Among Children in the Child Welfare System." There was no research involved. The grant was spent to acquire and implement the so-called Pathways Triple P, or Positive Parenting Program. Some comparisons are proposed between the outcomes of Triple P and the existing treatment methods used in the St. Louis child welfare system.[253] Aside from the fact that the small sample size of 140 is too small to detect any differences less than about 10 percent, the grant itself amounts to an inappropriate government intervention into private enterprise. The Triple P methods are the product of Triple P International, an Australian corporation with headquarters in Brisbane. The corporation claims its methods constitute "one of the most effective evidence-based parenting programs in the world, backed up by more than 35 years of ongoing research... Triple P is used in more 30 countries and has been shown to work across cultures, socio-economic groups and in many different kinds of family structures."[254] We have not investigated the Triple P claims, but there should be enough information for a due diligence determination on whether to adopt or try this method in St. Louis. NIH should not be doing the work for St. Louis child welfare services to decide whether to buy this approach or the promotional work of Triple P International to sell it.

Another such project paid Terra Nova Learning Systems (which seems to have gone out of business since) $120,126 to prepare a resource guide for caregivers of children with fetal alcohol spectrum disorder.[255] The project involved no research, only taking known information and preparing a book from it. Terra Nova still sells

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[250] "Implementing a School-Based Child Mental Health Prevention Program in Uganda," *NIH RePORTer*, Project Details, Project Numbers 1R21MH097115-01A1, 5R21MH097115-02.

[251] "mHealth Tools to Improve Service Delivery Quality of an Evidence-Based Family Home Visiting Intervention to Prevent Family Violence among High Risk Families in Sierra Leone," *NIH RePORTer*, Project Details, Project Number 1R21MH124071-01.

[252] "Social Inequality and Children's Mental Health," *NIH RePORTer*, Project Details, Project Numbers 1R01HD061298-01, 1R01HD061298-02, 1R01HD061298-03, 1R01HD061298-04.

[253] "Preventing Conduct Disorder Among Children in the Child Welfare System," *NIH RePORTer*, Project Details, Project Numbers 1R01HD061454-01A1, 5R01HD061454-02, 5R01HD061454-03, 5R01HD061454-04, 5R01HD061454-05.

[254] "Triple P Takes The Guesswork out of Parenting."

[255] "Improving the Lives of Children with FASD: An e-Learning Resource for Car," *NIH RePORTer*, Project Details, Project Number 1R43AA018230-01.

books on Amazon, although there is no sign of this one.[256] A for-profit business wrote and sold the books, so why is NIH subsidizing it?

Other projects funded in the child abuse area give further evidence of the wastefulness of this research. One project proports to test whether the presence of a dog in interviews with children has an effect on the interview. Another compares mothers' brain activity when shown pictures of dogs and children. A third wants to develop an online game to learn how foster and primary parents of neglected children can improve their cooperative parenting. This is one of several projects that tried substituting web-based tools of one sort or another to resolve parenting issues, without first having diagnosed the cause.[257]

11.2 Violence research/ Youth violence/ Youth violence prevention/ Violence against women/ Firearms research

Violence in its various manifestations is an important problem. Some violence arises from people with mental disorders that predispose them to engage in violent behavior. Those conditions are part of the NIH mental health research agenda. What is wrong with these "violence" categories is the implication that violence itself is an illness to be treated. Violence may be a symptom of some mental disorders, but it is not a disease itself. Violence (except in situations of self-defense) comes from immoral choices people make, not because of some disease that makes people do bad things.

Most of the "violence" projects funded by NIH are just financial supports for behavioral and social science topics masquerading as health problems. To think of violence as a disease is to minimize its threat and ignore its causes. The Civil War was not the manifestation of mental illness of epidemic proportions. The vast numbers of murders in the south side of Chicago aren't caused by the impurities in the drinking water there. Mexican drug cartels do not suffer from some genetic defect. Violence is mostly a matter of ethical choice. There are spectacular examples of mentally ill individuals perpetrating violent acts, but they are just that, single spectacular examples in a vast sea of smaller-scale immoral choices. The terrorists who have murdered Americans and other victims worldwide may appear to be crazy, but they have not made immoral choices because of some mental defect. They were trained that way or made conscious choices to harm others.

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[256] Terra Nova Learning Systems, *Channel Green* (Terra Noval Earning Systems, 2016).

[257] "Dog Presence and Children's Stress During Forensic Interviews for Child Abuse," *NIH RePORTer*, Project Details, Project Number 5R03HD070557-02. Luke E. Stoeckel, Lori S. Palley, Randy L. Gollub, Steven M. Niemi, Anne Eden Evins, "Patterns of Brain Activation When Mothers View Their Own Child and Dog: An fMRI Study," *PLOS One*, October 3, 2014. Conducted with funding from NIH grants K23 DA032612/DA/NIDA, K24 DA030443/DA/NIDA, P41 RR014075/RR/NCRR, UL1 RR025758/ RR/NCRR. "Online Training for Foster and Primary Parents of Neglected Children," *NIH RePORTer*, Project Details, Project Number 1R43HD077964-01. "Web-based Parenting Intervention for Mothers of Infants At-Risk for Maltreatment," *NIH RePORTer*, Project Details, Project Number 5R01HD064870-04. Edward G. Feil, Kathleen Baggett, Betsy Davis, Susan Landry, Lisa Sheeber, Craig Leve, and Ursula Johnson, "Randomized Control Trial of an Internet-Based Parenting Intervention for Mothers of Infants," *Early Childhood Research Quarterly* 50 (2020): 36–44.

By all means, we may need more research on mental conditions that predispose people toward violence, but to target health research on symptoms of violence broadly is wasteful, will have no meaningful effect, and ignores the vital-few real problems that cause the vast majority of violence.

So, what useful insights has NIH provided to help us through this long and bloody history of human violence? In one example at the cost of a mere $325,525, we have learned, "Wives would find marriage more satisfying if they could calm down faster during arguments with their husbands."[258] Really? That is a clear case of blaming the victim. But wait! There is more. The Department of Health and Human Services also featured this research in one of its "Healthbeat" broadcasts, beginning with a silky-smooth voice saying: "Calm down."[259] Not only did we pay for NIH-funded academics to tell us something both sexist and useless, but we then paid to publicize it with slick media.

The "firearms" classification within the larger violence category included 29 active, funded projects as this analysis began in August 2023. Only one, a study of the effects of copper fragments on brain tissue, could be reasonably considered a matter of human health.[260] The remainder are mere speculation about causes of violent behavior, not medical science.

NIH efforts to analyze firearm events seem like an instance of looking at symptoms for what is essentially a social problem. Firearms seem to be the only cause of death studied by NIH that has no origin in biological diseases and conditions. For example, in 2023 the number of deaths by firearms was 14.0 per 100,000. That was less than half as many deaths by poisoning (32.7 per 100,000), and slightly less than deaths from accidental falls (14.5). That was only a few more than deaths in automobile accidents (12.9). For most of the last 50 years automobile accident deaths have been much higher than firearm-related deaths, but the effects of COVID policy forced people to remain in close proximity to each other for extended periods, increasing opportunities for violent interactions while reducing travel and the attendant possibilities for accidents.[261] Yet there is no proposal from NIH to spend money to test whether homes with a car are more likely to suffer from deaths by automobile or conduct experiments to test alternative interventions on automobile storage or access. Where are its studies of the role of stairways with recommendations to remove stairways from homes? Or remove throw rugs? Or forbid the sale of poisonous cleaning solutions?

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[258] Senator Tom Coburn, MD, *Wastebook 2013*, p. 27, citing NIH Grant 5T32MH020006. Lian Bloch, Claudia M. Haase, and Robert W. Levenson, "Emotion Regulation Predicts Marital Satisfaction," *Emotion*, American Psychological Association, November 4, 2013.

[259] "Re: HHS Healthbeat: Calm down," Audio blog comment, HHS.gov, US Department of Health & Human Services, November 19, 2013.

[260] "Penetrating brain injury and copper fragments in a rat model of posttraumatic Epilepsy," *NIH RePORTer*, Project Details, Project Number 1R21NS123583-01.

[261] John Gramlich, "What the Data Says About Gun Deaths in the U.S." *Pew Research Center*, April 26, 2023; "Historical Fatality Trends: Car Crash Deaths and Rates," *National Safety Council*.

Among the current 28 projects in the firearms category, excluding the one study of the effects of copper fragments on brain tissue, only four propose to measure the relative effectiveness of existing interventions in reducing the incidence of firearm-related violence. While the topic is outside the purpose of NIH, these projects are at least plausible efforts to look at the effect of different interventions on firearm-involved violence.[262]

The remaining 24 projects do not even meet that low standard. Three projects might best be labeled as "overhead" projects, since they do not directly test any scientific hypotheses about improving health or even reducing gun-related violence. These overhead projects include the single largest project in the firearms category—$5.5 million to establish the "University of Michigan Multi-disciplinary Coordinating Center for the Community Firearm Injury Prevention Network."[263] This project features some of the prototypical failures of many of the projects, so we will look at it in more detail.

The abstract for the project begins, "Firearm injury is a major U.S. public health crisis requiring urgent attention. Firearm injuries have increased in the past decade, with >400,000 fatalities and ~1.2 million non-fatal firearm injuries. Disparities exist and are reflective of underlying structural factors (e.g., racism)." This statement is misleading. The "more than 400,000 fatalities" is the total for the entire decade, not the usual annual numbers that are reported either in normal discourse or in technical research. The structure of the sentence, while mentioning "decade" does so as "injuries have increased in the past decade," implying growth over the decade, not clearly documenting that the 400,000 is the sum of incidents for the entire ten years. More significantly, the abstract uses the total number of deaths rather than deaths per 100,000 people. That mistake might be understandable in the popular press, but the authors of NIH papers should be epidemiologists or other scientists who know that the incidence per 100,000 people is the proper measure. Furthermore, while there has been an increase in gun deaths over the last 10 years, that increase followed a long decline, and using the proper measure of events per 100,000 people, gun deaths have declined by 12 percent since 1974.[264] That 10-year increase is almost entirely the result of large COVID-related jumps in 2020-2021. It is too early to tell whether the higher level will endure going forward or is merely a special cause. Finally, the abstract claims, "Disparities exist and are reflective of underlying structural factors (e.g., racism)." That is stated as if it were a fact, not as a hypothesis to be tested, and no evidence is presented to suggest this is even a reasonable hypothesis.

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[262] Selected from "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)," March 3, 2023, *NIH RePORTer*, Projects Numbers 1R01HD108027-01, R01HD108017-01, 1R61MH125759-01, 1R61AA029064-01.

[263] "University of Michigan Multi-disciplinary Coordinating Center for the Community Firearm Injury Prevention Network," *NIH RePORTer*, Project Details, Project Number 1U24HD111315-01.

[264] John Gramlich, "What the data says about gun deaths in the U.S." Pew Research Center, April 26, 2023.

This project conducts no research. It is strictly overhead for running a network of more than 30 researchers at 14 universities. Its five stated aims are: (1) "Provide centralized administrative, operational, and logistical infrastructure," (2) "Provide expert consultation and technical assistance . . . as well as establish the data infrastructure," (3) "Ensuring community voice in the research design, methods, and results interpretation," (4) "Provide expert consultation . . . to enhance sustainability," and (5) "Disseminate key findings."

The other two overhead projects aim to develop a program to treat "burnout" among staff members working on gun violence research and to build staff to do research on gun violence. These are not research. They are traditional bureaucracy and government waste.[265]

Another 13 programs have been given money to implement specific interventions in some geographic areas and then evaluate them. They typically focus either on promoting storage protocols for firearms or on intervening with people in hospital emergency rooms identified "at risk" of firearm violence. They spend most of the money on implementing a chosen intervention, not research.

One project illustrates the frequent lack of strategic focus and relevance even within the topic area. It has spent $1.4 million in "Developing an upstream suicide prevention approach to encourage safe firearm storage in rural and remote Alaskan homes" of Alaskan Native families with teenagers.[266] There are only 20,151 Native Alaskan teenagers in the entire United States.[267] Assuming the project summary is correct that Native Alaskan teenagers have 18 times the suicide rate of American teenagers overall, that would imply 55 suicides annually among the total group. But only a fraction of the 55 live in Alaska, and still fewer in "rural and remote" homes. Each of the 55 would be a tragedy, but this is not spending that will solve the problem; this is spending on a wild guess that it might help. But the $1.4 million will not even change the state of knowledge about the problem from mere guess to fact. The proposed intervention on firearm storage will be tested on only 15 families, costing almost $100,000 per family. A sample that small has a less than a 10 percent chance of yielding any statistically significant outcomes. The project abstract concludes, "This formative research sets the stage for a larger fully powered randomized trial to evaluate FSN efficacy to increase safe household firearm storage of people who have multiple firearms, and whose youth are at extremely high risk for suicide." But it does not say what outcome would justify further spending. Since the sample sizes are inadequate to suggest any possibility of efficacy from this approach, does that mean that NIH plans on spending the money irrespective of the results?

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[265] Selected from "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)," March 3, 2023, *NIH RePORTer*, Projects Numbers 1R21AT011863-01 and 5R24HD087149-05.

[266] "Family Safety Net: Developing an Upstream Suicide Prevention Approach to Encourage Safe Firearm Storage in Rural and Remote Alaskan Homes," *NIH RePORTer*, Project Details, Project Number 1R61MH125757-01.

[267] United States Census Bureau, *Total Population by Sex, age, and Detailed Tribal Grouping Alone*.

Another seven funded projects propose to identify the underlying social root cause of firearm violence. There is some variation among the projects, but one captures most of the elements common to all of them. The project abstract begins, "Gun violence is an escalating national crisis that shapes overall levels of population health including average life expectancy. Crucially, in order to effectively address this crisis, it is imperative that we identify its root social causes, which may include social determinants of health (SDoH) such as income disparities and social mobility, and that we modify these root causes through corresponding policies."[268]

Note that the project begins with a false prior, namely that gun violence is escalating. As already shown, the rise is short-run and heavily influenced by the COVID-19 pandemic. Long-term, gun-related deaths are down from their peak. The proposal also quickly shifts into acronym jargon, using SDoH for social determinants of health as though they constituted some well-established set of factors, when in fact they are just hypotheses and could be almost anything. The project is not specific as to which hypotheses it will test and how they will be tested. The only two social determinants listed are income disparity and social mobility. Neither income disparities nor social mobility have a standard, accepted definition and measurement, so what metrics will the project use? Furthermore, an extensive research literature suggests that income inequality is modest and becoming smaller and that economic mobility is strong and growing.[269] The proposal shows no awareness of the literature on these points.

The proposed research would correlate the average of the social determinant variables such as income disparities and social mobility "by area of residence." The average values of race, socioeconomic status, and urban vs. rural residence for each of these areas will be correlated with the corresponding averages of mortality by homicide and suicide for the same areas. Even in high-crime neighborhoods, the number of people committing crimes, or who are victims of crime, is relatively small, so comparing averages across entire geographic areas will introduce substantial specification errors in any models developed. This is a poor choice of method that correlates averages of outcomes across some element of geography with other averages of hypothesized causes. That destroys all the variation within the geographic area and eliminates some of the most powerful and useful statistical tests, such as analysis of variance, Kruskal-Wallis[270], and others. At a minimum the proposal does not even show awareness of these issues, much less address how it will deal with them.

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[268] "Comparative Assessment of Modifying Social Determinants of Health to Reduce Firearm-Related Mortality and Disparities," *NIH RePORTer*, Project Details, Project Number 5R21MD015812-02.

[269] Phil Gramm et al., *The Myth of American Inequality: How Government Biases Policy Debate*, (Rowman & Littlefield, 2022); Bruce D. Meyer and James X. Sullivan, "Winning the War on Poverty: Poverty from the Great Society to the Great Recession," Working Paper no. 18718, National Bureau of Economic Research, January 2013; Daniel T. Slesnick, *Consumption and Social Welfare: Living Standards and Their Distribution in the United States* (Cambridge University Press, 2001), p.154 ff; Dirk Krueger and Fabrizio Perri, "Does Income Inequality Lead to Consumption Inequality?" Review of Economic Studies, March 2006.

[270] Kruskal-Wallis is a non-parametric test of centrality for three or more samples and is used instead of analysis of variance when data are not distributed normally. See Peter Sprent and Nigel C. Smeeton, *Applied Nonparametric Statistical Methods*, fourth edition, (Chapman & Hall/CRC, 2007), p. 196 ff.

But more important than the technical flaws in the analysis is the underlying failure to understand that both homicide and suicide are the result of individual human decisions to kill. These are ethical decisions based on the values that the individual has learned either formally or informally. If an individual's neurological makeup were to prevent normal human ethical reasoning, that would be a matter for psychoanalytical or neuroscience research, but SDoH regression analysis is inherently unable to make those determinations.

The vast majority of people with unequal incomes or failure to be upwardly mobile do not commit murder or suicide. In any group of people defined by the typical socioeconomic characteristics, such as those SDoH constructs, the vast majority do not commit murder or suicide. Research that attributes unethical behavior to individuals based on their extrinsic characteristics such as level of economic success or on the extrinsic characteristics of their victims treats humans as automatons driven by their environment rather than as free individuals capable of making choices. Killing a human being is the result of an ethical decision. Ethical decision making is not within the professional competence of NIH, nor within its legislated purpose. More critically, assessing and tinkering with ethical decisions is a major infringement on individual freedom and autonomy.

The third aim for this project on underlying social root causes of firearm violence is of particular consequence and concern. It explicitly states the intent to develop and promote policy changes by government.

Most NIH projects in the firearms category assert similar explicit intent. One project is even titled: "The Individual, Situational, and Contextual Risk Factors for Violent Firearm Injury and Firearm Homicide: A Comparative, Policy-Focused Approach." The development and promotion of policy with respect to gun control is explicitly prohibited by the "Dickey amendment," named after Representative Jay Woodson Dickey, Jr. (R, Ark.), who sponsored it in the 1996 appropriations bill. It provides that "None of the funds made available in this title may be used, in whole or in part, to advocate or promote gun control."[271] The amendment originally applied only to the Center for Disease Control and Prevention (CDC), but it was subsequently broadened to include NIH and incorporated into subsequent appropriation bills.[272] An explicit request by the Obama Administration to allocate funding for CDC work gun regulation was denied by Congress. The Committee Report accompanying the 2018 appropriations bill that included the prohibition language also included the following note: "[w]hile appropriations language prohibits the CDC and other agencies from using appropriated

[271] Centers for Disease Control and Prevention, "Additional requirement 13: Prohibition on Use of CDC Funds for Certain Gun Control Activities." Allen Rostron, "The Dickey Amendment on Federal Funding for Research on Gun Violence: A Legal Dissection," *American Journal of Public Health* 108, no. 7 (July 2018): 865–67. Rostron gives a good, short summary of the history of the Dickey amendment. Although he does not like the amendment and wants more research on policy changes, his description of the history and actual content of the amendment is clear and accurate.

[272] Consolidated Appropriations Act, Pub.L. No. 115-141 (2018).

funding to advocate or promote gun control, the Secretary of Health and Human Services has stated the CDC has the authority to conduct research on the causes of gun violence."[273] This does not change the plain reading of the original amendment in the bill itself, but many of the projects that have been funded since this addition certainly stretch, and probably violate, the provision, with or without the committee's citation of the Secretary's language. These cases skirting the explicit provision suggest that Congress needs to be more explicit in forbidding spending on firearms research related to making policy. It would also be wise to stop all government-funded research on firearm regulation and control, which can all arguably be precluded by the Second Amendment.

The project "The Individual, Situational, and Contextual Risk Factors for Violent Firearm Injury and Firearm Homicide: A Comparative, Policy-Focused Approach," implicitly raises an issue of substantial concern.[274] The study project leader Brendan Lanz recommends that any study should include not just the lethal use of guns, but also the physically non-injurious (such as a gun being brandished but not used) and injurious but not lethal. He makes the plausible case that the causes of events with no gun being fired or with non-lethal shots may differ from those with a lethal outcome, and that the policy effects may differ as well.

With that much insight, it is surprising that he did not expand his scope to include defensive gun use in addition to the offensive gun use that is the typical measure analyzed in most studies. It is plausible that he might include defensive uses in his expanded scope, but he does not mention it explicitly. Defensive gun use to prevent physical harm to oneself or others is almost never considered. But a study of defensive gun use by Gary Kleck and Mac Getz showed that defensive use of guns by adults other than those in law enforcement could be as high as 2.5 million times per year, even though the defender actually discharge the weapon in only 16 percent of the cases, and most were never reported in any official record. They also reported results from other studies that used different data sources and methods to calculate estimates of annual defensive firearm uses between 0.76 million to 3.6 million.[275] The project manager for this NIH study is in the same department at the same university as Kleck and Getz (Florida State University, College of Criminology and Criminal Justice) and would likely have at least some familiarity with their work, so it seems odd that he does not suggest that defensive use should also be added to the categories to be considered.

After the Kleck-Getz study was published, the CDC added questions about defensive use to its annual its Behavior Risk Factor Surveillance System survey for three successive years and then stopped. It never published

[273] *Division H – Departments of Labor, Health and Human Services, and Education and related agencies Appropriations Act, 2018*, 23.
[274] "The Individual, Situational, and Contextual Risk Factors for Violent Firearm Injury and Firearm Homicide: A Comparative, Policy-Focused Approach," *NIH RePORTer*, Project Details, Project Number 1R01MD017204-01.
[275] Kleck, Gary and Marc Gertz, "Armed Resistance to Crime: The Prevalence and Nature of Self-defense with a Gun." *Journal of Criminal Law and Criminology* 86, no. 1 (1995): 150-87.

or publicized the existence of these data, much less the results. However, the individual micro survey responses were included in the public-use data files from the full survey, which were found and analyzed by several people. The CDC data show approximately 1 million cases of defensive gun use annually. Although this estimate is smaller than the Kleck-Getz survey, the CDC survey suffered from several limitations that might explain the difference, but even this smaller number was apparently not acceptable to the CDC administrators at the time, so instead of publishing the data—which taxpayers paid for—the CDC merely tried to hide it. The CDC's only comment on its failure to publish the results was "Data from the optional module data were made available to the public to analyze via the BRFSS public use dataset online."[276]

Sometime around 2019, the CDC posted an undated fact sheet on its website summarizing research results on firearms. With new people at the helm, the fact sheet included the Kleck-Getz study along with many other citations of varying estimates. Then in late 2021 leaders of groups lobbying to restrict and eliminate private ownership of guns enlisted Senator Dick Durbin and the White House to pressure the CDC to remove the Kleck-Getz study. Emails between the outside advocates and CDC staff were obtained by The Reload newsletter through Freedom of Information Inquiries. They show that the gun-control advocates urged CDC to remove the offending references because "in the time that study has been published as 'a CDC Study' gun violence prevention policy has ground to a halt." In the end, the fact sheet was removed from the website.[277] While this was the CDC and not NIH in this case, the agencies of course discuss such matters among themselves, both CDC and NIH are subject to the same cabinet secretary and same Office of Research Integrity, and the group of researchers that are funded by either or both are well aware of the ongoing policy changes. Whether the research proposals self-censored to exclude defensive firearm use or were ordered to do so is not important. The fact is that none of the funded projects include consideration of defensive use of firearms after the intense political lobbying removed all reference to studies on the topic. The implicit message of the whole defensive-use episode was that government would pay for and publish only the data that fit with its priors, and that researchers seeking government funding should avoid the topic.

In Chapter 7 we demonstrated that increasing the "diversity" of researchers' secondary characteristics does not improve research outcomes, and may, in fact, make the research weaker and less reliable. Additional examples of how diversity objectives weaken strategy were included in Chapter 8. This failure repeats itself throughout the NIH work and the firearm category offers another example.

[276] Brian Doherty, "A Second Look at a Controversial Study About Defensive Gun Use," *Reason*, September 4, 2018.
[277] Stephen Gutowski, "Emails Show CDC Removed Defensive Gun Use Stats After Gun-Control Advocates Pressured Officials in Private Meeting," *The Reload*, December 15, 2022.

The project "Translating Behavioral Interventions for Health Disparity Populations" was awarded $1.6 million for which its number one priority was, "Mentoring to increase the diversity of the biomedical workforce. . . . mentored 13 NIH fellows and 12 non-NIH trainees (25 total during this reporting period). Of these, 23 were from groups that are diverse racial-ethnic groups."[278] Just how the extrinsic features of new members of the research team improved the mortality and morbidity of the population was never explained, but the project reported: "These trainee publications and presentations have been critical to their continued career progress." The project documents no improved health outcomes, but it does list papers on disparate health outcomes for "racially-ethnically diverse, low-income, and rural U.S. populations."

The disparities discussed in these papers include: "financial hardship . . . several neighborhood measures [like] racial-ethnic composition, population density, segregation measures, neighborhood socioeconomics, commercial and natural environment (e.g., green space, number of grocery stores), and neighborhood health care measures (e.g., medically underserved area) . . . stress management program among Spanish-speaking Latina breast cancer survivors, . . . individual and structural barriers which lead to disparities . . . trauma and gun violence disparities."

These studies have multiple technical difficulties. But the most significant failures are more fundamental. The leadership is focused on meeting "diversity" goals for the immutable physical characteristics of the researchers that create no value for reducing the population's mortality and morbidity. They also are both explicitly and by example teaching new, developing scientists to apply bad research habits.

This approach to "research" of testing dozens of outcome measures against multiple potential causative classifications—such as race, gender, sex, population density, density of grocery stores, etc.—is not science. It is simply rolling the dice. If the researcher tested 12 dependent outcomes variables by 12 independent variables of putative causes, there would be 144 combinations. Even if there were no real causal relationships, statistical testing would show seven of the combinations to be statistically significant simply as the result of random variation. If the computer runs showed 14 combinations to be significant, in fact about half of them would likely be merely random coincidence, and the other half would be meaningful. But there would be no way of knowing which was which without additional information.

[278] Anna Napoles, "Translating Behavioral Interventions for Health Disparity Populations" Project Number 1ZIAMD000014-05.

12 Projects Irrelevant to NIH's Mission

One of the common, documented behaviors of government and government workers is to use governmental power to keep expanding their reach of control and resource consumption. In the private sector, a business grows because it delivers goods and services that consumers willingly, even eagerly, purchase and consume. If they are happy with their purchase, they will return to buy more. If not, they will shift their spending elsewhere. But in government generally—and its bureaucratic creature NIH—growth in staffing and expenditure is driven by political maneuvering and trading favors.

In the case of NIH, expenditures began to explode from 1957 onward as an outlet for political determination to beat the Russians in space, although NIH had no role in that effort. While that initial impetus has waned, the natural bureaucratic impulse to spend more has grown. In other chapters, we have focused on failed strategic intent, multiple examples of funding that violated the canons of the scientific method, and projects that pose a threat to our liberty. In this chapter, we look at categories of NIH projects that have no meaningful relationship to improving American's morbidity and mortality.

NIH projects should be selected to advance the care and treatment of Americans suffering from diseases or poor health conditions. Then, and only then, should funding for the project be determined. Research in the private economy works successfully applying this mission-focused research model.

12.1 Behavioral and Social Science/Basic Behavioral and Social Science

Behavioral and Social Science constitutes almost 19 percent of NIH expenditures, but this is not medical, psychiatric, psychological, or biological science. It cannot detect, treat, or cure diseases. It is about how people behave and how to influence and control those behaviors. Medical conditions may influence behavior, so behavioral symptoms may be appropriate subjects for targeted research on specific medical conditions. But the intent of government financed behavioral and social science research should be cause for concern. Harmful behaviors induced by disease or that cause disease should be investigated as part of curing or preventing that disease, not as a behavioral social science exercise. Government should not be investigating how to influence and control its citizens. Citizens, on the other hand, have the right to influence and control their government.

Consider the budget justification for the National Institute on Aging. In the summary of its proposed research program, it highlights work on Alzheimer's disease, other age-related cognitive changes, research on the genetics and biology of aging, and clinical studies to reduce disease and disability. One might challenge

whether any of that work is most effectively conducted as a government enterprise, but it is certainly within NIH's stated mission. The list does not end there, however. Included with the expected efforts to reduce mortality and morbidity are "Investigations of the behavioral and social aspects of aging."[279] That is clearly outside the mission of NIH. Choices of behavior and socialization are personal and civic decisions. Government has no legitimate role in such decisions, which are not within the scope of reducing mortality and morbidity.

One of these projects spent more than $2 million on a grant to study the effects that singing in a community choir had on aging minority adults. The project recruited 450 "minority elders" to participate in choirs at senior centers in San Francisco. The only published paper that resulted from this grant was a study of a community choir in Finland.[280] How is that subject the proper concern of the federal government of the United States of America, especially at a $2 million cost?

Another series of grants totaling $432,000 funded interviews with 60 users of a mobile phone app designed to find sexual partners. The study was intended "to understand how sexual risk behaviors . . . may be facilitated by the nature of GPS-enabled smartphone applications, the way they are used, and the process by which sexual partnering occurs via smartphone applications," and to "Investigate the sexual and emotional states (e.g., more/less urgency, arousal, impulsivity) that [users] experience when seeking or meeting sexual partners using smartphone applications."[281] This is a particularly invasive and inappropriate subject for government investigation. Even if the topic were appropriate and useful, the study design is fatally flawed because it relies solely on the personal opinions of the 60 people in the study. There is no objective measurement.

In addition to being out of scope and lacking reliable data, the study design makes any results useless. The sample size is so small that the resulting sampling error would be very large with the results unable to distinguish statistically between one-third of the participants and two-thirds of the respondents giving a particular response. Even if the sample were large enough, there is no indication that the sample was drawn randomly from a nontruncated universe of users, so non-sampling error may be even larger than the huge sampling error. Finally, there is no control sample of otherwise identical non-users, so there is no way to know whether the observed responses of users are different than those of non-users.

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[279] "National Institute on Aging Congressional Justification FY 2004," p. NIA-9.

[280] "Community Choirs to Promote Healthy Aging and Independence of Older Adults," *NIH RePORTer*, Project Details, Project Number 5R01AG042526-03. Also, Elizabeth Harrington, "Feds Spend $2 Million to Get Old People to Join Choirs," *Washington Free Beacon*, September 30, 2014.

[281] "Use of Smartphones Applications for Partnering among MSM," *NIH RePORTer*, Project Details, Project Number 5R21MH096639-02. Summary of total grants see Elizabeth Harrington, "Feds Spent $432,000 Studying Gay-Hookup Apps," *Washington Free Beacon*, January 22, 2015.

Table 9.1 shows that 41.3 percent of total behavioral and social science spending is on "basic" behavioral and social science. This is a misuse of the term "basic," which is used in the physical and biological sciences to denote research on the fundamental, underlying laws of nature—for example genomics, search for the Higgs boson, Maxwell's equations, or improving the precision universal constants such as Planck's constant or the gravitational constant. "Basic" is meaningless in the context of behavioral and social investigations.

Next, we examine a few projects from this classification to see how the category is applied in practice. The project "Play & Learning Across a Year (PLAY)" has, so far, spent $6,341,419, paying 63 different researchers to make videos of 900 mother-infant (ages 12 to 24 months) pairs and "code" their behavior to "exploit the power of video to reveal the richness and complexity of behavior" and "demonstrate the value and feasibility of a cross-domain synergistic approach, and advance new ways to use video as documentation." There are no reported efforts to tie the work to the etiology of any disease, its symptoms or signs, its causes, its treatment, or health outcomes, just a new research methodology that codes infant-mother interactions into a series of subjective categories. The project reports "No outcomes available."[282]

The project claims to have funded 23 journal articles. The three most recent listed as of this writing offer some insight into the nature of this PLAY project. The first article documents a new method of how to measure dual language learning, with the conclusion that the new method "showed near-perfect associations" with a prior metric when applied to 10 bilingual mothers of children 18-24 months old. That sample is too small to be useful and likely contains significant non-sampling errors, since it is not a random sample of the relevant population. Equally important, the project offers no explanation or discussion of why one would develop and promote a new metric that offers no new insights and is merely a nearly perfect correspondence to the existing metric.[283]

The second paper. extols the virtues of using video in infant research.[284] A third paper concludes mothers of 13–23-month-old children spoke more to their child when they were within arms-length of the child and that the child spoke more words at an arm's length distance from its mother. The child, however, babbled with no recognizable words in equal amounts both within and outside close range.[285]

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[282] "Play & Learning Across a Year (PLAY)," *NIH RePORTer*, Project Details, Project Number 5R01HD094830-05.

[283] Catherine S. Tamis-LeMonda et al., "Comparing Apples to Manzanas and Oranges to Naranjas: A New Measure of English-Spanish Vocabulary for Dual Language Learners," *Infancy: The Official Journal of the International Society on Infant Studies* 29, no. 3 (2024): 302 –326.

[284] Karen E. Adolph and Robert C. Froemke, "How to Get Rich Quick: Using Video to Enrich Psychology and Neuroscience Research Comment on 'Beyond Simple Laboratory Studies: Developing Sophisticated Models to Study Rich Behavior' by Maselli et al," *Physics of Life Reviews* 48 (March 2024):16–18.

[285] Catalina Suarez-Rivera et al., "Within Arms Reach: Physical Proximity Shapes Mother-Infant Language Exchanges in Real-Time," *Developmental Cognitive Neuroscience* 64 (December 2023): 101298. DOI: 10.1016/j.dcn.2023.

These are typical social science papers. They are methodological and in the field of early childhood development without any indicated relevance to dealing with medical conditions. None are relevant to the etiology, diagnosis, treatment, or cure to any disease.

Summaries of the remaining 20 articles claimed by PLAY show that 18 have no documented relationship to morbidity or mortality. But two summaries hint that they might, so we looked at them in more detail.

The article "Autism: The face value of eye contact" appears to offer useful insights into the limitations of the long-established use of "face looks" in diagnosing and treating autism.[286] It appears to be the type of research that might contribute to diagnosing and treating a significant condition. Yet, we were disappointed to discover that while the "Play & Learning Across a Year (PLAY)" project claims to have funded the article, the journal publishing the article does not list the PLAY project as a funding source, though one of the authors is a principal investigator on the PLAY project. More fundamentally, the article is not reporting the authors' own research, but rather summarizing work by another researcher funded by a different grant and using an interesting and innovative method that is not included in the PLAY documentation.[287] Clearly, it is good that researchers read and even write about each other's results, but the PLAY project has spent more than $6 million and not produced any results relevant to health.

The paper "(Hyper)active Data Curation: A Video Case Study from Behavioral Science" looks like it might contribute the health literature, but it does not. It merely lists in minute detail how to create and curate a video library, using material from research on hyperactivity as an example of how to manage the video collection. There is no discussion of any material health outcomes from the research, just pages and pages of details about curating the recordings. Although the PLAY project includes this paper as part of the literature it has funded, the journal publishing the paper does not indicate funding from PLAY. Most importantly, this paper, as is the case with the rest of the project, shows no contribution to health.

The project "Successful Aging in a Time of Wildfires" has spent $1,297,394.[288] It proposes "to examine the effects of chronic and acute wildfire smoke exposure on the successful aging of community-dwelling older adults living in California." Nowhere in the description of the proposed project is the term "successful aging" defined. That is not because there is some widely accepted definition. As one paper on the subject notes, "a standard definition of successful ageing remains unclear and various operational definitions of concept have been used in

[286] Karen E. Adolph and Kelsey L. West, "Autism: The Face Value of Eye Contact," *Current Biology* 32, no. 12 (June 20, 2022): R577-R580.
[287] Julia Yurkovic-Harding et al., "Children with ASD Establish Joint Attention during Free-Flowing Toy Play without Face Looks," *Current Biology* 32, no. 12 (May 12, 2022) : 2739–2746.
[288] "Successful Aging in a Time of Wildfires," *NIH RePORTer*, Project Details, Project Number 5R56AG072567-02.

various studies."[289] If there is no clear, widely accepted definition, and the proposed project does not provide its own definition of how it will measure its effect, then it is vulnerable to mere subjective manipulation.

In the last three years, NIH has funded 27 other projects at the cost of nearly $19 million to measure the effects of wildfire pollution on people with limited lung or cardiovascular function. From these we know that one can counter the negative effects by avoiding breathing the polluted air by either moving way or by staying indoors with high-efficiency HVAC air filtration system. This project will focus on a sample of 1000 "community-dwelling older adults living in California." While none of the other 27 projects were confined to California, four included California in the sample, so it's not at all clear that there is any new information to be garnered from this project. The project says it will measure "how sociodemographic factors shape older adult exposure to wildfire smoke and how this exposure subsequently impacts the functional, cognitive, and socio-behavioral aspects of successful aging." It then describes in some detail how it will measure the levels of exposure, and that the sample will be "racially and ethnically diverse." None of this is new information.

The project posits as a goal, "to develop and test an ecological model for successful aging in older adults exposed to wildfire emissions that integrates exposure and behavioral data to determine the relationship between wildfire smoke exposure and successful aging outcomes." "Behavioral data" is the only element here that is not included multiple times in other projects and is this project's only distinction from dozens of others, yet it has no description. What behavior data will be collected and how? And what theories of its relationship to "successful aging" will be tested? The proposal is silent on those questions, which represent the one possible contribution it might make. That silence may be because the answer is already known. Those who move into or stay inside a structure with good HVAC will not suffer as much. What more could this project tell us for $1.3 million?

Three continuing projects in this category deal with Alzheimer's Disease, a condition affecting millions of Americans. Work on finding its causes is foundational to developing effective treatments, and one day cures. But in this category, NIH has funded 14 project years and spent $13.6 million so far on projects only to count, characterize, and create registries of the frequency of the disease in different demographic groups, 75 percent exclusively on the Arab ethnicity.[290] This obsessive focus on ethnicity has diverted funding from finding the root causes that could lead to treatment and cure for everyone.

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[289] Annele Urtamo et al., "Definitions of Successful Ageing: A Brief Review of a Multidimensional Concept," *Acta Biomedica* 90, no. 2 (2019): 359–63.

[290] "Alzheimer's Disease Risk and Ethnic Factors: The Case of Arab Americans," *NIH RePORTer*, Project Details, Project Number 5R01AG057510-05; "Brain Health and Ethnic Disparities in ADRD Risk: The Case of Arab Americans," *NIH RePORTer*, Project Details, Project Number 5R01AG070951-03; "The COEQUAL Registry: Creating Opportunities to Increase Health Equity and Equality for Persons at Risk for Alzheimer Disease and Related Dementias," *NIH RePORTer*, Project Details, Project Number 5R24AG074915-03.

NIH project number 1RF1NS127122-01, "Computational dynamics in neural populations of freely foraging vs. restrained monkeys," is classified as "basic behavioral and social science." It will subject monkeys to different experimental conditions to forage for rewards. In some, the rewards will be distributed randomly. In others, they will follow a pattern. In some cases, the monkeys will have full freedom of movement; in others, their heads will be held in a fixed position and will be subjected to virtual reality environments. Then the experimenters "will use advanced behavioral models and theory to infer internal states and to identify their neural representation and interactions across a broad network of interconnected brain areas . . . we expect that these experiments will rigorously illuminate the neural dynamics of foraging and spatial navigation behaviors."[291] Unless humans are suffering from lack of food caused by a heretofore unknown foraging dysfunction syndrome, this project is outside the scope of the work that taxpayers would expect from an agency with a mission to improve human health.

Medical research has a long history of applying physical tests and proposed treatments to non-human animal subjects related to their physical systems to test either the safety or effects. These efforts have been useful. Drawing inferences from animal behavior for human behavior is highly conjectural, especially in the absence of some direct connection that is not supplied in this project. This project is the type of misdirection that the NIH pipeline research model enables.

12.2 Homelessness

Homelessness is not a medical condition, although certain mental illnesses may predispose individuals to becoming homeless. This category is not about the medical knowledge required to detect, treat, or cure diseases, but about the political programming to deliver known solutions to particular populations, usually limited to a specific geography and/or socioeconomic group within the homeless population. With few exceptions, most of the projects in this category have nothing to do with preventing or eliminating homelessness, but rather with the delivery of known therapies for mental illness, substance and alcohol abuse, HIV/AIDS, COVID-19, and other conditions to the homeless population. Moreover, there is no evidence that the NIH initiatives in this area reduced any of the medical conditions within the population. From 2008 to 2022, NIH spent $239 million funding 712 projects while the homeless problem became *more* acute.[292]

[291] "Computational Dynamics in Neural Populations of Freely Foraging vs. Restrained Monkeys," *NIH RePORTer*, Project Details, Project Number 1RF1NS127122-01.

[292] John Kamp and Shannon Najmabadi, "U.S. Homeless Count Surges 12% to Highest-Recorded Level," *Wall Street Journal*, December 16, 2023.

A substantial number of projects in the homelessness category did not address either homelessness itself or conditions suffered by the homeless. We identified 75 projects within the homeless category that received $36 million in NIH grants but did not involve any research. These "overhead" projects were simply payments to institutions with no required deliverables. These project grants include money for indirect or overhead expenses such as buildings, utilities, and administration of payroll. In the homeless category, on average about one-quarter of each research grant was designated to pay for those expenses.[293] They are duplicative waste to build the bureaucracy.

An example of another type of overhead project is "Yale Scholars in Implementation Science," which has been funded at nearly $3 million over the last five years toward "developing the next generation of implementation scientists skilled in research, knowledge translation, and leadership."[294] The funding request is from a university that grants hundreds of advanced degrees to tuition-paying students in medicine, biological sciences, mathematics, and other related disciplines, while maintaining an endowment of $41 billion. We accept that research education does not stop with the PhD—at our own advanced ages these authors continue to learn—but further research education at taxpayers' expense should be harnessed to a research project that is inherently important and for which the participant is prepared to contribute, rather than being undertaken only as a vehicle for postdoctoral training.

Other overhead activities, such as "Adolescent Medical Trials Unit," seek to recruit and maintain panels of potential test patients, while running medical services in communities where the recruits reside. These projects are not proper research.[295] Many "overhead" projects even include words like "core" or "administrative" in their titles. For example, one such "Administrative Core" project simply paid medical residents and physician assistant students because their patients had been recruited to participate in various COVID and other screening studies.[296] And an "Analytical Core" project provided ad hoc consulting on study design and analytics on a variety of unspecified projects.[297]

Perhaps the most intriguing in this overhead set are those projects entitled "TBD," which were funded over four years with $1.4 million but provided no update relevant to the stated purpose in its title: "Our ultimate goal is to help to reduce health and mental health disparities, improve health equity, and enhance the quality of life for individuals, families, and communities." This purpose was further elaborated as "Important considerations for reducing health disparities may include implementation, monitoring, and tracking of local, state and national

[293] Calculated from the 15,499 projects contained in the "Health Services" category of *NIH RePORTer*, National Institutes of Health, "RePORTER."
[294] "Yale Scholars in Implementation Science," *NIH RePORTer*, Project Details, Project Numbers 1K12HL138037-01 through 5K12HL138037-05.
[295] "Adolescent Medical Trials Unit," *NIH RePORTer*, Project Details, Project Number 5U01HD040476-10.
[296] "Administrative Core," *NIH RePORTer*, Project Details, Project Number 3U54MD007598-12S5.
[297] "Analytic Core," *NIH RePORTer*, Project Details, Project Numbers 1U19HD089886-01 through 3U19HD089886-05.

health policies; improving access to comprehensive, integrated and patient-centered quality healthcare; and promotion of culturally centered prevention and intervention approaches."[298] This is the description of an undergraduate seminar paper, not a serious medical research project.

Perhaps the least useful projects are those designed to coach providers on how to code their claims to Medicaid and other insurers to receive maximum reimbursement under the emerging value-based purchasing system. One project summary claims, "Clinics are challenged by limited resources and a workforce that doesn't have the requisite experience or education in quality improvement methods."[299] That claim displays ignorance. Thousands of healthcare professionals have been trained in and practiced quality improvement methods for more than three decades, and there are dozens of competent training and educational organizations who continue to provide that expertise.[300]

Government contracts have become a way of life for too many academic researchers, including many who have demonstrated limited or no scientific capability in their work. For example, a series of multi-year contracts with the same primary investigator purported to study the behavior of older homeless adults, especially as it related to their choices on whether to live with housed family members. The first series of contracts spent $8.1 million over 11 years, right up until the current moment.[301] The results were merely summaries of conversations with homeless individuals over the age of 50. The title of the published results betray not just a non-scientific, but even an anti-scientific approach to the problem: "Ground-Truthing the Experiences of Homeless Older Adults' Recent Stays with Family and Friends: A Case Study of Participatory Data Analysis."[302] "Ground-truthing" is an invented term that denies the need for real data analysis and "participatory data analysis" is merely the combination and editing of the opinions held by a number of different people. While soliciting opinions and testing alternative methods for data analysis are part of the scientific method, that is only the first step. To be scientific, the proffered theories need to be tested with real data using proven statistical methods, which are missing from these million-dollar projects.

The report on this project was used to justify another project by the same principal researcher to spend $1.6 million over five years to observe the behavior of homeless older adults and their interactions with their families to develop a "toolkit" to be used by social work personnel to facilitate moving homeless older adults into homes with

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[298] Funded for years 2012-2015. "TBD," *NIH RePORTer*, Project Details, Project Numbers 5U54MD008173-04 through 5U54MD008173-04.

[299] "Coaching Performance Driven Practice Change in the Context of Value Based Purchasing Under New York Medicaid," *NIH RePORTer*, Project Details, Project Numbers 5R33DA049252-04 through 5R33DA049252-04.

[300] Donald M. Berwick et al., *Curing Health Care: New Strategies for Quality Improvement* (Jossey-Bass, 1991). One of the many expert sources continues to be the Institute for Healthcare Improvement, www.ihi.org. One of the authors (Early) has personally trained at least 1,000 individuals.

[301] "Aging among the Homeless; Geriatric Conditions, Health and Healthcare Outcomes," *NIH RePORTer*, Project Details, Project Numbers 1R01AG041860-01A through 4R01AG041860-05.

[302] Margaret A. Handley, "Ground-Truthing the Experiences of Homeless Older Adults' Recent Stays with Family and Friends: A Case Study of Exploring Participatory Data Analysis," *Journal of Health Care for Poor and Underserved* 33, no. 2 (February 2022).

their families. This is not significant medical research; it is simply basic operational development for social service agencies. After five years and $1.6 million of taxpayer money, the published results and recommendations were:

> There are potential opportunities and concerns surrounding temporary stays between older adults experiencing homelessness and their family or friends. Policy solutions should support the potential mutual benefits of temporary stays, while addressing interpersonal barriers to strengthen kinship and friendship networks and mediate the negative impacts of homelessness.[303]

That is virtually meaningless and adds no new scientific knowledge. A newly minted Master of Social Work should have been able to write this after a few minutes of reflection. There are no reported results achieved.

In addition to this spin-off project, the same principal investigator extended the original project for another six years, spending an additional $3.9 million, for a total of $8.4 million collecting and massaging people's opinions. The project abstract for the third $3.9 million tranche claims, "The long-term goal of this project is to increase the trustworthiness of health care providers and institutions and decrease the rates of medical mistrust among homeless-experienced older adults, thereby, improving health outcomes." That is not medical research, but an effort to influence public opinion. That is not only outside of NIH's mission; it is not even within the proper scope of government activity. And after spending $4.5 million on the topic, what specific improvements in medical outcomes are expected? They don't say.

Reducing substance and alcohol abuse within the homeless population might have been a plausible objective for some projects, but there is no evidence of any positive results in the overall data. Rather, much of the spending was on projects that had no plausible connection to homelessness. For example, 28 projects have been funded at $10.7 million to reduce smoking in the homeless population.[304] That has no plausible connection to reducing homelessness, and, in fact, raises the question of why government should be messing with people's personal preferences.

Like many other categories, the homelessness projects included grants related to conditions in foreign countries—Peru, West Africa, Sub-Saharan Africa, Sierra Leone, Kenya, Uganda.[305] Most of these were

[303] Kelly R Knight et al., "Temporary Stays with Housed Family and Friends among Older Adults Experiencing Homelessness: Qualitative Findings from the HOPE HOME Study," *Qualitative Social Work* 21, no. 3 (May 2021): 542–58.

[304] Tabulated from National Institutes of Health, *NIH RePORTER*, Project Numbers 1R37CA248448-01A1, 5R37CA248448-02, 1R21DA031897-01, 5R21DA031897-02, 1K07CA216321-01A1, 5K07CA216321-02,5K07CA216321-03, 5K07CA216321-04, 5K07CA216321-05, 2R01HL081522-05A1, 5R01HL081522-02, 3R01HL081522-02S1, 3R01HL081522-02S2, 5R01HL081522-03, 3R01HL081522-03S1, 5R01HL081522-04, 3R01HL081522-04S1. 5R01HL081522-06, 3R01HL081522-06S1. 5R01HL081522-07, 7R01HL081522-08. 5R01HL081522-09. 1R01CA235617-01, 5R01CA235617-02. 5R01CA235617-03, 1R01CA204004-01A1, 5R01CA204004-02, 5R01CA204004-03.

[305] "Efficacy of a Differentiated Care Intervention for Adolescents Transitioning to Adult HIV Care in Peru," *NIH RePORTer*, Project Details, Project Number 1R01MH131414-01; "K23 Award to Study Intergenerational Conflict among West African Forced Migrants," *NIH RePORTer*, Project Details, Project Numbers 7K23HD059075-01 through 7K23HD059075-05; "Social Networks of West African Forced Migrants," *NIH RePORTer*, Project Details, Project Number 1R15HD079008-01A1; "Social and Biological

addressing population displacements from war or social unrest, and were unrelated to homelessness in the same sense as in the United States.

12.3 Health Services

Projects in the Health Services category of NIH spending support the implementation and continued improvement of systems for delivering health care, not research into the causes and treatment of diseases and medical conditions, which is the stated reason for the agency's existence. This spending is not even for the initial development of delivery. For improvement in the health of Americans, we need research, development, and delivery. NIH is chartered only with the first, not with the second, and certainly not with the third, yet it supports an entire category of spending that does no research and not even development. It merely pays health delivery institutions when they do their job for which they are paid by the consumers of the service.

Consider the project "Cancer Genetics Professional Education in a Global Community of Practice." This project justifies itself as having developed training materials and courses in delivering genetic counseling for existing clinicians in all 50 states and 27 countries. That is not research nor even a clinical trial. It is support of established medical operations with government subsidies. The secondary dimensions of its self-justification were also irrelevant to health research, namely that many course participants "were underrepresented minorities," and "12% (50) practice in low/middle income countries."[306]

Since 2008, NIH has spent more than $56 million on more than 200 projects that had training existing clinical work forces as their sole purpose. These training projects were not on new methods inherent in running clinical research. Rather, they were mass training efforts for implementation within existing medical practices and facilities, often concerning topics that are long-established medical standards.

For example, the project "Building Community Capacity for Disability Prevention for Minority Elders" made the following claim:

> Promising results in a few international studies show improved access and quality of mental health outcomes and reduced disability when interventions are delivered by Community Health Workers [CHW]. Yet limited and inconsistent evidence of the efficacy of CHW-led

Mechanisms Driving the Intergenerational Impact of War on Child Mental Health: Implications for Developing Family-Based Interventions," *NIH RePORTer*, Project Details, Project Number 1R01MH128928-01; "Preventing HIV Risk Among Adolescent Orphans in Kenya," *NIH RePORTer*, Project Details, Project Number 5R34MH079749-03. "International HIV ARV Adherence, Resistance and Survival," *NIH RePORTer*, Project Details, Project Numbers 5R01MH054907-13 and 5R01MH054907-15.

[306] "Cancer Genetics Professional Education in a Global Community of Practice," *NIH RePORTer*, Project Details, Project Number 5R25CA171998-10. Plus, Project Numbers 5R25CA171998-09, 5R25CA171998-08, 5R25CA171998-07, 5R25CA171998-06.

> interventions in the US context remains. While the number of community-based health interventions has grown exponentially to address these service disparities, there is a lack of systematic assessment of whether they lead to increased community capacity and systems change, and whether they improve the quality of care and potentially decrease disability. Our proposed study endeavors to address this limitation.[307]

Yet 11 years and 18 grants totaling more than $94 million later, it was still taking more money to

> "create and evaluate a toolkit to disseminate the program, with a focus on developing cultural and age appropriate evidence-based messaging, packaging, and an overview of the implementation process and financing. This dynamic toolkit will be designed for use by community organizations, community health workers (CHWs), exercise trainers, and program participants, targeting strategies for capacity building as well as implementation. Drawing on the feedback from participating sites, we envision refining materials in the last 6 months of the project to have a lasting product that can be disseminated, and that not only facilitates positive intervention outcomes but additionally support organizations to optimize implementation success, fidelity, and sustainability."[308]

This wasteful, drawn-out project demonstrates several important points. First, it is not health research, which is the whole purpose of NIH. Second, it was justified by the claim that previous projects had not demonstrated results. If multiple projects on a theory did not demonstrate any results (either positive or negative), then the no-effect result has been replicated and further taxpayer-funded projects on the same theory should be stopped. This is a basic business-process measurement and improvement project. In private business, projects of this type and magnitude are completed in six to 18 months with measurable real business results, not nine years with no documented results.

Another cluster of 44 projects received more than $6.6 million to urge people to get tested for cancer and related conditions. No research was involved. In fact, the testing being promoted was standard stuff such as traditional colorectal cancer screening, breast cancer screening, and HPV vaccination. A typical project description was: "The Cancer Outreach Program (COP) is as [sic] a service intended to educate and mobilize communities to take action to prevent and control cancer. A goal is to increase the number of people who are in racial/ethnic minorities who are screened for cancer. The common, unifying theme for the Partnership is to deploy Community Health Advisors

[307] "Building Community Capacity for Disability Prevention for Minority Elders," *NIH RePORTer*, Project Details, Project Number 1R01AG046149-01A1,

[308] "Building Community Capacity for Disability Prevention for Minority Elders," *NIH RePORTer*, Project Details, Project Number 3R01AG046149-09S1.

(CHAs) to provide cancer-related health promotion and cancer education to the public." The project leader claims this a "dissemination research project."[309] But no research hypotheses were tested and no outcomes reported. These projects measured no improvement in testing rates and no reduction in either morbidity or mortality.

Also involving wasteful overhead—and no research—are more-than 1,100 projects labeled as "core" or similar words, sometimes with further descriptives such as administrative core or community engagement core. The general area of research such as cancer or HIV is sometimes included in the project description, but these are basically overhead activities and are not attributable to any specific piece of research. One typical description reads: "The objective of the Administrative Core of the University of Pennsylvania Telehealth Research Center in Cancer Care (Penn TRC) is to ensure that the impact of the Center is greater than the sum of its parts. The Administrative Core will accomplish this objective by maximizing collaboration and The "specifics" are listed as "1) Provide essential leadership and integration, . . . 2) Create interdisciplinary research capacity and collaborations; 3) Coordinate communication and dissemination . . . and 4) Monitor and evaluate . . . progress and leverage findings to inform iterative refinement."[310] If the project staff for which this "core" project is providing "leadership and integration" is unable to do these basic tasks, then they should have never been funded.

Projects in the Health Services category that are conducted in foreign countries fare no better. These are not research projects to investigate the causes of diseases such as dengue fever or Ebola virus with origins in foreign environments that might pose threats to the United States, but pedantic efforts covering a wide array of standard practices in foreign populations—such as reducing smoking, tinkering with the populations' sex practices, increasing the availability of mental health treatments, reducing stigma against patients with certain conditions among health care providers, training health care providers in cancer prevention and control, training providers of services to cancer survivors, implementing software and wireless applications, identifying patient preferences for treatment and adherence to regimens, mobile health interventions for perinatal care, setting up disease databases, establishing a taxi-based emergency medical transport system, treatment of alcoholism, improving diet adherence for diabetes patients, care for depressed elders in China, and so forth. A total of 493 such projects in the Health Services category were funded in foreign countries at a cost of more than $153 million.

Some domestic projects were just as wasteful. As of this writing, "Disseminable [sic] Evidence-Based Treatment for the Dental Office: Virtual Exposure Tools for Dental Fear – neVR Fear the Dentist" is in its fourth year and has spent $1.9 million in taxpayer funds to promote the marketing of existing trademarked

[309] "Community Outreach Program," *NIH RePORTer*, Project Details, Project Number 5U54CA118638-10.
[310] "Administrative Core," *NIH RePORTer*, Project Details, Project Number 1P50CA271338-01.

commercial product called "neVR Fear the Dentist."[311] The patients are shown how to develop a "Pre-Game" plan to relieve their fears and then receive a virtual reality simulation. The commercial product already exists, so no research is required. The company simply needs to sell it to patients and/or dentists—something that should come out of its marketing budget, not taxpayers' pockets.

"El Trabajo no te Debe Dañar [work ought not hurt you]: Reduction of Hazardous Exposures in Small Businesses through a Community Health Worker Intervention" will send "community health workers" out to small beauty salons and auto repair shops in the Sonora and El Rio communities in Arizona and work with the owners and employees, which the proposal claims are heavily Latino with limited education, literacy and computer skills.[312] There is no research involved here; the nominal investigators will simply try to implement best practices for the use of the "volatile organic compounds" found in these environments. But taxpayers already fund a huge bureaucracy at the Department of Labor's Occupational Safety and Health Administration that publishes specific guidelines for safe procedures for beauty salons[313] and auto repair shops.[314] The State of Arizona provides additional supplements for beauty salons[315] and auto repair.[316] NIH has spent $3.4 million on this needlessly duplicative exercise from 2018 through 2023 and still has not reported completion or any measurable results.

Here is a short list of other wasteful and inappropriate projects in this category that have no relationship to reducing mortality and disabling morbidity for the American population.

- Five years and $3.3 million trying to discover any correlation between constructing a light-rail train line in Portland Oregon and health outcomes and costs.[317]
- Looking for any correlation between mortgage foreclosures from 2005 to 2009 and the concurrent utilization of emergency department visits and hospital admissions, "because the recent massive rise in foreclosures is arguably due to the recession rather than to personal characteristics of those affected."[318] This assumption was false because empirical analysis of the record foreclosure rates during this time showed that the cause was the "personal characteristic" of homeowners taking on more mortgage

[311] "Disseminable Evidence-Based Treatment for the Dental Office: Virtual Exposure Tools for Dental Fear - neVR Fear the Dentist," *NIH RePORTer*, Project Details, Project Number 4R42DE030040-02,
[312] "El Trabajo no te Debe Danar: Reduction of Hazardous Exposures in Small Businesses through a Community Health Worker Intervention," *NIH RePORTer*, Project Details, Project Number 5R01ES028250-04,
[313] "Hair Salons: Facts about Formaldehyde in Hair Products," Occupational Safety and Health Administration.
[314] "Autobody Repair and Refinishing," Occupational Safety and Health Administration.
[315] State of Arizona, Office of the Governor, Guidance for Barbers and Cosmetologists (Office of the Governor, n.d.).
[316] Arizona Department of Education, *Automotive Collision Repair Technical Standards* (June 2023).
[317] "Health and Economic Effects of Light Rail Lines: A Natural Experiment," *NIH RePORTer*, Project Details, Project Number 5R01DK103385-05.
[318] "Health Consequences of Foreclosure Crisis: Effects on ER Visits & Hospitalization," *NIH RePORTer*, Project Details, Project Number 1R21AG041404-01.

debt than their income could support. That excess debt was the result of government regulations forcing lenders to give mortgages to those who did not meet sound financial criteria.[319] The only journal article reporting the results from this project revealed significant weaknesses in the project's methods.[320] The data tested were not for individuals, comparing whether who had a foreclosure made more hospital visits. It merely tested differences in community averages of foreclosures and hospital visits.

- Spending five years and $1.3 million to look for health effects from government-compelled sick leave and family leave.[321] The choice of whether employers should fund the time their employees take for their health care and family activities is an economic decision, not a health question. It is not government's proper role to force the choice, which will inevitably be suboptimal for some individuals. Likewise, it is not appropriate for government to take taxpayer dollars to research the option.
- Spending $3.0 million to use existing data to support "policymakers and other stakeholders seeking to optimally balance the complex risks and benefits of direct-to-consumer [pharmaceutical] advertising."[322]
- Spending $2.4 million over four years to look for the effects of sleep patterns of staff in hospital emergency departments.[323] This is not a medical research problem, but a common staffing and scheduling problem for healthcare staff, that is not unique to healthcare, and has no effect on general mortality and morbidity. Hospitals may find it useful to do such research on their practices, but that is part of running an effective hospital, not a subject for medical research.
- Two large NIH projects in this group assert that "Taxi drivers are a marginalized, large, growing minority male population with multiple health risks" and tried to encourage taxi drivers to rise from their sedentary lifestyles and use pedometers. The first three-year project spent $1.2 million, with

[319] Peter J. Wallison, *Hidden in Plain Sight: What Really Caused the World's Worst Financial Crisis? And Why It Could Happen Again* (Encounter Books, 2016). Not everyone agreed with Wallison's assessment, but most financial economists did, and at a minimum the NIH-funded research team should have at least acknowledged this competing research result. For a short summary of Wallison's study and the reaction to it see Richard W. Rahn, "Shining a Light on the Cause of the Great Recession," *Washington Times* February 9, 2015.

[320] Janet Currie and Erdal Tekin, "Is there a Link Between Foreclosure and Health?" *American Economic Journal: Economic Policy* 7, no. 1 (February 2015): 63–94.

[321] "Paid Sick Leave Mandates and Cancer Prevention," *NIH RePORTer*, Project Details, Project Number 5R01CA237888-04, and "Paid Family Leave and Prevention of Respiratory Tract Infections in Young Infants," *NIH RePORTer*, Project Details, Project Number 1R03HD108526-01A1.

[322] "Televised Direct to Consumer Pharmaceutical Advertising and Patient Outcomes," *NIH RePORTer*, Project Details, Project Number 5R01HL107345-04.

[323] "The Identification of Modifiable Emergency Department and Sleep Factors Contributing to Psychological and Cardiovascular Risk in Clinicians," *NIH RePORTer*, Project Details, Project Number 5R01HL146911-03.

apparently no success[324] because a second project followed, spending an additional $2.9 million through the most recent reported year without reported success.[325]

- The Affordable Care Act of 2010 required that restaurants post caloric content of menu items. The project claims that prior research showed that there was little or no effect on the number of calories ordered, so this project spent $1.3 million looking for other possible positive effects. The "outcomes" section of the project database reports the following effects of the federal law requiring posting caloric content of menu items: (1) There was some reduction in body mass indexes, but no reduction in obesity, (2) There was an increase in the number of restaurants that posted calories, (3) Restaurants "did not substantially change the items offered on the menu," (4) Consumers became "more likely to notice calories on menus after the federal menu labeling requirement." and (5) "Consumers are more likely to eat meals at chain restaurants affected by the federal menu labeling requirement."[326] While the project gave this short list in the database, after four years it has not yet published anything in a scientific journal or anywhere else. The short database entry shows there were no meaningful health improvements from the law requiring restaurants to apply resources. But this has not been highlighted or published anywhere six years after the end of the funding. Why? This looks like censorship of results showing failure of government mandates to deliver as advertised.

12.4 Obesity

The management of obesity and of type 2 diabetes have been transformed by the development of the GLP-1 agonists. These include exenatide (manufactured by AstraZeneca and approved in 2005/2012), liraglutide (Novo Nordisk, approved 2010), albiglutide (GSK, approved 2014), dulaglutide (Eli Lilly, approved 2014), lixisenatide (Lyxumia/Rybelsus, approved 2016), semaglutide (Novo Nordisk, approved 2017) and tirzepatide (Mounjaro/Zepbound, approved 2022).

These drugs, which represent a triumph of pharmaceutical company research, also offer the prospect of real advances in the treatments of conditions as various as cardiovascular disease, polycystic ovary syndrome, and non-alcoholic fatty liver disease. One should expect such game-changing developments in the field to be reflected in

[324] "The Taxi Network," *NIH RePORTer*, Project Details, Project Number 5R24MD008058-03.
[325] "Taxi STEP (Social Networks, Technology, and Exercise through Pedometers)," *NIH RePORTer*, Project Details, Project Number 5U01MD010648-05.
[326] "Understanding the Effect of Calorie Menu Labels on Obesity: Producer and Consumer Responses to the ACAs Calorie Posting Requirement," *NIH RePORTer*, Project Details, Project Number 5R01DK107686-04.

the "Strategic Plan for NIH Obesity Research,"[327] but neither the Full Report for the scientific community,[328] nor its complementary non-technical Summary Report even mentions the GLP-1 agonists.[329]

The strategic plan for obesity research was issued in March 2011. There are two concerning consequences regarding that date. First, the strategic plan was completed six years after the first GLP-1 agonist drug exenatide was approved, one year after the second, liraglutide was approved, and after at least two others were in the approval pipeline. Second, that strategic plan has not been updated in 15 years. Yet, NIH stated in the strategic plan webpage that this plan had been reviewed as of February 2024. That means that NIH's publicly stated baseline strategy with respect to obesity and diabetes had not changed in the last 15 years. A failure to update a research strategy that ignores major technical breakthroughs would never occur in a private enterprise that hoped to continue to exist.

The current strategic plan for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDKD) was written more recently, in 2021, but it also fails to mention the GLP-1 agonists.[330] Instead, the NIH remains focused on a social-disparity approach to these conditions, as can be seen in the opening words of the NIDDKD's strategic plan:

> As a whole, the diseases that fall within NIDDK's mission are chronic, costly, and consequential for patients, their families, and the Nation, often with differential impact on populations that have been marginalized.

This distracting theme carries over in the very first scientific research opportunity listed in the plan: "Research Opportunity 1.1: Identify and characterize factors that affect human health in diverse populations."

Social disparities in the impact of diseases may be a significant matter for public policy in some cases, but the NIH's remit is to discover the causes of diseases and human biological conditions and to identify paths for treatment and cures. Congress should be concerned that the first sentence of the strategic plan for one of the constituent NIH institutes and its first research proposal give priority to such disparities rather than the fundamentals of causes, treatment, and cures. Such emphasis can crowd out the NIH's core mission of improving the science of health.

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[327] National Institutes of Health, "Obesity Research at the National Institutes of Health (NIH): Strategic Plan,"

[328] "Strategic Plan for NIH Obesity Research," U.S. Department of Health and Human Services, National Institutes of Health, NIH Publication No. 11-5493, March 2011. Download link from https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/niddk-strategic-plan-for-research.

[329] "Strategic Plan for NIH Obesity Research: Summary," U.S. Department of Health and Human Services, National Institutes of Health, NIH Publication No. 11-5493-a, March 2011. Download link from https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/niddk-strategic-plan-for-research.

[330] "Overview and Introduction," in *National Institute of Diabetes and Digestive and Kidney Diseases: Strategic Plan for Research*, NIH Publication no. 21-DK-8159 (National Institute of Diabetes and Digestive and Kidney Diseases, 2021), p. 1.

12.5 Foodborne Illness

"Foodborne illnesses" is a strange category on which to spend $157 million annually. These illnesses arise almost exclusively from individual failures in the consumption and preparation of food. The project list contains no mysteries that seem to require research; they mostly are implementation activities around well-established best practices. Wash and cook the food sufficiently and the pathogens are eliminated. The FDA, Department of Agriculture, and CDC all have specific food-related programs that are responsible for assuring that pathogens are not introduced into the food chain during food processing. These safeguards fail only rarely, but these failures are neither caused by nor preventable by more research. When failures occur, we know how to discover what went wrong and how to fix it.

There are approximately 9.4 million episodes of foodborne illness, 55,961 hospitalizations, and 1,351 deaths from foodborne pathogens. Most (58%) of the illnesses were caused by norovirus, followed by nontyphoidal Salmonella spp. (11%), Clostridium perfringens (10%), and Campylobacter spp. (9%). Leading causes of hospitalization were nontyphoidal Salmonella spp. (35%), norovirus (26%), Campylobacter spp. (15%), and Toxoplasma gondii (8%). Leading causes of death were nontyphoidal Salmonella spp. (28%), Toxoplasma gondii (24%), Listeria monocytogenes (19%), and norovirus (11%).[331] There are no reported cases from pathogens that have not been known and fully understood for many years.

Salmonella accounts for nearly a third of deaths from foodborne pathogens, so it should not be surprising that it receives about one-third of pathogen-specific grants. But for other pathogens, the relationship between disease burden and funding makes little sense.

The foodborne infection receiving the second largest share of grants (22 percent of the total) is cholera, which is nowhere in the list of top contributors to foodborne infections. Cholera is "caused by the bacteria Vibrio cholerae, is rare in the United States and other industrialized nations. Cholera can be life-threatening, but it is easily prevented and treated . . . Cholera infection is often mild or even without symptoms . . . With proper treatment, even severely ill patients can be saved."[332] Long before modern bacteriology, the source and prevention of the disease were well known, dating from the famous Broad Street pump analysis in London in 1854, when John Snow demonstrated that contamination from sewage effluent was the source of the disease and that simple sanitary measures would prevent it. NIH itself has published this well-known story.[333]

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[331] Elaine Scallan et al., "Foodborne Illness Acquired in the United States—Major Pathogens," *Emerging Infectious Diseases* 17, no. 1 (January 2011).

[332] "Cholera," Center for Disease Control, May 29, 2025.

[333] Theordore H. Tulchinsky, "John Snow, Cholera, the Broad Street Pump; Waterborne Diseases Then and Now," *Case Studies in Public Health* (March 30, 2018): 77–99.

No cholera outbreaks have occurred in the last 100 years in the United States.[334] On average, there are five confirmed cases per year, almost all of which arise from foreign travel, and no one dies.[335] Even worldwide, total deaths from the disease are estimated at between 21,000 and 143,000 annually.[336] For comparison, seasonal influenza deaths in the United States range between 4,900 and 51,000 annually.[337] Yet since 2008, the first year for which there are records, NIH has funded 438 grants at a cost of $173 million to investigate this disease.[338] Cholera projects have more research support than projects addressing five of the six most significant pathogens for foodborne infections, yet Cholera causes zero deaths in the United States and single digit numbers of illnesses in most years.

One reason for this striking disparity is that a large share of NIH cholera research focuses on foreign countries.[339] NIH's foreign cholera spending mostly consists of implementing preventive measures that have been known for ages. The work is mostly routine public health administration. There is no research involved, so the projects add little, if anything, to the body of scientific knowledge, and do not contribute to improving Americans' health.

12.6 Screening and Brief Intervention for Substance Misuse

In other spending categories we have seen projects that are justified as training vehicles for already highly educated PhDs. We also have noted that the value of projects should begin with delivering valuable results for improving health, and that the individuals leading or participating in the projects should bring with them the skills necessary to do the job. New postdocs should bring significant skills to the job, but they may gain still more capability with a mentor or working as a key member of a project team under the guidance of an experienced principal investigator. Yet, NIH's failure to use mission-driven project identification is repeated in projects directed at interventions for substance abuse.

The project "Feasibility of SBIRT for Underserved HIV+ Adults 50+ in Primary Care Settings" states that its goal "is to support Dr. Nicole Ennis Whitehead, a Clinical Psychologist, in developing the critical skills necessary to become an independent researcher in the implementation of substance use interventions in real world settings."[340] The one-year spending was $153,781. The trainee was supposed to gain experience implementing an existing treatment protocol called "Screening, Brief Intervention and Treatment" (SBIRT), which had already

[334] Peter Gilligan, Ph.D., "Cholera in Times of Chaos," American Society of Microbiology, March 14, 2023.

[335] Anna E. Newton et al. "Cholera in United States Associated with Epidemic in Hispaniola," *Emerging Infectious Diseases* 17, no. 11 (November 2011).

[336] "Cholera," World Health Organization, December 5, 2024.

[337] Center for Disease Control, "About Estimated Flu Burden," accessed 2023.

[338] Calculated by authors from National Institutes of Health, "RePORTER."

[339] NIH has spent $173 million on cholera projects since 2008. 10% of the cholera projects were in a foreign country; 22% of foreign projects in foodborne illnesses were for cholera. Calculated by authors from National Institutes of Health, "RePORTER."

[340] "Feasibility of SBIRT for Underserved HIV+ Adults 50+ in Primary Care Settings," *NIH RePORTer*, Project Details, Project Number 7K23DA039769-04,

been shown to be effective, according to the project description. The protocol was also to be augmented with an additional peer navigator (adding a PN to make it SMITR-PN), which the project description claims has also been shown by earlier data to be more effective in adults aged 50 and older.

As in other projects, NIH gets its justification backward. Determinations of NIH funding should start with the health outcome to be achieved, not the researchers' career development. Gaining experience implementing an existing treatments protocol is not research. It is operations and out of the scope of NIH.

To NIH's credit, the first training aim listed by NIH for this project at least relates to health: "Describe and differentiate optimal methods of substance use intervention with vulnerable populations." But this is not a proper research objective, merely a general, non-quantitative observation. The researcher is supposed to be learning about research, but this project begins by describing research objectives and doesn't progress from there. Somewhat more substantive aims for the project's implementation were: "Aim 1: Pilot effectiveness of SBIRT-PN versus treatment as usual in HIV primary care clinics to improve substance-use treatment engagement and HIV appointment adherence among adults aged 50 and older. Aim 2: Describe the influence of demographic factors, depression and pain on substance-use treatment engagement outcomes. Aim 3: Examine and enhance feasibility (recruitment, dose, retention) of intervention uptake for a larger trial." But even those aims are wanting. Outcomes should be measured, and the effectiveness of the protocol should be proven or disproven, not just described. For example, a more appropriate objective would something like "Test whether the SMITR-PN protocol delivers with at least 95% certainty a 30% increase in early remission (3-12 months) rates and a 50% increase in sustained remission rates, compared with existing best practice.[341]

Another set of projects comprises replicated implementations in slightly different environments. This is not research; it is daily work. "Integrating Addiction and Infectious Diseases Services into Primary Care in Rural Settings," spent $3,519,397 over three years repeating in West Virginia what had been done elsewhere.[342] The work might be worthwhile, but it is not research and not a proper function of the federal government.

[341] See for other possible metrics, *Measuring Recovery from Substance Use or Mental Disorders: Workshop Summary*, Committee on National Statistics; Board on Behavioral, Cognitive, and Sensory Sciences; Division of Behavioral and Social Sciences and Education; Board on Health Sciences Policy; Health and Medicine Division; National Academies of Sciences, Engineering, and Medicine, Washington (DC): National Academies Press (US); September 19, 2016, Chapter 4. National Academies of Sciences, Engineering, and Medicine, *Measuring Recovery from Substance Use or Mental Disorders: Workshop Summary* (National Academies Press, 2016), chap. 4.

[342] "Integrating Addiction and Infectious Diseases Services into Primary Care in Rural Settings," *NIH RePORTer*, Project Details, Project Number 5R01DA054703-02.

13 Projects of Pure Waste

Previous chapters have presented analysis and examples of a broad range of failures by NIH to deliver on improved health due to its lack of strategic focus, use of the "linear" model of research, prioritization of research for political gain rather than improved health, violation of fundamental of scientific research principles, pursuit of initiatives that danger our liberty, and funding of projects irrelevant to its mission. But there are still more projects that are nothing but waste, including the following categories.

13.1 Adolescent Sexual Activity

In fiscal year 2022, NIH gave more than $80 million to 209 research projects related to adolescent sexual activity. That is a lot of money for social behavior among minors that should be the primary concern of parents. Sexual activity among children is not appropriate for many reasons, but it is not a disease within the NIH purview. It is also noteworthy that 27 percent of the projects in this category, spending 21 percent of the money, simply repeated tests in foreign countries that had already been conducted in the United Sates or elsewhere.[343]

Even within the United States, the funded studies tended to focus on methods used to survey tiny subpopulations about their sexual behavior. A typical project is: "Preventing Alcohol Exposed Pregnancy among Urban Native Young Women During the COVID-19 Pandemic." It proposes an experiment using a smartphone app to message girls or young women ages 16-20 of American Indian and Alaskan Natives (NIAN) heritage who live in urban communities, rather than on reservations, where previous research had been done. The grantees offer no evidence that NIAN young women in urban areas would be different in their behaviors than urban young women of other ethnic backgrounds. In fact, they claim that their research is unique because NIAN youth are spread throughout urban areas and not concentrated in specific areas like some ethnic groups. This means that they live in communities with significant variation in economic, social, and cultural features and evidence is provided that they are different from their neighbors. The proposal asserts,

> However, this group is likely to experience different cultural, social, and economic impacts of the pandemic compared to those living in reservation settings. Those differences are likely critical to alcohol-exposed pregnancy (AEP) risk. Early data in the general population indicate increased alcohol use by youth, and decreased access to effective contraception among women. The combination is likely to increase risk of AEP, and for urban AIAN young women—often with

[343] Authors' calculations from National Institutes of Health, "RePORTER."

> limited local resources—that risk may be especially elevated. Yet, as research efforts scramble to monitor risk of the most vulnerable in a pandemic, this demographic often becomes invisible.[344]

That description is most likely unfounded speculation because it is never supported with data and the existing literature, including at least one paper listed as a source in this study, contradicts that description. That paper concluded "AIANs aged 12–17 and 18–25 reported the highest levels of heavy alcohol use in the past month except for Whites."[345] In other words, their claim of uniquely higher risk for this tiny subpopulation is wrong. The proposal authors should have known this if they had read their own references. The target population, although at higher risk than other minority populations, was at *lower* risk than the majority population among which they are living in their dispersed urban environment.

The decision to drink alcohol and have unprotected sex are both voluntary and fully avoidable. These are behaviors chosen by young people and influenced by their parents and other adults around them. They are not diseases. They are voluntary behaviors determined by individual values from family, community, religion, and other groups. Since there is no disease, these behaviors are not within the scope of NIH's mission to reduce mortality and morbidity. That flaw alone should disqualify this work. But even in the context of the project itself, there are serious failures.

The project used a sample of only 700 individuals randomly split into two subsamples. One subsample group received a smartphone app that mimicked in-person interventions for AEP, while the other served as a control.[346] A sample this size could not produce a significant result, unless the intervention reduced AEP by 23 percent or more.

Furthermore, the researchers claim that "To contextualize these findings, we will . . . conduct in-depth interviews with participants purposively selected based on baseline survey responses. To maximize insights in the diversity of experience of the pandemic and gain timely, in-the-moment, insights, we will recruit and interview young women from our RCT sample (n=32) over 2 years. We will also interview selected participants (n=8) at regular intervals over 2 years to capture their experiences longitudinally as circumstances of the pandemic shift." Not only are these over-time samples absurdly small, their being "purposively selected" relies

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[344] "Preventing Alcohol Exposed Pregnancy among Urban Native Young Women During the COVID-19 Pandemic," *NIH RePORTer*, Project Details, Project Number 3R01AA025603-05S1.

[345] Carol E. Kaufman et al., "A Virtual Randomized Controlled Trial of an Alcohol-Exposed Pregnancy Prevention Mobile App with Urban American Indian and Alaska Native Young Women: Native WYSE CHOICES Rationale, Design, and Methods," *Contemporary Clinical Trials* 128 (May 2023): 107167.

[346] "Preventing Alcohol Exposed Pregnancy among Urban Native Young Women During the COVID-19 Pandemic," *NIH RePORTer*, Project Details, Project Number 3R01AA025603-05S1.

on discredited 19th century anthropological field methods—the only difference is their being in the addition of a slick mobile phone app.

The grant was designated for "Preventing Alcohol Exposed Pregnancy." So how many alcohol-exposed pregnancies did this effort prevent? Neither the NIH nor the people paid by the grant tell us. The published paper from the project only says, "The study described in this article provides an outline of a unique and innovative approach to research with AIAN communities . . . Our description here provides intentional planning and design for virtual randomized controlled trials. Our study offers a template for building trust and extending reach to this underserved population while also providing important lessons and insights on advances in virtual or hybrid research approaches."[347] There is nothing new, important, or even marginally useful in the results. Taxpayers should demand a refund.

Furthermore, none of the detailed information about the project are available without having to pay for access. NIH claims that all published papers based on research funded by taxpayers must be available without charge. But one continuing and widespread deficiency in NIH research is that, while the public pays the bills to do the research and write the papers, the papers are often published on platforms that charge high fees to access the results. A pdf file of this published paper costs $27.95, even though it is virtually costless to create that file from the finished paper and the writing of the paper was fully funded by taxpayers. If the public paid for it, the public should be able to read it without paying more money. NIH set up the PubMed website within the National Center for Biotechnology Information in the National Library of Medicine to hold all these papers, but many, such as this example, are merely abstracts, with most of the details missing. In 2023, NIH extended this mandate to include providing all data from taxpayer-funded research without charge. We'll see how that works out over the long run, but the evidence so far is not encouraging. The majority of papers that we attempted to find for our white paper were incomplete, despite the longstanding requirement. And, while many papers have claimed that the data underlying them is available upon request, a study published in 2022 found that only 7 percent of recently published papers making that claim provided it when asked.[348]

Another project delivered even worse results while spending even more money. A professor at the University of Pittsburgh received 10 grants from 2019 to 2023 totaling $3,697,335 for a series of 12 classes for groups

[347] Carol E. Kaufman et al., "A Virtual Randomized Controlled Trial of an Alcohol-Exposed Pregnancy Prevention Mobile App with Urban American Indian and Alaska Native Young Women: Native WYSE CHOICES Rationale, Design, and Methods," *Contemporary Clinical Trials* 128 (May 2023): Page 107167.

[348] Steven Salzberg, "Major Medical Journal Reverses Itself On 'Research Parasites' as NIH Beefs Up Data Sharing Rules," Forbes, January 1, 2024.

of children in "marginalized neighborhoods" to "explore race, gender, sexual identity, and social class."[349] The principal investigator claimed this would reduce youth violence by addressing the racism and discrimination that supposedly caused this violence, even though most violence occurs between individuals of the same ethnic group.[350] Five years and $3.7 million later, the official NIH record reports, "No outcomes available."[351]

13.2 Cost-Effectiveness Research

As we have noted before, there is little or no evidence in the NIH budget submission of any analysis to support the scientific and economic value of the projects funded. One might hope to find some such evidence in this group of projects that putatively address cost-effectiveness. The project, "Cervical Cancer Moonshot," appears to be part of the vaunted Cancer Moonshot initiative and thus is of special interest. The disease is certainly serious, and perhaps it and related projects could contribute to cutting cancer mortality among Americans by more than half to meet the "Moonshot" goals in a cost-effective manner.[352]

A search of the cost-effectiveness projects in this group yielded 236 projects focused on specific cancer diseases. Of that number more than a quarter (26.7 percent) claimed to study cervical cancer, even though cervical cancer accounts for only 0.7 percent of all cancer mortality (see Table 7.2). The "Cervical Cancer Moonshot" project began as a modest $38,339 effort in 2018, but by 2023 it was spending $10,446,162 per year, consuming a total of $24,376,201 over six years. That is hardly a model of cost-effectiveness.

The efficiency and strategic focus of the study was likely impaired by funding subprojects in Peru,[353] the Amazon,[354] and Nigeria.[355] The footnotes in these publications say that they supported the work of dozens of people on what were relatively modest investigations—again, hardly a model of cost efficiency.

But the ultimate signal as to just how poorly this project was conceived and executed is apparent in its official description, which has been sitting in the NIH project database since 2018. It appears there as follows, including the long string of "x's" instead of any description of the intended outcomes.

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[349] "Creating Peace: Community-Based Youth Violence Prevention to Address Racism and Discrimination," *NIH RePORTer*, Project Details, Project Number 3R01MD013797-4S2. The title of this project suggests it does not belong in the Adolescent Sexual Activity category, but that is the first assigned category by NIH, presumably because the work included effects on "sexual identity."

[350] Alexandra Thompson and Susannah N. Tapp, "Just the Stats, Violent Victimization by Race or Hispanic Origin, 2008–2021." Federal Bureau of Investigation, Expanded Homicide Data, Table 6.

[351] "Creating Peace: Community-Based Youth Violence Prevention to Address Racism and Discrimination," *NIH RePORTer*, Project Details, Project Number 3R01MD013797-4S2.

[352] *NIH RePORTer*, Project Details, Project Number 1ZIACP010230-05.

[353] Catya Lopez-Ampuero et al., "Squamocolumnar Junction Visibility Among Cervical Cancer Screening Population in Peru Might Influence Upper Age for Screening Programs," *Preventive Medicine* 174 (September 2023): 107596.

354 Kátia Luz Torres et al., "Moving Towards a Strategy to Accelerate Cervical Cancer Elimination in a High-Burden City—Lessons Learned from the Amazon City of Manaus, Brazil," *PLOS One* 16, no. 10 (2021): e0258539.

[355] Kanan T. Desai et al., "Design and Feasibility of a Novel Program of Cervical Screening in Nigeria: Self-Sampled HPV Testing Paired with Visual Triage," *Infectious Agents and Cancer* 15, no. 60 (2020).

> The goals of the cervical cancer moonshot are to: Validate the effectiveness and cost-effectiveness of novel screening methods, as the basis for implementation of cervical cancer screening and triage strategies in high- and low-resource settings; Improve efficiency of cervical cancer prevention in high-resource settings; and Develop practical and accurate screening strategies that improve coverage for low-resource settings and can be integrated with vaccination programsxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
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> xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx [sic]

One of many other projects related to cervical cancer screening is "A Randomized Controlled Trial of Mail-Self Stamped HPV Testing to Increase Cervical Cancer Screening Participation Among Minority/Underserved Women in an Integrated Safety Net Healthcare System."[356] The investigators propose to test whether they could entice more women in Houston, Texas, who are covered by government-paid medical care to get screened for human papillomavirus (HPV), a precursor to cervical cancer. Both the screening for HPV and related Papanicolaou (Pap) testing are covered at no cost to the target women. But the investigators were not pleased with the number of women showing up for the free tests, even when "patient reminders and recalls, patient education, and patient navigation are the basis for many behavioral interventions to increase screening participation."

The researchers propose to send women a free self-sampling kit that they can use in their own home and then mail in. They think more women will take their free offer this way. There is no medical or biological research required. All they want to do is modify people's behavior to buy what they are giving away for free by using a more aggressive marketing technique—the kind of work hundreds of companies do every day, applying methods that anyone who passed an intermediate statistics course could execute without difficulty. Yet this proposal has already cost taxpayers $3,370,136, and the project is still not complete. Even more fundamentally, these are grown women. The government is not their parent or guardian. It has no right or authority to conduct this exercise in behavior modification, nor should it compel taxpayers to pay for it.

Another project in the cost-effectiveness category, "Equity and Economic Effects of MTM Services," illustrates features that are common to many projects classified here.[357] The project concerns the Medication Therapy Management (MTM) programs mandated by the Center for Medicare and Medicaid Services (CMS) for health insurers that administer drug benefits for Medicare or Medicaid coverage. The MTM programs

[356] *NIH RePORTer*, Project Details, Project Number 5R01MD013715-03.
[357] *NIH RePORTer*, Project Details, Project Number 5R01AG040146-07.

target patients using many different medications, typically the elderly or others with multiple or complex chronic conditions.

This project has been conducted by the same principal investigator over 12 years at a taxpayer cost of $2,761,548. There is no medical, biological, or other scientific investigation involved. The project uses existing Medicare and Medicaid databases. It began by seeking to eliminate racial and ethnic differences in individuals who participate in one of these programs. The researcher claimed that "MTM eligibility criteria may be too restrictive for racial/ethnic minorities . . . because MTM eligibility is based on utilization of medications, which minorities tend to use less." Notice the circular contradiction in this logic. People who consume more medications need more management of their medications to prevent adverse interactions among them. Some minority populations use fewer drugs, which reduces the opportunities for adverse interactions. This, in turn, leads to fewer of them being enrolled less in MTM programs. That is an inequity that the researcher wants to supposedly "fix."

Some people freely choose to use less medication. The majority of the people in question in this population pay little or nothing for their medications. Some people also choose not to be part of a "managed" population like MTM, having had enough of that in other spheres of their life. So why should we support research that seeks to move people from their free choices to being managed by government and its agents?

The researcher claims that the first years of the project showed that the requirements for enrollment in MTM were too rigid and "CMS attempted to relax MTM eligibility thresholds, citing our research, but potential disparities remain with the utilization-based eligibility criteria." In other words, the first $1.3 million spent to fix this hypothetical problem did not work because people continued resisting the mandates from bureaucrats. So now the same researcher wants to spend another $1.5 million to try again.

13.3 Smallpox

Smallpox is no longer a health issue. The last case on earth was diagnosed on 26 October 1977. When NIH prepared its research budget for 2024 there hadn't been a single case of the disease anywhere in the world for 46 years. Where have these folks been? The Centers for Disease Control and Prevention and the Department of Defense have security functions with plans in place to deal with the threat that terrorists might get a hold of laboratory samples of the pathogen. So why is NIH spending $39 million annually on a disease that no longer exists and other departments are covering the defense needs?

13.4 Allergic Rhinitis (Hay Fever)

Allergic Rhinitis has the smallest annual expenditure of any of the categories we studied, but even a small class of projects can have a lot of waste. Nasal allergic reactions are annoying, but almost all of them can be controlled with existing medication. Commercial pharmaceutical companies continue to turn out ever more effective and convenient medications to control this condition, so why does NIH need to do more research? One project has been running for 14 years with the same two principal researchers in charge for the whole time, during which they spent $7,896,932.[358] The project abstract claims "Over 100 million people worldwide suffer from birch pollen allergy. However, identification of molecular determinants driving the allergic responses to Bet v 1, the major birch pollen allergen, remains elusive." If after 14 years and almost $8 million they have not figured it out, then it is time to halt the project. If they are correct and 100 million people have the condition, then if each person were to pay $1.00 per month for relief, that would be $1.2 billion of annual revenue. Mission-focused private company researchers in a market economy would have found that solution by now, or the investors would have pulled their support and turned instead to either a different research team or a more promising target. But there is no mission here, just maintenance of an unfruitful pipeline.

13.5 Tobacco/Tobacco Smoke and Health

Smoking is a known cause of serious health problems such as lung cancer and a variety of cardiovascular conditions. The solution for most, although not all, cases is simple. Do not smoke. As documented above, research completed more than 70 years ago has led to the incidence of smoking declining systematically since 1954 and smoking in the United States is now down by more than 75 percent.[359] But instead of declaring victory and moving on to look for the causes of other diseases, NIH has funded 336 projects at $145 million over the last 15 years focused on figuring out how to get more people to stop smoking, often trying to slip anti-smoking efforts into the treatment protocols for conditions such as HIV, serious mental illness, and routine dental procedures.[360] For example, the project "Effect of Tobacco Advocacy at the State Level" has spent $2.6 million from 2016 to 2020 and an unknown amount from another 22 prior, but undocumented, grants, evaluating state laws and regulations to inhibit tobacco use.[361] There is no legislative or constitutional basis for federal spending to evaluate and promote state legislation and regulation

[358] *NIH RePORTer*, Project Details, Project Number 1ZIAES102906-13.
[359] Jeffrey M. Jones, "U.S. Cigarette Smoking Rate Steady Near Historical Low," Gallup, August 18, 2023.
[360] Calculated by authors from projects assigned by NIH to Spending Category "Tobacco" or "Tobacco Smoke and Health."
[361] *NIH RePORTer*, Project Details, Project Number 5R01DA043950-27.
The "-27" tag on the project number tells us that this has been the 27th grant in a series, but a note in the database says that the project number has changed, so we can't trace the prior spending.

to inhibit tobacco use. At this point, we know for certain what the consequences of smoking are and how to avoid them. We don't need more research on how to manipulate people's preferences. We do need treatments and cures for dozens of diseases with unknown causes.

13.6 Contraception/Reproduction and Infertility

Some research related to both maternal and infant pathology and disease during pregnancy and delivery is included in this group, but many of the projects are not related to improving health or reducing mortality. By definition, contraception is intervention to prevent a normal, healthy human response, not a means to prevent or treat a disease. It is not necessary for preventing morbidity or mortality. Furthermore, there are scores of safe, effective, and affordable methods for preventing pregnancy, including pharmaceuticals, medical devices, and behavior. If there is demand for easier or more convenient methods, the market is capable of providing them for those who are willing to pay for them. The biology for preventing pregnancy is no mystery, and if users are demanding improvements, pharmaceutical or medical device companies can readily produce them.

Following are a few of the many wasteful projects in these categories:

- "Evaluation and Testing of a Decision Support Aid in Contraceptive Decision Making" spent $367,410 over three years to provide "a period of mentored research and career development activities, which will assist [applicant] in [applicant's] long-term goal of becoming an independent investigator in the area of women's contraceptive decision making." This is not critical research for improving longevity or health. This is three years of free support at taxpayer expense for someone who already has a doctorate degree to write and test a web-based application to guide women deciding on which, if any, contraceptive they would use. The test detected absolutely no difference in the choices made with or without the app, yet the researchers would not take "no" for an answer and concluded that, "Future studies could focus on testing the decision aid in different clinical settings."[362] Hopefully not at taxpayer expense.
- Dozens of projects do no research, but train people to be researchers—skills they had presumably required during their graduate education. For example, NIH funded a series of 15 training sessions entitled "Frontiers in Reproduction (FIR) Training Course" at a cost of almost $3 million. This is complemented by a five-year $1.5 million grant for the "Georgia Regents University Women's

[362] Madden, Tessa, et al., "Evaluation of a Computerized Contraceptive Decision Aid: A Randomized Controlled Trial," *Contraception* 102, no. 5 (2020): 339–345.

Reproductive Health Research Career Development Plan," for which "Members of underrepresented groups will be recruited proactively." For all that money, the University of Georgia will train the grand total of four individuals, presumably from underrepresented populations.[363]

- Another has spent $27.8 million to support 60 graduate physicians in three-year fellowships to prepare them to obtain certification from the American Board of Obstetrics and Gynecology in the Subspecialty of Reproductive Endocrinology.[364]
- Another grant has spent $7.6 million to train doctors "to be able to function as a consultant to pediatricians, family practitioners, obstetricians and gynecologists for girls from birth up to age 18-21 years with pediatric gynecologic concerns."[365]
- Two programs spent a combined $4.7 million for Reproductive Epidemiology training.[366] This money goes to simple career training with no research objectives.
- A $3.4 million project attempted to transplant spermatogonial stem cells from fertile rhesus macaques into the testes of infertile rhesus macaques to see if the monkeys so treated can father "normal" offspring. The speculation was that if it worked in monkey, maybe it would work on human males and thus help avoid existing "artificial" means of impregnating their partner.[367] This is clearly not a project of major public health concern any more than the lack of great stature or extraordinary muscle strength is a condition requiring publicly financed research to enable folks like the authors to become professional basketball or rugby players. Moreover, it is a waste of taxpayer dollars because private fertility clinics that help couples wishing to become pregnant are thriving and achieving results.
- NIH spent $708,146 in the first year of a project studying "Developmental Origins of Cardiovascular Disease in Offspring from Non-human Primate Pregnancies at Advanced Maternal Age."[368] (Advanced maternal age being age 35 or greater.) The project does not reveal why one would study monkeys rather than humans. The project seems to require no treatments and no invasive testing and the sample sizes are tiny—16 mothers who are "old" and 16 who are "young." Yet studying the mothers and children of 32 humans should not be hard. The one plausible justification for using non-human primates might be that the offspring from the tested mothers would mature earlier and

[363] *NIH RePORTer*, Project Details, Project Number 5K12HD085817-05.
[364] *NIH RePORTer*, Project Details, Project Number 1ZIEHD008737-22.
[365] "Pediatric and Adolescent Gynecology Training Program," *NIH RePORTer*, Project Details, Project Number 1ZIEHD008985-04.
[366] *NIH RePORTer*, Project Details, Project Number 5T32HD007440-25.
NIH RePORTer, Project Details, Project Number 5T32HD055172-10.
[367] *NIH RePORTer*, Project Details, Project Number 3R01OD028223-04S1.
[368] *NIH RePORTer*, Project Details, Project Number 1R56HL164434-01.

thus be available for testing sooner. But the project will not use the offspring from the study's mother cohort, it will use "current 8- to 10-year-old adult vervets" from entirely different mothers. One could do the same with humans. In fact, the faster maturation among vervets would at least suggest caution in any conclusions from them about slower maturing humans. The project claims that advanced maternal age is a "non-modifiable risk factor for adverse pregnancy outcomes." Logically, that is nonsense. It's very simple to modify the age at which a person chooses to become pregnant. The increasing age of pregnancy is a result of many individual choices, and hardly a necessary expenditure of taxpayer funds. Clinics wishing to provide services to women seeking pregnancies at older ages can certainly conduct such tests themselves.

- One project spent $884,758 to observe the behaviors of more than 300 baboons during pregnancy and early years of raising their offspring?[369] Human children are not baboons, so if improving mothering is the objective, observing real human mothers would be far more useful.
- The ten-years-and-counting project "Inferring the function of sleep-associated polymorphisms across species" looks like a typical "pipeline" research project with no clear mission. It has spent $2.1 million comparing the genes of Drosophila melanogaster, better known as the fruit fly, with those of "mutant mice" to get some idea about whether genes that determine the quality and quantity of sleep also affect the evolutionary success of an organism, as implied by the number of fly offspring and the performance of mice on a learning and memory test.[370] The similarities of these genes with human genes have already been explored, with no clear indication of the human disease or condition they are seeking to understand.
- The project "Molecular Biology of Mammalian Gametogenesis, Fertilization and Early Development," has so far burned through $13.8 million to understand the physical and chemical processes that create both the female and male germ cells during cellular division in mammals. Deficiencies in this process can lead to infertility. This is an interesting biology question, but this is a pipeline project looking at mammals in general and not focused on a mission related to a particular human health issue. In fact, it does not seem to be relevant to improvements in either mortality or morbidity. And it is not the only project on this general topic of cell-division and chemistry related to fertility, most of which examine non-human mammals such as mice and primates either exclusively or in addition to

[369] *NIH RePORTer*, Project Details, Project Number 5P51RR013986-13.
[370] *NIH RePORTer*, Project Details, Project Number 1ZIAHL006167-10.

humans. At least another $46.3 million has been spent by these other projects immediately preceding or coincident with this project.[371]

- Like many of the other expenditure categories, Contraception/Reproduction and Infertility projects heavily involve taxpayer-funded efforts to influence people's behavior, such as "Randomized Trial of an Intervention for Preventing Alcohol Exposed Pregnancy among Women in a Remote Reservation Community." There is no fundamental research required. Stop drinking and there is no alcohol-exposed pregnancy. This five-year project spent $1.4 million looking for a different answer, partly justifying its existence because previous studies had not included either rural folks or American Indians or Alaska Natives.[372]
- Perhaps the biggest surprise in this group of projects was the set of 17 projects that spent $13.9 million working on cures for erectile dysfunction. This is a condition that is neither debilitating nor contributory to mortality and doesn't even prevent impregnation. Commercial medication and fertility clinics have had huge successes in addressing this condition, but NIH keeps playing with tax dollars for no added benefit.
- Now consider the project with the stimulating title "Task Order 19: Invited" that spent $1.2 million from September 2021 to July 2023 to "carefully evaluate the hormonal, ovulatory, and overall menstrual cycle changes that occur with vitamin D treatment. Vitamin D supplementation may be a low-cost intervention that improves menstrual cycle function and fertility."[373] This is not basic science research, but a simple test that fertility clinics or vitamin manufacturers might reasonably conduct as part of their normal business operations. After being completed for nearly two years, this project reports no results and no publications.

[371] *NIH RePORTer*, Project Details, Project Number 5R01HD058631-05; *NIH RePORTer*, Project Details, Project Number 5R01HD065435-10; *NIH RePORTer*, Project Details, Project Number 3R01HD013254-23S1; *NIH RePORTer*, Project Details, Project Number 1R01HD105358-01A1; *NIH RePORTer*, Project Details, Project Number 1R01HD072189-01; *NIH RePORTer*, Project Details, Project Number 3R15GM123447-01S1; *NIH RePORTer*, Project Details, Project Number 5R03HD053602-02; *NIH RePORTer*, Project Details, Project Number 2R01HD087417-06; *NIH RePORTer*, Project Details, Project Number 5R01HD094395-05; *NIH RePORTer*, Project Details, Project Number 7R01DK110477-05; *NIH RePORTer*, Project Details, Project Number 2P20RR016480-09; *NIH RePORTer*, Project Details, Project Number 1ZIADK015603-12; *NIH RePORTer*, Project Details, Project Number 1Z01DK015603-02; *NIH RePORTer*, Project Details, Project Number 5P42ES013660-14; *NIH RePORTer*, Project Details, Project Number 5P50HD055764-15; *NIH RePORTer*, Project Details, Project Number 5P50HD076210-05; *NIH RePORTer*, Project Details, Project Number 5P50HD068157-05.

[372] *NIH RePORTer*, Project Details, Project Number 5P60AA026112-05.

[373] *NIH RePORTer*, Project Details, Project Number 273201600003I-P00003-759602100019-2.

13.7 Pregnancy

One project provides a clear prototype and representation of the work in this category. In the most recent fiscal year with complete data (FY 2022), NIH spent $30.5 million for "NHLBI Maternal Morbidity and Mortality (3M) Administrative Coordinating Center." The project is divided into eight separate parts, which may give it the appearance of different projects, but all the money went to Westat, Inc. in Rockville, Maryland, a large consulting firm that has specialized in government contracting for decades.[374]

The project description begins with a false premise: "Over the past three decades, there have been alarming upward trends in the rates of maternal morbidity and mortality in the United States." This assertion is not some incidental public relations by a consulting firm; it is featured in the Budget Executive Summary from the Director of the NIH, Lawrence A. Tabak, which states, "In response to rising maternal mortality (MM) in the United States, the Implementing a Maternal Health and Pregnancy Outcomes Vision for Everyone (IMPROVE) Initiative will support research on how to mitigate preventable MM, decrease severe maternal morbidity (SMM), and promote health equity in the United States."[375] This is fifth in a list of 32 featured initiatives, well ahead of cancer initiatives and in a list that does not even include the number one killer in the United States, cardiovascular disease.

Both NIH and Westat should know better. The touted rise in maternal mortality is not real, but is an artifact of a change in the way the Centers for Disease Control and Prevention (CDC) counts the cases. The "official" statistics claim that maternal deaths rose from 9.65 per 100,000 live births in 1999-2002 to 23.6 in 2018-2021. If the results are adjusted to correct for the change in counting method, the number of maternal deaths per 100,000 live birth was virtually unchanged at 10.2 in 1999-2002 and 10.4 in 2018-2021. The difference arises from the fact that CDC mandated that all death certificates include whether the death occurred while pregnant or within one year of the end of pregnancy and then began counting all those as MM. This led to counting cases of deaths from preexisting conditions, cancer, and dozens of other causes unrelated to pregnancy and childbirth. Poor implementation procedures also caused operational errors that counted hundreds of women over age 70 as "being certified as pregnant at the time of death or in the year before death."[376]

What is more important, within that total number of deaths, the total number arising from direct obstetrical causes decreased sharply from 7.05 to 5.82 per 100,000 live births. All the rest were from preexisting conditions

[374] *NIH RePORTer*, Project Details, Project Number 3OT2HL158287-01S7Project Number 3OT2HL158287-01S7.
[375] Office of Management and Budget, *Overview of the FY 2024 President's Budget*, p. 8.
[376] K.S. Joseph, MD, PhD, et al., "Maternal mortality in the United States: are the high and rising rates due to changes in obstetrical factors, maternal medical conditions, or maternal mortality surveillance?," *American Journal of Obstetrics & Gynecology* 230, no. 4 (April 2024): 440.e1–440.e13. For a less technical summary see Allysia Finley, "Abortion and America's Phony 'Pregnancy Crisis,'" *Wall Steet Journal*, March 25, 2024.

or incidental causes, some of which would have been counted even under the old method of counting. The focus needs to be on primary causes unrelated to childbearing—such as cardiovascular conditions, cancer, and substance abuse.

The Westat project conducted no research with its $30.5 million in that one year. It describes its activities as follows: "The goal of the NHLBI 3M Administrative Coordinating Center (3M ACC) is to engage communities and networks in areas that experience high levels of maternal morbidity and mortality. The 3M ACC will support the preliminary work necessary to identify and prepare a group of community-based organizations to respond to future funding opportunities. The 3M ACC will develop the infrastructure to support this group of Maternal Morbidity and Mortality Regional Coalitions (3M RCs) and provide scientific support and coordination to NHLBI on emerging scientific needs. Specifically, the 3M ACC will support these programmatic objectives:

- Identify research groups and organizations with existing and relevant expertise and community partnerships.
- Conduct landscape analyses and community-informed needs assessments.
- Identify within each community implementation opportunities and barriers to improve delivery of evidence-based care to reduce maternal morbidity and mortality.
- Develop and conduct early-stage tests of implementation approaches to identify potential strategies to ensure the proposed approaches are acceptable, feasible, scalable, and sustainable and to identify barriers."[377]

Besides not funding any actual research, this project is poor use of taxpayer dollars. Even the administrative activities that it funds are related only to implementation and community organization, not supporting research. Note how the project's own description highlights "support the preliminary work necessary to identify and prepare a group of community-based organizations to respond to future funding opportunities." In other words, it will use taxpayer dollars to organize other groups to apply for more grants presumably to repeat the same fruitless activities.

13.8 Alcoholism, Alcohol Use and Health

Alcoholism is a subclass of substance misuse, so most of the projects in this category, could have been included in the substance abuse category, which includes some alcohol-related projects already. NIH includes a National Institute on Alcohol Abuse and Alcoholism (NIAAA), so this category would seem to be a comprehensive

[377] *NIH RePORTer*, Project Details, Project Number 3OT2HL158287-01S7.

catalog of its work. And sure enough, two of the top projects on the list from the NIH RePORTER system are "NIAAA Pay Plan Solution System and Microsoft Azure Cloud Support"[378] and "NIAAA Pay Plan System Enhancements to add functionality."[379] These projects seem to pay for computer system work for compensating the bureaucrats that run this department. In fiscal year 2022 they spent $817,765 and included the provision for "two (2) twelve month options to extend to 09/27/2025." This NIH human resource administration system is not even remotely medical research, and yet it includes about $2.5 million masquerading as such.

Two projects with almost identical names and sequential project numbers spent a total of $742,569 in fiscal year 2022 for "Alcoholism Solutions: Synthesizing Information to Support Treatments."[380] The project descriptions provide no information as to why these projects are needed, why NIH does not require that grant recipients provide such information in the first place, or why NIH's vast staff cannot fill this role. There is no special research skill required to provide these summaries, so it is misleading to include them in the database of research being performed.

Other non-research grants include:

- "NIAAA Publications and Exhibits Support" at a cost of $1,698,172 for one year.[381]
- "Partial Support for the Core Activities of the Government-University-Industry Research Roundtable," which "is charged with improving the research enterprise of the United States by successfully resolving the cross-sectoral issues that prevent the U.S. research enterprise from reaching its full potential."[382] The project description provides no information on exactly what type of cross-sectoral issues exist and why the highly paid NIH staff cannot work to resolve them. The reported spending for the project is a seemingly modest $18,000 in fiscal year 2022, but the fact that the project claims to provide only "partial support" implies that there is other spending scattered among the thousands of other projects. Moreover, the project appears four times in the official database with the exact same title and spending for the same fiscal year.
- "To provide marketing and outreach for the NIAAA SBIR/STTR program to help communicate the objectives of the program," for which NIH hired a marketing agency for $228,226 in fiscal year 2022.[383]
- Also lacking any value whatsoever for research is the project "To Support and Improve the Institute's

[378] *NIH RePORTer*, Project Details, Project Number 94022A00194022F00001-0-0-1.
[379] *NIH RePORTer*, Project Details, Project Number 94022A00194022F00002-0-0-1.
[380] "Alcoholism Solutions: Synthesizing Information to Support Treatments (ASSIST 2.0)," *NIH RePORTer*, Project Details, Project Number 75N94022C00003099991; *NIH RePORTer*, Project Details, Project Number 75N94022C00003-0-9999-2.
[381] "NIAAA Publications and Exhibits Support," *NIH RePORTer*, Project Details, Project Number 75N94020F00067P0000601 (P00006).
[382] "Partial Support for the Core Activities of the GovernmentUniversityIndustry Research Roundtable (GUIRR)," *NIH RePORTer*, Project Details, Project Number 263201800029IP000017598021000171 (P00001).
[383] *NIH RePORTer*, Project Details, Project Number 75N94022F00139001.

Ability to Provide Accurate, Relevant, and Up-to-date Information on its Public Websites," at a cost of $851,049 for fiscal year 2022.[384]

There are projects in this classification that at least look like research. The project "Mechanisms Underlying Individual Variations of Taste and Smell in Obesity" is funded by the National Institute on Alcohol Abuse and Alcoholism.[385] The project description provides no information on why differences in taste and smell by obese people compared to non-obese people is relevant in the treatment of alcoholism, or any other significant medical condition. The project has spent $917,082 for four years through fiscal year 2024. It looked at only 124 obese subjects and the same number of non-obese. In other words, the project spent nearly $1 million over four years to sort out whether 124 obese folks have a different sense of smell from non-obese. So far, the NIH database reports no results. The study sample size is so small that it is highly unlikely to yield any statistically significant results. Even if the results pass normal significance test, the sample selection is described as "recruitment" rather than random selection, so non-sampling errors may well outweigh sampling errors.

Another project illustrates work that might be useful but does not belong in NIH or any place else in government. "Records for Alcohol Care Enhancement (RACE)" has spent $1,562,934 over five years ending 2023.[386] Its objective was to use the existing Electronic Health Record (EHR) in a hospital that is part of an accountable care organization (ACO) to set up flags to alert providers to patients that potentially suffer from alcohol use disorder (AUD) and provide them with existing best-practices care protocols for treatment. This is not medical research. It is a straightforward process improvement that most good hospitals, HMOs, and CMOs already do, and that any hospital could readily implement. The project further specifies that the ACO is "in a diverse underserved community." The project charter does not say why that makes any difference (though it probably checks a political box).

One of these authors (Early) has facilitated projects like this in hospitals and large group practices for other conditions such as diabetes, COPD, and asthma. They typically required 6 to 12 months to complete by part-time teams with other assignments, and never cost close to $1.6 million. For this type of project, the primary focus should be on achieving specific measurable outcomes, not conclusions with vague statements that it "will inform likely effectiveness for improving care and lead to better clinical outcomes from less heavy drinking to fewer emergency department visits." If project sponsors cannot set specific numeric goals for precise metrics, they

[384] *NIH RePORTer*, Project Details, Project Number 75N94022F00123001.
[385] *NIH RePORTer*, Project Details, Project Number 1ZIAAA000135-04.
[386] *NIH RePORTer*, Project Details, Project Number 7R33AA027597-05.

are not prepared to do the project. Without specific, measurable, timed goals, it is not surprising that after seven years, the NIH database entry for this project reports "No outcomes available."

13.9 Nutrition

One of the oldest scientific misconceptions is that breakfast is intrinsically healthful. In 1847 Dr William Roberston claimed breakfast to be "the most important meal of the day."[387] But Roberston, who practiced in the United Kingdon in the spa town of Buxton, was a so-called water physician who believed that drinking his waters for breakfast cured diseases.

A century later, the widely read nutritionist Adelle Davis said we should "eat breakfast like a king, lunch like a prince, and supper like a pauper."[388] But Davis believed, absurdly, that dangerous early morning hypoglycemia was epidemic.[389]

The reality is that, all else being equal, eating breakfast increases daily calorie intake by about 300 calories, so—in this era of obesity—promoting breakfast is anything but healthful.[390] Moreover, mornings are a time of insulin and glucose resistance, which makes breakfast a challenge for the growing number those who are prediabetic.[391]

Nonetheless, once a misconception has becomes entrenched, and the scientific elite has invested in it, it behooves researchers with strong career ambitions to select their data to fit the preconceptions of the reviewers of grants, papers and promotion committees.[392] But we should be able to look to the NIH to elevate the practice of science, not to reinforce its failings, so let us ask: did the NIH help break that vicious cycle in breakfast research?

The project "Exploring strategies to increase school breakfast consumption in middle schools" spent $303,264 in grants over two years.[393] The mere existence of this project is not encouraging because why would we want to increase school breakfast consumption in a world of obesity? The researchers offered neither data nor informed analysis on that question. Nor did the researchers report any positive value of such increased consumption. The only publication they listed in the NIH project database as having come from the project was entitled "Middle-school students' school lunch consumption does not meet the new Institute of Medicine's National School Lunch Program

[387] William Robertson, Treatise on Diet and Regimen, 4th ed. (John Churchill, 1857), p. 285.
[388] Adelle Davis, Let's Eat Right to Keep Fit (Harcourt, Brace, 1954), p. 28.
[389] Terence Kealey, *Breakfast is a Dangerous Meal* (4th Estate, 2016), pp 21–22.
[390] David Levitsky and Carly Pacanowski, "Effect of Skipping Breakfast on Subsequent Energy Intake," *Physiology & Behavior* 119 (2013): 9–16.
[391] Diabetes UK, *Prediabetes: Preventing the Type 2 Diabetes Epidemic* (Diabetes UK, 2009).
[392] Terence Kealey and Patrick Michaels, ed., "Larding the Fat: The Dietary Fat Fiasco," in *Scientocracy: The Tangled Web of Public Science and Public Policy* (Cato Institute, 2019), pp. 9–36.

[393] "Exploring Strategies to Increase School Breakfast Consumption in Middle Schools," *NIH RePORTer*, Project Details, Project Number 5R21HD051661-02.

recommendations," which reported that in school lunches in five middle schools in southeast Texas students did not select servings of fruits, vegetables and whole grains in the recommended amounts.[394] This paper attempted to answer an entirely different question about compliance with lunch standards rather than about increasing breakfast consumption, the stated purpose for funding the project. That is one more example of the failure by NIH to enforce standards that require the grantees actually spend the money on the subject for which they were funded.

These grantees eventually published a paper entitled "Exploring strategies to promote middle school student participation in the school breakfast program" and attributed support from this NIH grant, along with three others, but they never added it to the NIH database. That paper only concluded that uptake of breakfast doubled when middle school students were offered a free breakfast at school, accompanied with an active marketing promotion by school staff and parents.[395] There were no measures of any changes in actual academic achievement or improved health.

This was a modest finding compared to a much larger and more scientifically robust study of free breakfasts for school children in Great Britain, conducted in 2014-2015.[396] It reported not only on the uptake of free or subsidized breakfasts across a large number of schools but also reported on their effects on students' weights, their academic attainment, and their attendance. It also separated the nutritional from the social effects of the breakfast programs. Indeed, without such outcome data, a paper exploring strategies to promote middle school student participation in the school breakfast program is of little or no value.

The British study found that, at the schools offering free school breakfasts, students' weight did not increase, academic performance increased by the equivalent of two extra months of learning, and average pupil absences fell by almost half a day per year. Yet robust analysis of the data showed that the benefits were attributable not to any increased nutrition (eating breakfast at school simply substituted for eating breakfast at home), but to the extra socialization the students enjoyed while eating breakfast at school before the formal education began.[397]

The following are other breakfast projects that offer no useful results, largely repeat the conventional wisdom, and ignore not only research that contradicts it but even their own results.

- A group of researchers published a paper in 2013 entitled "Beneficial effects of a higher-protein breakfast on the appetitive, hormonal, and neural signals controlling energy intake regulation in overweight/

[394] Karen Cullen et al., "Middle-School Students' School Lunch Consumption Does Not Meet the New Institute of Medicine's National School Lunch Program Recommendations," *Public Health Nutrition* 14 (2011): 1876–81.
[395] Karen Cullen et al., "Exploring Strategies to Promote Middle School Student Participation in the School Breakfast Program," Journal of Child Nutrition and Management 36 (2012).
[396] Claire Crawford et al., "Magic Breakfast: Evaluation Report and Executive Summary," (Institute for Fiscal Studies, 2019).
[397] Terence Kealey, "Eating or Meeting? The Dubious Case for Free School Breakfasts," (Institute of Economic Affairs, 2017).

obese, 'breakfast skipping,' late adolescent girls." The study's authors found that "with the addition of a 350-kcal HP [high protein] breakfast, daily intake, albeit nonsignificant, was greater (~120 kcal) compared with when breakfast was skipped."[398] The experiment's insignificant increase means only that it is not different from zero. A beneficial effect would have been a *reduction* in energy intake. To claim that the change was beneficial (i.e. a reduction), as the authors do in their title, is misleading.

- A subsequent 2015 paper from the same group was entitled "A high-protein breakfast prevents body fat gain, through reductions in daily intake and hunger, in 'Breakfast skipping' adolescents." It was as misleading as their 2013 paper because body weights in the high-protein breakfast-eaters' body fat did not decrease.[399] They base their claim of preventing body fat gain only on the fact that the increased energy intake by the experimental group was less than the increased intake of the control group. When a control group shows counter-expectation behavior in a variable, sound scientific practice would be to discard the relationship or provide proof as to the cause. Moreover, the control group is an unjustifiably small nine people, so this difference is most likely just random variation, but the paper does not even note this weakness, much less provide proof of the validity of their claim.
- The two studies immediately above were not funded by NIH, but after publishing them the same researchers began receiving NIH grants across five years totaling $3,335,755 under the title "Increased Protein at Breakfast for Weight Management in Overweight Adolescents."[400] The history and subsequent results of this grant show poor judgement in both making and managing it. This grant was made to the same group that had published two papers on the same topic that demonstrated no beneficial impact of the increased protein breakfast proposed for study and then misrepresented those findings. No publications, clinical studies or patents are reported on the NIH database for this project after more than five years.
- NIH granted $155,000 for "School breakfast program mandates and childhood obesity."[401] The funded proposal claimed it would "investigate the impact of eating breakfast through the School Breakfast Program (SBP) on childhood obesity." But the project database reports no results, and the only

[398] Heather J. Leidy et al., "Beneficial Effects of a Higher-Protein Breakfast on the Appetitive, Hormonal, and Neural Signals Controlling Energy Intake Regulation in Overweight/Obese, 'Breakfast Skipping,' Late Adolescent Girls," *American Journal of Clinical Nutrition* 87, no. 4 (2013): 677–88.

[399] Heather J. Leidy et al., "A High-Protein Breakfast Prevents Body Fat Gain, through Reductions in Daily Intake and Hunger, in 'Breakfast Skipping' Adolescents," *Obesity* 23, no. 9 (2015): 1761–64.

[400] "Increased Protein at Breakfast for Weight Management in Overweight Adolescents," *NIH RePORTer*, Project Details, Project Number 5R01DK107390-05.

[401] "School Breakfast Program Mandates and Childhood Obesity," *NIH RePORTer*, Project Details, Project Number 5R03HD067490-02.

documented output of the project was a paper "Nutrition and cognitive achievement: An evaluation of the School Breakfast Program," which is an entirely different topic. A search of Google Scholar showed no publication by the grantee with a subject like that proposed for the grant, so NIH failed to enforce compliance with documented basis for funding the project. Why? Was it mere sloppiness, waste, or abuse? Or did the research fail to uphold the conventional priors and was, therefore, suppressed? (Recall from Chapter 10 NIH's suppression of hormone replacement therapy results.)

- More confusion over breakfast came from the NIH-funded Health Professionals Follow-Up Study (HPFS), which followed 51,529 middle-aged professional white men who were recruited in 1992. Among these men 17 percent were breakfast skippers, and in a series of papers the HPFS recorded that the skippers were more likely to gain weight, develop type 2 diabetes, and develop coronary heart disease than were the breakfast eaters.[402] These data were only associations, because, as the HPFS acknowledged in the resulting papers, skipping breakfast is associated with dangerous lifestyle choices, including smoking, drinking, snacking, being unmarried, and avoiding regular health checkups. Moreover, the HPFS acknowledged that breakfast eaters ate 123 more calories a day than did skippers. Nonetheless, the HPFS maintained even after statistical correction for dangerous lifestyle choices, that breakfast was healthful and that skipping breakfast was unhealthful because fasting was stressful and stress was unhealthful.[403] This claim of stress from fasting was not supported by empirical data. In short, the NIH-funded Health Professionals Follow-Up Study did not help break the vicious cycle in ill-begotten breakfast research from NIH.

A similarly ill-conceived series of projects and pronouncements fueled a decades-long debacle that promoted low-fat and high-carbohydrate diets and ended in failure.[404] In general, the federal government's attempts to promote healthy nutrition have been failures. While the details of each of the failure may differ, the fundamental factors leading to those failures include the following:

1. Government has a bias "to do something" and "something" in this context often means forcing or encouraging people to change their eating habits. This bias is inherent in public choice behavior

[402] Amber Van der Heijden et al., "A Prospective Study of Breakfast Consumption and Weight Gain in US Men," *Obesity* 15, no. 10 (2007): 2463–69; Rania A. Mekary et al., "Eating Pattern and Type 2 Diabetes Risk in Men: Breakfast Omission, Eating Frequency, and Snacking," *American Journal of Clinical Nutrition* 95, no. 5 (2012): 1182–89; Leah E. Cahill et al., "Prospective Study of Breakfast Eating and Incident Coronary Heart Disease in a Cohort of Male U.S. Health Professionals," *Circulation* 128, no. 3 (2013): 337–43.

[403] Terence Kealey, *Breakfast Is a Dangerous Meal* (4th Estate, 2016).

[404] Terence Kealey, "Why Does the Federal Government Issue Damaging Dietary Guidelines?" Cato Institute Policy Analysis no. 846, July 10, 2018.

because it directly encourages the expansion of government and the rewards for those employed by it. Doing something also indirectly grows bureaucratic scope with attention-grabbing headlines that build public awareness and support.

2. When prescribing eating less of food A, it ignores the fact that the consumer, of necessity, will substitute something else, say food B, which may have unknown or even worse effects.
3. Government is slow to react and may even ignore independent science by the private sector that demonstrates results that are contrary to its advice.
4. Government often adopts simple prescriptions that give some indication of a diet's effect on a disease, without full scientific proof, while ignoring the more likely complex interactions of multiple causes, many of which may not be related to diet. Furthermore, the resulting recommendations almost never are based on randomly selected, double-blind, randomly assigned controlled experiments over a long period of time or robust statistical analysis.
5. When those simple prescriptions lead to a recommendation, then government adopts an asymmetric demand that canceling the recommendation must be supported by proof that is much stronger than the proof supporting its adoption.

The NIH nutrition project "Assessment of Post-Prandial Effects of a Fast-Food Meal on Inflammatory Markers" has been funded since 2007, spending $1,128,470 to date and still going. Over all those years, the annual description of the project has barely changed, except that in the early years the authors described an intention to do the work, and in the latter years they said they had done most of the work, but not the final analysis.[405]

The project is simple; 30 subjects were fed a meal of either high-saturated or low-saturated fats and then, after a 3-day interval, the alternative fat meal. The subjects' responses in terms of circulating blood levels of metabolites and cytokines were then measured. This should have been a one-year, $150,000 program, not an 18-year million-plus dollar program. The stated purpose of the project is "is to determine the acute effect of eating *a fast-food meal* high in saturated fat and whether it results in greater increases in inflammatory markers and declines in testosterone than eating a meal with low levels of saturated fat and higher levels of mono-unsaturated fat." (Emphasis added.) The project description is of comparing meals of high- and low-saturated fats, and the authors have extrapolated that to studying fast food. Yet they haven't studied actual fast foods; they've studied high- and low-saturated fats. This is not a pedantic objection because fast foods are not

[405] "Assessment of Post-Prandial Effects of a Fast-Food Meal on Inflammatory Markers," *NIH RePORTer*, Project Details, Project Number 1ZIAAG000631-18.

synonymous with high-saturated fats. They are also with low fiber, low vitamins, high-carbohydrate, high-protein and other consequences of high processing.

The project still seems not to have been completed, in that the NIH website posts no papers that have been published from it; moreover, a search on Google Scholar seems to show no publications from it either. *Prima facie*, this project is typical of so many we have reviewed. It speaks of the degree of laxity that would not be found within the foundation, company, or independent charity sectors. Projects such as this contribute to the slow adaptation of government-funded scientific research to developments elsewhere, and its proclivity for favoring simplistic solutions that do not meet exacting scientific standards.

14 How can we fix NIH?

Improving health is important, but it does not necessarily follow that government needs to be involved in that quest. In fact, as we have shown, the vast annual government expenditure of $51 billion has funded NIH growth into an undisciplined behemoth that has impeded the rapid improvement in longevity and other health indicators. As of this writing, a new administration is starting work in Washington, including a new director of NIH. It is our earnest hope that the overall strategic review and operational details that we have documented in these pages can help them map out the work needed to transform the failing NIH and return the United States to its former more rapid progress in effective health research.

14.1 Radical Shift in Structure and Strategy

The first and crucial step in this transformation is to adopt the successful model of *mission* research—thus discarding the failed linear model—and focus on the institution's stated purpose: to reduce morbidity and mortality among Americans. This change will help replicate the success of returning the Advanced Research Projects Agency to its roots of performing defense mission research only, making that research more effective, and freeing unneeded resources toward more productive private sector and philanthropic work—the kind that helped launch the personal computer and internet revolutions.

In keeping with this redefined research model, each project should have a clearly defined mission with measurable goals that can offer immediate and obvious benefit to the American people, defining specifically the disease(s) being researched and the health outcomes to be achieved. Goals should include target dates for completion, with intermediate targets at least quarterly. Each project should be held accountable for achieving its mission goals. The budget documents submitted to OMB and Congress should include a summary of the projects to be undertaken and detailed definitions of how each project will proceed. Each project should also include a justification for why only the government can conduct this research. Each project budget should include a full tally of overhead and administrative costs. For projects that have already begun, intermediate progress against goals should be reported on at least a quarterly basis. The overhead and administrative costs for NIH not paid directly by funded projects should not exceed 1 percent of the total NIH funding budget.

These changes will result in a significant shrinkage of the NIH domain and increased private sector activity. This will leave NIH better positioned to identify and complete research to promote health, as it will be more focused on meeting the needs of the people paying for the results. Other projects may be more appropriate for the

wide range of private foundation, charity, or university funding, which financed almost all private sector medical research before 1960. Projects of little or no value will naturally disappear. A smaller, more focused NIH will also enable better oversight by Congress and the public, leading to more considered and meaningful budgets.

14.2 Immediate and continuing elimination

As the foregoing chapters have shown, some categories of projects should be eliminated immediately. The following categories can be identified quickly, and they constitute 40.9 percent of project spending. Eliminating all projects in the following categories would have no adverse health effects:

- All behavioral and social science projects, including those classified as such in the Research, Condition, and Disease Condition system, as well as projects that are not medical research to support the diagnosis, prevention, or treatment of a disease. This criterion would disqualify projects to modify people's behavior, other than behavior that is *caused* by mental or physical disorders that would be recognized as such by most individuals. This management initiative will eliminate at least 18.6 percent of all NIH project spending immediately with no loss to health.
- Projects that implement or operate treatment facilities. These are not research. The facilities implementing a program should fund that program. That would save another 6.8 percent of spending.
- Projects related to nutrition, alcohol, tobacco, violence, firearms, obesity, climate-related exposures and conditions, climate change, complementary health, homelessness, contraception, fertility, sexual practices, cost-effectiveness research (except cost-effectiveness research as part of evaluating the results of a clinically focused project), allergic rhinitis, or smallpox. These topics are either unrelated to health, have no need for further research, are already well covered by the private sector, or have a history of such poor performance as to be problematic. These would eliminate 15.5 percent of spending.
- Projects in foreign countries, except projects investigating the origins of infectious diseases that arise in those countries and constitute a threat to infecting people in the United States. Closing down the Fogarty International Center at NIH, which funds only foreign projects, would save almost $100 million annually, a little less than 1 percent of the NIH spending. But, as we have seen in our detailed reviews, there are also foreign projects funded under other NIH categories, which also should be eliminated, but have not been fully identified by this analysis. If expenditure for other health projects in foreign countries are deemed to be in the United States' best interests,

then the funds should be appropriated explicitly for those objectives and administered by the Department of State. We do not see any major likelihood of that being important but cannot preclude it *a priori*.

Most of the above candidates for ready elimination are reasonably obvious based on their high-level subject matter. Other projects for elimination require more examination of the details of how they are approaching the subject matter. Projects with the following features should not be funded in the first place, and funded projects with these characteristics should be stopped. Because these features are project-specific and do not apply to entire categories, we cannot estimate the budget impact of each. Projects that test, implement, or operate a treatment, drug, device, or procedure that is commercially available.

- Projects that test a proposed remedy without first proving the root cause.
- Projects intended to benefit the participants in any limited private group—a community, a specific business or set of businesses, a nonprofit organization, or anyone other than the general American public.
- Projects with any goals, aims, or objectives related to the race, ethnicity, sex, national origin, or any other secondary characteristics of either the patient or the researcher.
- Projects that do not adhere to strict scientific standards. These include projects that apply non-scientific concepts such as indigenous knowledge, "other ways of knowing," participatory data analysis, "ground truthing," or the transcription and analysis of people's attitudes, feelings, and beliefs.
- Projects justified, whether in whole or in part, on providing career development to a specific individual. Junior researchers may be employed on projects at their appropriate skill level, with the ancillary benefit of their gaining knowledge, experience, and ability.
- Projects for the benefit of the researchers or care providers such as eliminating their "burnout" or increasing claim payments from Medicaid.
- Projects that provide overhead support, including for facilities, administration, logistics, public relations, cleaning up and reconciling results from previous projects, maintaining research materials and animals, or giving support to groups seeking to apply for funding. Each project should include the funding of any overhead or administrative costs that it expects to incur.
- Projects that study animal behavior. Animal subjects for physical studies may be employed, but only when there is scientific evidence that the specific animal system being tested provides an efficient and

effective test for the similar human system in the context of developing diagnosis, treatment, or cure of a human condition.

- Projects that develop or recommend social or government policies. NIH-funded projects should aim only to find physical causes and treatments. Examples of failures to observe scientific principles and engage in policy recommendations have been documented above for gun control, pharmaceutical advertising, and government-mandated family leave.
- Projects that make any direct or inferential claims about possible criminality (such as "shaken baby syndrome").
- Projects that seek social determinants of Health (SDoH) such as income disparities, social mobility, or structural racism. As discussed in Chapter 11, these are ideological exercises, not scientific research into the causes of disease.

14.3 Radically Improve What Remains

NIH should implement true quality assurance on all projects that it sponsors. Projects should observe scientific best practices. Key features to be assured should include:

- When testing hypotheses, samples must be large enough to assure significant results if the alternative hypothesis (to the null hypothesis of no effect) has a physically meaningful difference. Significance must be determined at the 1 percent alpha level—namely less than 1 percent chance of incorrectly accepting the alternative hypothesis. Samples must be drawn randomly from a large population and assigned randomly to treatment and control groups, with a double-blind assignment process when physically possible.
- All data used to justify a project or to support its conclusions must be correct. We have shown examples of this failure to use correct data, such as in the false claims about an upward trend in material morbidity and mortality rates or rising mortality related to climate change.
- Tests of statistical significance are performed on all claims of outcomes, and the results are not misinterpreted, such as the false claims that hormone replacement treatment causes cancer or that mediation and exercise reduce acute respiratory infections rates.
- All projects must test statistical claims with the best-established methods. For example, they must use Fisher's exact test for comparing proportions rather than the normal approximation. They also

> must avoid the "big data" approach of testing all possible combinations of dozens of dependent and independent variables and then picking out those that pass a significance test without follow-up analysis that accounts for the possible failure that testing like this will yield some apparent significance strictly by chance.

Many of the facts we have laid out to assess the effects of NIH on American health have been negative because so much government medical research has been misdirected. But, despite these shortcomings, gifted scientists both in and out of government have conducted groundbreaking research that has helped to greatly improve and lengthen our lives. Dr. Scott W. Atlas of Stanford University and the Hoover Institution created an extensive compendium of peer-reviewed international medical literature. The results are overwhelming. When a patient develops a serious disease in the United States, he or she is far more likely to be treated sooner, using better methods, and achieving better outcomes, not by just a little bit but by huge margins.[406] All this achievement was in the face of the barriers we have identified. Yet, there could have been so much more improvement if medical research had been freed from the crowding out by NIH that has gone on for so long, and if NIH had shown more strategic focus and greater commitment to rigorous science. Americans' health deserves nothing less.

[406] Scott W. Atlas, MD., *Excellent Health: Setting the Record Straight on America's Health Care* (Hoover Press, 2011).