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A 21st Century Moonshot: How President Obama's Call to Cure Cancer Gets Tax Dollars to Scientists

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I. Introduction

On May 25, 1961, President John F. Kennedy declared to a special joint session of Congress that the United States would land a man on the moon before the turn of the decade.[1] It was an extraordinary and historic moment in American triumphalism, but it was as big a moment for the scientific community—the promise of increased focus and funding to achieve our goals through research and development. Not to be outdone by the last man elected to the highest office in the land from a Senate seat, President Barack Obama paid homage to President Kennedy in his final State of the Union Address, but shifted the American people's gaze from the heavens to the helix in a new "moonshot": "For the loved ones we've all lost, for the families that we can still save, let's make America the country that cures cancer once and for all."[2]

This historic announcement came just one month after the President signed a new budget that increased the National Institutes of Health's (NIH) funding from $30 to $32 billion—its largest increase in funding in 12 years[3]—and the National Cancer Institute's (NCI) funding from $4.95 billion to $5.21 billion.[4] The funding increase included a $200 million for President Obama's Precision Medicine

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[1] President John F. Kennedy, Special Message to the Congress on Urgent National Needs (May 25, 1961), https://catalog.archives.gov/id/193915.

[2] Press Release, The White House, *Remarks of President Barack Obama – State of the Union Address As Delivered*, January 13, 2016

[3] Jocelyn Kaiser, *2016 spending bill gives NIH $2 billion raise, largest in 12 years*, SCIENCE, Dec. 18, 2015, http://www.sciencemag.org/news/2015/12/updated-budget-agreement-boosts-us-science.

[4] *Budget & Appropriations*, NATIONAL CANCER INSTITUTE, http://www.cancer.gov/about-nci/budget.

Initiative aimed at curing cancer using individualized treatment.[5] Given the political climate of rallying cries to reduce the deficit, the Budget Control Act of 2011's sequestration, and recent scaling back of Research Project Grants,[6] it is all the more surprising that this increase received strong bipartisan support.[7] It is *even more* surprising that the President's own budget proposal only called for a one billion dollar increase in NIH funding[8]; a Republican Congress with substantial bipartisan support pushed the increase even higher.[9]

To understand what the political and scientific significance of this appropriations windfall, it is necessary to trace the NCI's and NIH's historical origins and rise in the scientific community as well as its paralleled appropriations

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[5] *See* Kaiser, *supra* note 3 ("The bill includes $350 million in new spending for Alzheimer's disease research, a 60% increase over the 2015 amount and well above the president's request of $51 million. It contains the $200 million requested by Obama for his Precision Medicine Initiative, $85 million in new funding for the BRAIN Initiative, and a $100-million boost for NIH's role in a federal initiative on antimicrobial resistance. The National Children's Study (NCS) follow-on, a revamped version of a study that NIH scrapped last year, receives $165 million, the same amount allocated for the NCS in 2015."); *see also* THE PRECISION MEDICINE INITIATIVE, THE WHITE HOUSE, https://www.whitehouse.gov/precision-medicine.

[6] FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY, NIH RESEARCH FUNDING REBOUNDS IN PRESIDENT'S FY 2016 BUDGET, https://www.faseb.org/Portals/2/PDFs/opa/2015/2.10.15%20NIH%20Funding%20Cuts%202-pager.pdf.

[7] Sarah Karlin, *NIH sees reversal of fortune with proposed funding boosts*, POLITICO, July 7, 2015, http://www.politico.com/story/2015/07/national-institutes-of-health-funding-119696.html.

[8] *See* Francis S. Collins, BUDGET REQUEST, OFFICE OF THE BUDGET, NATIONAL INSTITUTE OF HEALTH, https://officeofbudget.od.nih.gov/pdfs/FY16/Overview%20(Volume%20I).pdf; FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY, NIH RESEARCH FUNDING REBOUNDS IN PRESIDENT'S FY 2016 BUDGET, https://www.faseb.org/Portals/2/PDFs/opa/2015/2.10.15%20NIH%20Funding%20Cuts%202-pager.pdf.

[9] Karlin, *supra* note 7.

history. For this reason, Part I of this paper traces the growth and development of government sponsored scientific research, particularly highlighting cancer research, and the appropriations put forward to make that happen.[10] Additionally, I include concurrent laws, executive orders, administrative guidelines and policy positions that informed the federal government's policy on cancer research. Next, I discuss the principles of Grant Funding in Part II and show them as applied to the realm of cancer research. Part III details the role of funding from the private sector, ranging from non-governmental organizations and charities to academic medical institutions; moreover, this section discusses the interplay and coordination of the various parties. Finally, Part IV details the merits and detriments of the proposals put in place for how the NIH, and specifically the President's Precision Medicine Initiative,[11] should be structured to maximize efficacy of research dollars as well as how they should measure success and progress in cancer research.

[10] The pages that follow tell the story of the evolution of the predecessor organizations with a special emphasis on funding over time. For an excellent, exhaustive historical perspective covering substantially similar ground timelines in greater detail, see *infra* notes 17, 33.

[11] Kaiser, *supra* note 3 ("The bill includes $350 million in new spending for Alzheimer's disease research, a 60% increase over the 2015 amount and well above the president's request of $51 million. It contains the $200 million requested by Obama for his Precision Medicine Initiative, $85 million in new funding for the BRAIN Initiative, and a $100-million boost for NIH's role in a federal initiative on antimicrobial resistance. The National Children's Study (NCS) follow-on, a revamped version of a study that NIH scrapped last year, receives $165 million, the same amount allocated for the NCS in 2015."); THE PRECISION MEDICINE INITIATIVE, THE WHITE HOUSE, https://www.whitehouse.gov/precision-medicine.

II. From the Marine Hospital Service to today's NIH and NCI: A Brief History of Federal Funding of Medical Services and Research in the United States

To best understand where we are today, including the policies proposed by the President, and potential alternatives, a genuine understanding of the NIH's current and historical structure is necessary. Today, the National Institutes of Health comprise the U.S. government's primary biomedical research agency. The NIH comprises 27 separate institutes and centers—the NCI being one of them—created separately (though sometimes multiple were enacted at one time) to respond to public health concerns. The NIH features both internal research (conducted by employees hired directly by the agency at agency-owned and run facilities)[12] and extramural (contracted external help such as professors operating at independent facilities such as academic medical centers). But both the NIH and NCI stem from quite humble origins.

i. From targeted duties to Congressional appropriations and the humble origins of government-sponsored research

On July 16, 1798, President John Adams signed into law an Act for the relief of sick and disabled seamen ("Seaman's Act").[13] This would mark the beginning of the government funding any form of healthcare, albeit not yet funding preventative healthcare, i.e. research. The Seaman's Act mandated the "master or owner of every

[12] "As a whole, the IRP [Intramural Research Program] is the largest institution for biomedical science on earth, with a scientific staff of over 1,200 Principal Investigators and 4,000 post-doctoral fellows." *Intramural Research Program: About Us*, NATIONAL INSTITUTES OF HEALTH, http://irp.nih.gov/about-us/organization-and-leadership.

[13] Pub. L. No. 77, 1 Stat. 605 (1798).

ship or vessel of the United States" to pay the port's collector 20 cents per seaman aboard for every month he was aboard.[14] The captain was permitted to fund this payment by withholding the amount from each of the seaman's wages. Section 3 of the Act directed the port collectors "to make a quarterly return of the sums collected . . . to the Secretary of the Treasury," and authorized the President "to provide for the temporary relief and maintenance of sick or disabled seamen, in the hospitals or other proper institutions now established . . . ."[15] Section Four of the Seaman's Act, expanded the mandate to permit the construction of more facilities:

> That if any surplus shall remain of the monies to be collected . . . after defraying the expense of such temporary relief and support, that . . . together with such private donations as may be made for that purpose (which the President is hereby authorized to receive) shall be invested [and, when financially reasonable, liquidated] to purchase or receive cessions or donations of ground or buildings… and to cause buildings, when necessary, to be erected as hospitals for the accommodation of sick and disabled seamen.[16]

Though the Act didn't explicitly mention the creation of an organization to execute its mandate, the United States Marine Hospital Service (MHS) was nonetheless established[17] and its funds named the Marine Hospital Fund (MHF)[18] to execute the law.

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[14] *Id.* at § 1.

[15] *Id.* at § 3.

[16] *Id.* at § 4.

[17] *See Legislative Chronology*, NIH OFFICE OF HISTORY, https://history.nih.gov/research/sources_legislative_chronology.html [hereinafter *NIH Legislative Chronology*].

[18] LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 156 (2nd Ed. 2008); *NIH Legislative Chronology*, *supra* note 17.

The following year, the Seaman's Act was expanded to include all "officers, seamen and marines of the navy of the United States,"[19] and was again amended two years later to permit hospital administrators to admit seamen of foreign nations for a daily fee.[20] This practice went on unabated for most of the 19th century, with influences from the Secretary of War (the precursor to the Secretary of Defense) regarding hospital locations in light of the growing nation and subsequent changes in strategic military lands.[21]

The MHS was further tinkered with through the tail end of the 19th century. Congress first raised the MHF dues to forty cents per man per month.[22] Simultaneously, Congress increased the Service's organization by creating the position of Supervising Surgeon. The role was to be appointed by the Secretary of the Treasury to "supervise all matters connected with the marine hospital service, and with the disbursement of the fund . . . ."[23] Congress would shortly make the position of Supervising Surgeon—now known as Surgeon General—a Senate-

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[19] An Act in addition to "An act for the relief of sick and disabled Seamen", 1 Stat. 729 § 3 (1799).

[20] An Act to amend an act intituled[sic] "An act for the relief of sick and disabled Seamen," and for other purposes, 2 Stat. 192 § 5 (1802).

[21] An Act to provide for certain harbors, and for the removal of obstructions in and at the mouths of certain rivers, and for other purpose, during the year one thousand eight hundred and thirty-seven, 5 Stat. 187 (1837) (stipulating the funds to be appropriated for the maintanence or building of MSH provided "that suitable plans and estimates be prepared, under the direction of the Secretary of War, for the construction of said hospitals, and submitted to Congress, at the commencement of the next session thereof."). *See also* FIRST ANNUAL REPORT OF THE SUPERVISING SURGEON OF THE MARINE HOSPITAL SERVICE OF THE UNITED STATES FOR THE YEAR 1872, UNITED STATES MARINE HOSPITAL SERVICE SUPERVISING SURGEON-GENERAL 11 (1872).

[22] An Act to reorganize the Marine Hospital Service, and to provide for the Relief of sick and disabled Seamen, 16 Stat. L. 169 § 1 (1870).

[23] *Id.* at § 6.

confirmable Presidential appointment.[24] In 1878, Congress passed what would be the first iteration of the National Quarantine Act "to prevent the introduction of contagious or infectious diseases in the United States.[25] Precipitated by 1878's yellow fever epidemic,[26] the Act gave the "MHS the authority to make rules and regulations governing the retention of vessels having cases of contagious diseases on board, or coming from foreign ports at which contagious diseases existed. Unfortunately, the MHS was given no appropriations to carry out the requirements of the NQA."[27] "Notwithstanding this fact, everything has been done under the Act which could be accomplished without the expenditure of money."[28]

A year later in 1879, Congress created the National Board of Health (NBH),[29] creating the country's "first organized, comprehensive Federal medical research effort."[30] Months after the enabling act, Congress "clarified and strengthened the NBH's authority and gave the new board wide quarantine powers," including transferring much of the quarantining authority from the prior year's National

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[24] In 1875, Congress made the position of Surgeon General a Senate-confirmable Presidential appointment. 18 Stat. L. 377 (1875).

[25] 20 Stat. L. 37 (1878).

[26] W.G. Smillie, *The National Board of Health 1879-1883*, 33 AM. J. PUB. HEALTH NATIONS HEALTH 925, 926 (1943).

[27] Jerrold M. Michael, *The National Board of Health: 1879-1883*, 126 PUB. HEALTH REP. 123, 126.

[28] BESS FURMAN, A PROFILE OF THE UNITED STATES PUBLIC HEALTH SERVICE: 1798–1948 143 (1973).

[29] An Act to Prevent the Introduction of Infectious or Contagious Disease into the United States and to Establish a National Board of Health, 20 Stat. L. 484 (1879).

[30] *NIH Legislative Chronology*, *supra* note 17 *citing* An act to prevent the introduction of contagious or infectious diseases into the United States, 21 Stat. 5 (1879).

Quarantine Act from the MHS to the NBH.[31] However, the authorizing act was undermined when the MHS was later directed to investigate leprosy in the United States.[32]

ii. Building out federally-sponsored research infrastructure

The 1880s profoundly altered the course of government funded medical research with two foundational developments: first, the seamen's hospital tax was abolished, meaning the responsibility for payment was no longer shouldered by only those who would benefit from it directly, and the "cost of maintaining Marine hospitals was paid out of a tonnage tax"; second, "[a] bacteriological laboratory, known as the Laboratory of Hygiene, was established under Dr. Joseph J. Kinyoun at the Marine Hospital, Staten Island, N.Y., in August, for research on cholera and other infectious diseases."[33]

After the turn of the century, Congress blazed a path to develop the infrastructure for government-funded research. Congress set apart specific appropriations—$35,000—in 1901 to bring the Laboratory out of the Marine Hospital and build its own separate facility, the first dedicated to "investigations of contagious and infectious diseases and matters pertaining to public health."[34] MHS was officially retitled the Public Health and Marine Hospital Service (PHMHS) and

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[31] Michael, *supra* note 27, at 127.

[32] *Id. citing* An Act For the investigation of leprosy, 30 Stat. L. 976 (1899). The Act was funded "from the fund preventing the spread of epidemic diseases" not exceeding $5,000. *Id.*

[33] *Chronology of Events | National Institutes of Health (NIH),* NIH http://www.nih.gov/about-nih/what-we-do/nih-almanac/chronology-events.

[34] *A Short History of the National Institutes of Health 2*, NIH https://history.nih.gov/exhibits/history/docs/page_02.html.

its facilities were reorganized to be more efficient.[35] The newly imagined organization was then put in charge of regulating the transportation or sales of "biologics" such as "viruses, serums, vaccines, antitoxins, and analogous products"[36] and given a new 5-acre campus in Washington, D.C.[37] Finally, the tonnage tax was repealed and PHMHS's costs were officially supported by direct congressional appropriations.[38]

After another name change from the PHMHS to the Public Health Service (PHS) and a broadening of research programs and foci,[39] Congress passed the Chamberlain-Kahn Act in 1918.[40] The act was driven in large part because "at any given time typically one-third of active soldiers were laid low by sexually transmitted infections (STIs)."[41] Though particularly controversial because it permitted quarantining individuals—particularly women—suspected of having

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[35] Act To increase the efficiency and change the name of the United States Marine-Hospital Service, Pub. L. 57-236, 31 Stat. L. 1086 (1901).

[36] *NIH Legislative Chronology*, *supra* note 17 *citing* Biologics Control Act of 1902, Pub. L. 57-244, 32 Stat. 728 (1902)

[37] *A Short History of the National Institutes of Health* 2, NIH, https://history.nih.gov/exhibits/history/docs/page_02.html.

[38] The first year's appropriation was one hundred and seventy thousand dollars. An Act Making appropriations for sundry civil expenses of the Government for the fiscal year ending June thirtieth, nineteen hundred and seven, and for other purposes, Pub. L. 59-383, 34 Stat. 697 (1906).

[39] An Act to change the name of the Public Health and Marine-Hospital Service to the Public Health Service, to increase the pay of offices of said service, and for other purposes, Pub. L. 62-265, 37 Stat. 309 (1912).

[40] An Act Making appropriations for the support of the Army for the fiscal year ending June 30, 1919, 40 Stat. 845 (1918).

[41] MELISSA HOPE DITMORE, PROSTITUTION AND SEX WORK 53 (2011).

venereal diseases,[42] the act played a large role in the development of NIH in that it was the first time in which the federal government conferred power to an organization to outsource scientific research. One of the duties of the Interdepartmental Social Hygiene Board created by the Act was:

> To select certain universities, college, or other suitable institutions or organizations, to which allotment of money may be made for the purpose of discovering more effective medical measures in the prevention and treatment of venereal diseases; and for the purpose of discovering and developing more effective educational measures in the prevention of venereal diseases.[43]

And venereal diseases were just beginning. In 1922, PHS investigators established a Special Cancer Investigations Laboratory at Harvard Medical School, the first federally recognized lab devoted to cancer research.[44]

The tail end of the 1920s saw the first introduction of legislative action specific to cancer. Championed by Senators M. M. Neely and W. J. Harris of West Virginia and Georgia, respectively, four unsuccessful bills were introduced in the second half of the decade to encourage cancer research, raising both awareness and need. The first bill was purely economic incentives, authorizing an award of $5 million to successfully cure cancer—and prove it.[45] Next, Sen. Neely introduced a bill to "authorize the Public Health Service and the National Academy of Sciences jointly to investigate the means and methods for affording Federal aid in

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[42] *Id.*

[43] ANNUAL REPORT OF THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE OF THE UNITED STATES FOR THE FISCAL YEAR 1919 234 (1919).

[44] *See NIH Legislative Chronology*, *supra* note 17; *Chronology of Events*, *supra* note 33.

[45] 69 S. 5589 (1927).

discovering a cure for cancer."[46] The third effort was largely a replica bill.[47] The fourth, however, was an intelligence-gathering bill, "[a]uthorizing a survey by the Public Health Service in connection with the control of cancer."[48]

iii. The Enactments of the NIH and NCI

The 1930s ushered in the next major milestones of the federal government's role in science research. The Ransdell Act of 1930[49] reorganized and expanded the purview of the Hygienic Laboratory, as well as renamed it: the National Institute of Health.[50] Moreover, the Act established fellowship programs akin to those employed, and coveted, today.[51]

The decade's other main development was the creation of the National Cancer Institute (NCI) as a division of the Public Heath Service in 1937[52] after three failed attempts to appropriate moneys for cancer research. The first sought to "[a]uthoriz[e] the Surgeon General of the Public Health Service to control and prevent the spread of the disease of cancer" with $1 million annually appropriated.[53] Another sought to establish a National Cancer Center within the Public Health Service with an initial appropriation of $2,400,000 for overhead costs

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[46] 70 S. 3554 (1928).

[47] *Compare id*. *with* 70 S. 466 (1929) (sharing an identical title and very similar language).

[48] 71 S. 4531 (1929).

[49] Pub. L. 71-251, 46 Stat. L. 379 (1930).

[50] *Id.* at § 1.

[51] *Id.* at §§ 2, 3.

[52] An Act to provide for, foster, and aid in coordinating research related to cancer; and to established the National Cancer Institute; and for other purposes. Pub. L. 75-244, 50 Stat. L. 559 (1937) ("National Cancer Institute Act").

[53] 75 H.R. 6100 (1937).

and $1 million annually thereafter.[54] The final failed attempt was the first iteration to establish the National Cancer Institute.[55]

A near-replica of the failed attempt was ultimately passed in 1937. As laid out in the legislation, the National Cancer Institute was designed:

> (a) To conduct, assist, and foster researches, investigations, experiments, and studies relating to the cause, prevention, and methods of diagnosis and treatment of cancer; (b) To promote the coordination of researches conducted by the Institute and similar researches conducted by other agencies, organizations, and individuals; (c) To procure, use, and lend radium as hereinafter provided; (d) To provide training and instruction in technical matters relating to the diagnosis and treatment of cancer; (e) To provide fellowships in the Institute from funds appropriated.[56]

The Act structured of the National Advisory Cancer Council as a governing board of the Institute and charged it with: reviewing cancer research projects, collecting information of recent studies relating to cancer research, reviewing applications for cancer research projects from universities, hospitals, laboratories, or other institutions, and making recommendations to the Surgeon General.[57] The Act also empowered the Surgeon General to provide facilities for "training and instruction . . . in all technical matters relating to the diagnosis and treatment of cancer,"

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[54] An Act To promote research in the cause, prevention, and methods of diagnosis and treatment of cancer, to provide better facilities for the diagnosis and treatment of cancer, to establish a National Cancer Center in the Public Health Service, and for other purposes, 75 H.R. 6767 (1937).

[55] An Act To provide for, foster, and aid in coordinating research relating to cancer; to establish the National Cancer Institute; and for other purposes, 75 H.R. 7931 (1937).

[56] *Id.* at § 2.

[57] *Id.*

establish cancer research fellowships, provide research grants, and consult outside experts.[58]

Most important for the question of funding, the National Cancer Institute Act "appropriated a sum not to exceed $750,000 for the erection and equipment of a suitable and adequate building and facilities for the use of the Institute" and "appropriated the sum of $700,000 for each fiscal year, beginning with the fiscal year ending June 30, 1938, for the purpose of carrying out the provisions of th[e] Act."[59] Additionally, the act established a framework for accepting charitable donations.[60]

At this point, it is a good idea to take stock of what such an appropriation meant. The NCI, as the first issue-specific Institute under the NIH, represented nearly 90% of the NIH's total budget. As years passed and new institutes were created, that number would steadily fall until hitting 16% since 2007. The new budget proposal would see that number rise to 17%. Moreover, the United State's Gross Domestic Product (GDP) was hovering at around $1.1 trillion dollars, and the country's budget was $83 billion.[61] Thus, the initial investment in the Act's mission was less than 0.001% of government spending, and a laughably diminutive amount

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[58] *Id.*

[59] *Id.* at §§ 7(a)–(b).

[60] Including stipulating that "Donations of $500,000 or over in aid of research under this Act shall be acknowledged permanently by the establishment within the Institute of suitable memorials to the donors." *Id.* at § 6.

[61] *See 1938 United States Budget*, INSIDE GOVERNMENT, http://federal-budget.insidegov.com/l/40/1938. *See also BEA National Economic Accounts*, BUREAU OF ECONOMIC ANALYSIS, http://www.bea.gov/national/index.htm#gdp.

relative to GDP. Table 1 and Appendix A provide a complete historical account of relative spending.

iv. Two Paths Diverge: NCI as its own entity

To trace the history of government-funded research beyond the NCI Act one would need to consider the growth of the NIH and all of its 27 subsidiary Institutes—including the NIH's own Office of the Director, which affords itself financial support to research that overlaps with individual Institutes. But to trace the history of government-funded *cancer* research in particular, a more appropriate path is to remain focused on the NCI's growth separate from the NIH.

On July 1, 1944, the groundbreaking Public Health Service Act (PHSA)[62] passed. Not only did the act create fellowships in health sciences, but it also authorized the Surgeon General to "make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the National Advisory Health Council, or, with respect to cancer, recommended by the National Advisory Cancer Council."[63]

Following reorganization within the NCI "to provide an expanded program of intramural cancer research, cancer research grants, and cancer control activities . . . [the] Research Grants and Fellowship Branch was established" in 1947.[64] The first round of grants was given that year to "medical, dental, and osteopathic schools . . .

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[62] Pub. L. No. 78-410, 58 Stat. 682 (codified as 42 U.S.C. §§ 201–300).

[63] *Id.* at §301.

[64] *See* National Cancer Institute (NCI), NIH, http://www.nih.gov/about-nih/what-we-do/nih-almanac/national-cancer-institute-nci.

for improvement of training in the field of cancer research, diagnosis, and treatment."[65]

The 1950s brought about two major structural changes and one major scientific development. Regarding the former, the NCI asked for and was granted appropriations to fund "a full-scale clinical research program in the new Clinical Center" and establish the "Cancer Chemotherapy National Service Center . . . to coordinate the first national, voluntary, cooperative cancer chemotherapy program"[66] in 1953 and 1955, respectively. The scientific progress? The first cancer cured via chemotherapy, choriocarcinoma, met its match in 1957.

The 1960s saw increased developments in cancer research, but little of note structurally or financially; the 1970s, meanwhile, brought about tremendous change. When President Nixon signed the National Cancer Act of 1971 (NCA),[67] it was the commencement of what would come to be colloquially called a 'war on cancer.'[68] The Act empowered the Director of the NCI to coordinate all cancer-related NIH programs.[69] Moreover, among many amendments to the PHSA, the

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[65] *Id.*

[66] *Id.*

[67] Pub. L. No. 92-218, 85 Stat. 778 (1971).

[68] *See, e.g.*, Thomas C. Erren et al., *What Do We Know 40 Years After Nixon Declared the 'War on Cancer'? On the Origin, Prevention and Treatment of Cancer*, 27 J. CANC. EDUC. 597, 597 (2012) *citing* Remarks on Signing the National Cancer Act of 1971, Richard M. Nixon, Dec. 23, 1971, http://www.presidency.ucsb.edu/ws/?pid=3275.

[69] *See* 42 U.S.C. § 281 (1972). It is interesting to note, however, that the text of the statute refers to coordinating such activities "with the National Cancer Program," *id.*, yet "legislation never fully defined the concept of a national cancer program, which remains a topic of individual interpretation to this day," Anna D. Barker & Hamilton Jordan, *Legislation History of the National Cancer Program*, *in* CANCER MEDICINE (6th ed., Kufe et al., eds. 2003), http://www.ncbi.nlm.nih.gov/books/NBK13873/.

NCA: augmented the NCI Director's power; encouraged research coordination between private industry, state health agencies, and the federal NIH; established a President's Cancer Panel and a National Cancer Advisory Board; and further encouraged—and sometimes mandated—peer review procedures for grant programs.[70] The Act appropriated actions in two ways: first, it established and appropriated for "programs as necessary for cooperation with State and other health agencies in the diagnosis, prevention, and treatment of cancer."[71] These programs were appropriated $20, $30, and $40 million for the fiscal years of 1972, 1973 and 1974 (the first three years). Then, it appropriated sums to "[for] the purpose of carrying out" all other aspects of the Act – $400, $500, and $600 million in its first three years, respectfully. Interestingly, the Act also stipulated requirements for grant approval: grants up to $35,000 only required "review for scientific merit" by the NCI Director, whereas grants exceeding $35,000 required review and recommendation by the National Cancer Advisory Board.[72]

The NCA's effect on NCI's budget with respect to the overall budget and its future trajectory cannot be overstated. Before that time, the NCI *averaged* 0.0571% of the federal budget, maxing out at 0.1399% in 1963. The NCA augmented both of those figures up to over 0.2%, as shown in Table 1, albeit for a short time, as

[70] *See* 42 U.S.C. § 281 (1972).

[71] *Id.*

[72] *Id.*

Reagan's 1980 election was the hallmark of a different ideology, "particularly with a constrained federal budget in an era of aggressive deregulation."[73]

The NCA spurred further development in the 1970s, arguably its most important decade for development into what today's iteration looks like. There was another reorganization in 1972,[74] the establishment of Comprehensive Cancer Centers, the Division of Cancer Control and Rehabilitation, and growth in Advisory Board purview and NCI services and facilities. For budgetary purposes, the next most important development was the National Cancer Act Amendment of 1974.[75] The update appropriated the NCI's funding for the next three years at a significantly higher budget – $53.5, $68.5 and $88.5 million for the cancer control programs and $600, $750 and $985 million for all other programs in the subsequent three years.[76]

This represents one of the NCI's best-funded periods as a function of total government spending, representing approximately 0.2%. Put another way, for every $1,000 the government spent, NCI received about $2. But a more staggering perspective may be gained by comparing this to GDP. In 1975, U.S. GDP was 1.689 trillion.[77]

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[73] BENJAMIN J. HURLBUT, EXPERIMENTS IN DEMOCRACY: HUMAN EMBRYO RESEARCH AND THE POLITICS OF BIOETHICS 108–09 (forthcoming 2017).

[74] *See National Cancer Institute (NCI)*, *supra* note 64.

[75] Pub. L. No. 93-352, 88 Stat. 358, 42 U.S.C. § 282 (1974).

[76] *Id.* at § 107.

[77] *BEA National Economic Accounts*, BUREAU OF ECONOMIC ANALYSIS, http://www.bea.gov/national/index.htm#gdp.

After the Biomedical Research Extension Act of 1977[78] "extend[ed] the NCI mandate for one year"[79] and appropriated funds (albeit decreasingly for both the cancer control programs and overall appropriations by approximately $4 million and approximately $62 million respectively[80]), 1978 brought about a change in the mission of the NCI. The Community Mental Health Centers Act of 1978 (CMHCA)[81] "amend[ed] the National Cancer Act to emphasize education and demonstration programs in cancer treatment and prevention, and stipulate[d] that NCI devote more resources to prevention, focusing particularly on environmental, dietary and occupational cancer causes."[82]

The 1980s saw three important NCI-driven laws. The Health Programs Extension Act of 1980[83] and the Health Research Extension Act of 1985[84] appropriated NCI funding increases. The latter law included modest, though specific language about the information dissemination mission.[85] On the other hand, the Health Research Extension Act of 1985[86] appropriated further increases

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[78] Biomedical Research Extension Act of 1977, P.L. 95-83, 91 Stat. 383 (1977).

[79] *See National Cancer Institute (NCI)*, *supra* note 64.

[80] Biomedical Research Extension Act, *supra* note 78, at § 203(2). It did not touch cancer program extensions.

[81] Pub L. No. 95-622, 92 Stat. 3412, 42 U.S.C. § 2689 (1978).

[82] *National Cancer Institute (NCI)*, *supra* note 64. This emphasis was done by inserting provisions to emphasize such foci into myriad aspects of the NCI, including Cancer Research and Demonstration Centers, the functions of the NCI Director, the President's Cancer Panel, etc. *Id. citing* 42 U.S.C. § 2689 (1978).

[83] Health Programs Extension Act of 1980, Pub. L. No. 96-538, 94 Stat. 3183 (1980).

[84] Health Research Extension Act of 1985, Pub. L. No. 99-158, 99 Stat. 820 (1985).

[85] *Id.* at § 410.

[86] Pub. L. No. 99-158, 99 Stat. 820 (1985).

but added the requirements of "assess[ing] the incorporation of state-of-the-art cancer treatment into clinical practice and the extent to which cancer patients receive such treatments and include the results of such assessments."[87]

The NIH Revitalization Act of 1993[88] had both an appropriations component and another mission-based component. Regarding the latter, the Act specified an emphasis women's issue, namely breast cancer, as well as look more towards biological and environmental markers.[89] Merging these two components, the Act mandated a certain percentage of the NCI's budget be dedicated to cancer control.[90]

In an interesting funding twist, the Stamp Out Breast Cancer Act[91] "establishe[d] a special alternative rate of postage up to 25% higher than a regular first-class stamp" such that 70% of the profits go directly to breast cancer research.[92] This act was extended in 2000,[93] 2002,[94] 2005,[95] 2007,[96] and 2011.[97]

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[87] *Id.* at § 112.

[88] Pub. L. No. 103-43, 107 Stat. 122, 42 U.S.C. § 201 (1993).

[89] *Id.* at §1911, 42 U.S.C. § 280.

[90] *See, e.g., id.* at §402, 42 U.S.C. § 285.

[91] Stamp Out Breast Cancer Act, Pub. L. No. 105-41, 111 Stat. 1119, 39 U.S.C. § 101 (note) (1997).

[92] *National Cancer Institute (NCI)*, *supra* note 64.

[93] Semipostal Authorization Act, Pub. L. No. 106-253, 114 Stat. 634, 39 U.S.C. § 101 (note) (2000).

[94] Making appropriations for the Treasury Department, the United States Postal Service, the Executive Office of the President, and certain Independent Agencies, for the fiscal year ending September 30, 2002, and for other purposes, Pub. L. No. 107-67 115 Stat. 514 (2002).

[95] Pub. L. No. 109-100, 119 Stat. 2170, 39 U.S.C. § 414(h) (2005).

[96] Pub. L. No. 110-150, 121 Stat. 1820, 39 U.S.C. § 414(h) (2007).

[97] Pub. L. No. 112-80, 125 Stat. 1297, 39 U.S.C. § 414(h) (2011).

The early 2000s saw multiple bills that went towards specific research foci. Ranging from blood cancers[98] to gynecologic cancers[99] to breast and cervical cancers[100] to pediatric-based cancers,[101] Congress continued expand the powers and or appropriate funds for the NCI—or NIH at large—to raise awareness and study enumerated, specific cancers.

The final major development that fundamentally impacted the NCI was the American Recovery and Reinvestment Act.[102] In an effort to revitalize the American economy, President Obama's stimulus package sent $10 billion to the NIH,

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[98] *See* Hematologic Cancer Research Investment and Education Act of 2002, Pub. L. No. 107-172, 116 Stat. 541 (2002).

[99] *See* Gynecologic Cancer Education and Awareness Act of 2005, Pub. L. No. 109-475 (2005). Also known as "Johanna's Law," the law "directs the HHS Secretary to carry out a national campaign to increase the awareness and knowledge of health care providers and women with respect to gynecologic cancers." *National Cancer Institute (NCI)*, *supra* note 64.

[100] *See* National Breast and Cervical Cancer Early Detection Program Reauthorization Act of 2007, Pub. L. No. 110-18, 121 Stat. 80 (2007). The law "allows states to apply for federal waivers to spend a greater share of funds on hard-to-reach underserved women. This bill authorizes funding up to $275 million by 2012; $201 million is authorized for 2007." *National Cancer Institute (NCI)*, *supra* note 64. *See also* The Breast Cancer and Environmental Research Act of 2007, Pub. L. No. 110-354, 122 Stat. 3984 (2007). This act "amends the Public Health Service Act to authorize the Director of the NIEHS to make grants for the development and operation of research centers regarding environmental factors that may be related to the etiology of breast cancer. The bill establishes an Interagency Breast Cancer and Environmental Research Coordinating Committee within HHS." *National Cancer Institute (NCI)*, *supra* note 64.

[101] *See* Caroline Pryce Walker Childhood Cancer Act of 2007, Pub. L. No. 110-287, 122 Stat. 2649 (2007) This act "amended the Public Health Service Act to advance medical research and treatments into pediatric cancers, ensure patients and families have access to the current treatments and information regarding pediatric cancers, establish a population-based national childhood cancer database, and promote public awareness of pediatric cancers." *National Cancer Institute (NCI)*, *supra* note 64.

[102] American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115 (2009).

including $1.3 billion to the NCI specifically.[103] A comprehensive timeline can be seen in Figure 1.

v. Historical Perspective and Today's NCI Funding

Having traced the lineage of the NCI, it's worthwhile to gain some historical perspective on NCI Budgeting. Since its inception, NCI has averaged 0.1180% of all federal spending. It's peak—from a percentage standpoint—came in 2003, when the NCI represented 0.2126% of the budget. Under the enacted FY2016 budget, the NCI will receive a grand total of $5.2 billion, or approximately 0.13% of the budget. The President's FY2017 budget only asks for an increase to $5.89 billion, which, under the proposal, would be 0.14% of the proposed $4.2 trillion, staying within one standard deviation of average of federal spending. Table 1 offers a full breakdown of spending as in both absolute and percentage terms historically.

Finally, the NCI has offered the exact language it wishes to see enacted:

> For carrying out section 301 and title IV of the PHS Act [the subsection of the U.S. Code authorizing and appropriating for the National Cancer Institute] with respect to cancer, [$5,214,701,000] $5,097,287,000, of which up to [$16,000,000] $50,000,000 may be used for facilities repairs and improvements at the National Cancer Institute—Frederick Federally Funded Research and Development Center in Frederick, Maryland.[104]

Budget committee members have not said anything further beyond this language.

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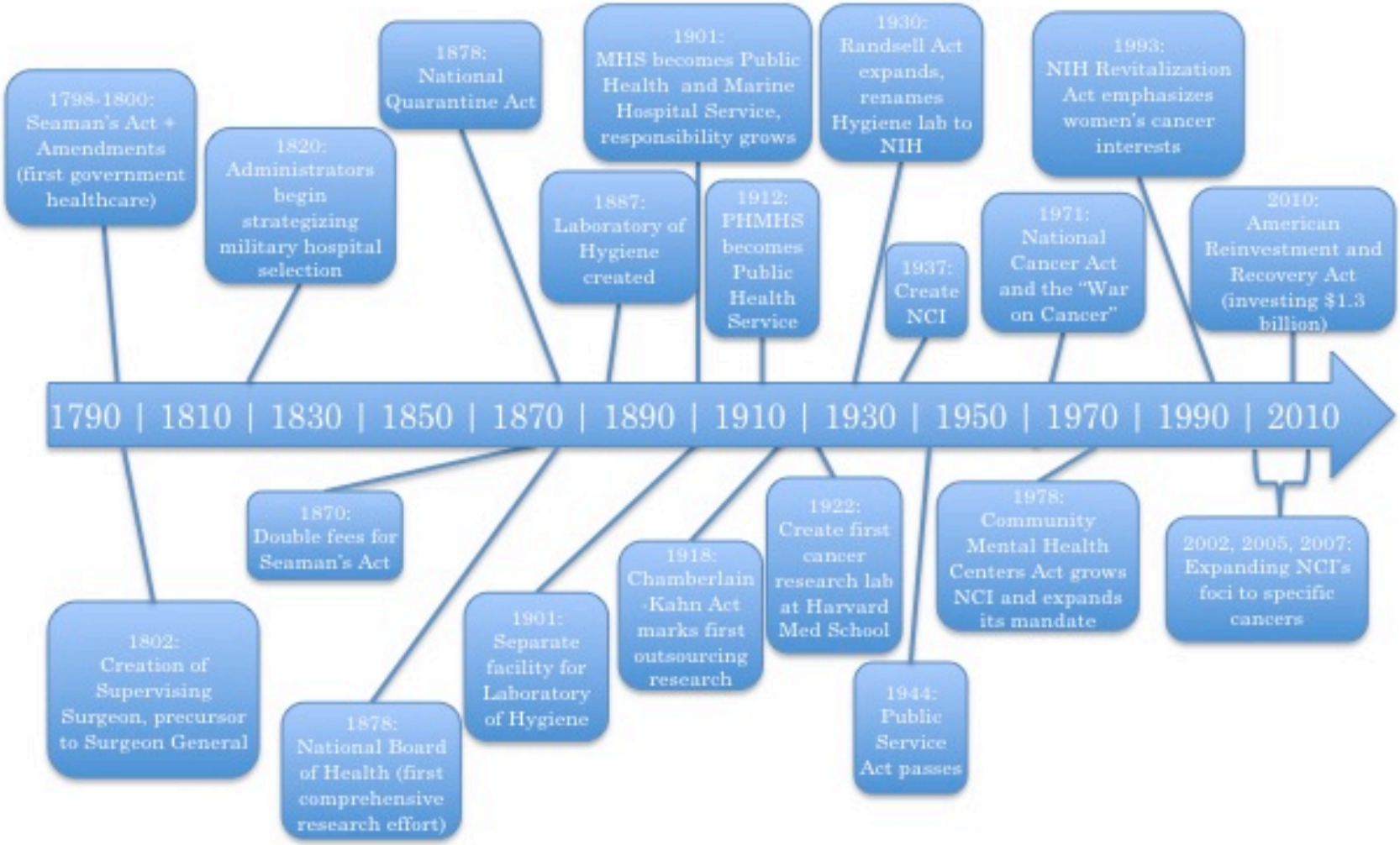
[103] *Id*. at 123 Stat. 175–76. Of the $10 billion in funding the NIH received, "NCI received $1.3 billion in Recovery Act funds to be distributed during the two-year span of 2009 and 2010." *National Cancer Institute (NCI)*, *supra* note 64.

[104] CONGRESSIONAL JUSTIFICATION FOR FISCAL YEAR 2017 3 (NIH 2016), http://www.cancer.gov/about-nci/budget/congressional-justification/fy2017-nci-congressional-justification.pdf [hereinafter CONGRESSIONAL JUSTIFICATION].

Figure 1. Timeline.



III. NIH Funding

Before delving into the way NIH grants work, it is important to clear up a vital distinction: NIH grants are not formally the same as federal grants, but are functionally similar in some important aspects. Primarily, direct federal budget grants are specific line items that are appropriated straight from Congress to the Agency responsible for executing that grant, while NIH grants are funded through NIH general appropriations then doled out without specific Congressional appropriation. To better understand the NIH grant structure, it is important to detail how the three types of direct federal budget grants work: categorical grants, block grants, and general revenue sharing.[105]

i. Typical Grant Funding

"Block grants are a form of grant-in-aid that the federal government uses to provide state and local governments a specified amount of funding to assist them in addressing broad purposes . . . ."[106] Proponents of the block grant cite federalism and it's practical byproducts—more targeted appropriations and thus lower cost—as its advantage. Federalism concerns simply speak to the albatross that is the federal government; given its size, precise yet dynamic spending is unlikely at best. Moreover, elected and appointed officials may well be "out of touch with grassroots

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[105] *See generally* ROBERT JAY DILGER & EUGENE BOYD, BLOCK GRANTS: PERSPECTIVES AND CONTROVERSIES, CONGRESSIONAL RESEARCH SERVICE (Jul. 15, 2014), https://fas.org/sgp/crs/misc/R40486.pdf.

[106] *Id.* at 2.

needs and priorities."[107] More targeted—and theoretically effective—spending would thus increase efficiency and permit more dual short-term and long-term strategic planning.[108] But an additional unique aspect of block grants are the variety of solutions that may be attempted by different states, realizing "the vital 'laboratories of democracy' envisioned by Justice Louis Brandeis."[109] Opponents, however, offer similarly weighty counters. Specifically, they cite "concerns about recipients' management capacity and commitment to the program, recipients' ability to make the 'right' allocation choices, and the possibility [of diminished] ability to provide effective program oversight."[110]

Categorical grants, on the other hand, are specific apportionments that "can be used only for a specifically aided program and usually are limited to narrowly defined activities [where the appropriating] legislation generally details the program's parameters and specifies the types of funded activities."[111] Politically, categorical grants may be more advantageous because they allow "politicians more opportunities for credit claiming."[112] Of late, however, Congress has recognized the importance to nuance and elasticity when it comes to appropriations and, as such,

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[107] Carl W. Stenberg, *Block Grants and Devolution*, *in* INTERGOVERNMENTAL MANAGEMENT FOR THE 21ST CENTURY 263, 263 (Paul Posner & Timothy Conlan, eds., 2007).

[108] DILGER & BOYD, *supra* note 105, at 2, 7.

[109] Stenberg, *supra* note 107, at 263.

[110] DILGER & BOYD, *supra* note 105, at 6.

[111] DILGER & BOYD, *supra* note 105, at 2.

[112] Pietro Nivola, Comments "Block Grants: Past, Present, and Prospects," The Brookings Institution, (Oct. 15, 2003), http://www.brookings.edu/~/media/events/2003/10/15welfare/20031015_panel2.pdf.

has "increased programmatic flexibilities for some categorical grants, making them look increasingly like block grants."[113]

Finally, general revenue sharing (GRS) "provides state and local governments funds that are distributed by formula, accompanied with few restrictions on the purposes for which the funding may be spent, and have the least administrative conditions of any federal grant type."[114] Of all grant types and subtypes, GRS "imposes the least restraint on recipients."[115]

ii. Applicability to NIH and NCI

The NIH and its subordinate Institutes don't exactly function along the lines of any of these three grant structures. The NIH operates like any other agency for appropriations. It has its own formulation process in line with the President's thinking, presents an overview of what its seeking and gives detailed testimony as to why it feels the figures are accurate to cover its needs and, more fundamentally, why it's needs are as stated. Essentially, Congress wants accountability as to motivations and executions before blindly signing the appropriations. To complete that process, the Directors of each subordinate Institute submit a budget to the NIH Director. After careful study and tweaking, he or she submits a compiled budget request to the OMB to be placed within the President's budget, including the detailed testimony. After its own review, Congress appropriates funding to the individual Institutions as well as the Office of the Director to carry out their

[113] DILGER & BOYD, *supra* note 105, at 4.

[114] *Id. See also* STEVEN MAGUIRE, GENERAL REVENUE SHARING: BACKGROUND AND ANALYSIS, CONGRESSIONAL RESEARCH SERVICE (JAN. 9, 2009).

[115] DILGER & BOYD, *supra* note 105, at 3.

purposes.[116] Finally, the Institutes allocate their funds to myriad grants it so chooses in a peer review process. Therefore, we can certainly rule out analyzing the NIH or its subordinates like a GRS; but block grants and categorical grants are not the worst way of thinking about the NIH's structure overall.

While the NIH does not fit neatly in these grant structures, it may be framed as a functional amalgamation of block grants and categorical grants to aid in our understanding of how it works. The NIH could be viewed as a block grant with the "broad purpose" of conducting medical research. In this hypothetical, the NIH must execute a large idea, dole out appropriations to its subordinate entities—though instead of state and municipal governments, its subordinates are the Institutes—while permitting those subordinates a broad amount of latitude to decide for itself how best to use the allocated funds.

Research Project Grant appropriations are more appropriately compared to categorical grants. RPGs are specifically delineated by size and purpose. Moreover, their award requires a competitive, peer-review process in which expert scientists evaluate the strength of the application by myriad factors. (A more thorough discussion of the peer review process will follow in later sections.) Although its parameters are not legislated but rather regulated by the Institute, it could be viewed as a categorical grant in light of its specificity.

[116] Consolidated Appropriations Act of 2016, Pub. L. No. 114-113, Div. H Title II (2015) (appropriating each individual Institute as well as the Office of the Director to carry out the missions of each Institute detailed in the PHS Act).

However, the best way to understand cancer funding through the NCI may be to supplant the old familiar structure and lexicon for its own unique pipeline. Because it is appropriated under via

iii. The NCI Pipeline From A to Z

As is the case for any executive agency, each fiscal year the NCI (and its parent organization, the NIH) "prepares for the President and Congress its best professional judgment on the optimum funding needed to make the most rapid progress against cancer."[117] Every Institute has a dedicated purpose, ranging from the Institute on Aging to the Institute on Alcohol Abuse and Alcoholism to the Cancer Institute. In making its budget request, each puts forward a more itemized request—be it research grants, research centers, training, etc.—and explains how each of these figures will go towards realizing its purpose.

The NCI, obviously, "conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients."[118] This year's NCI budget request incorporated the moon shot effort, as well as remarked on its relevance for this year's funding: "[i]n addition to the $680 million for FY 2017, NCI

[117] *About the Annual Plan and Budget Proposal*, NCI, http://www.cancer.gov/about-nci/budget/annual-plan.

[118] *NCI Overview*, NCI, http://www.cancer.gov/about-nci/overview.

will also begin the initial work on many components of this [moonshot] effort during FY 2016."[119]

Unfortunately, because this moonshot is an integrated, multi-year "enterprise . . . [that] has many important facets, including broad engagement across the cancer research and oncology community, and engagement with many other partners and stakeholders to make progress against all forms of cancer," tracing it with any degree of particularity is difficult. Instead, it is likely best to break down the President's FY2017 Budget as compared to the enacted 2016 budget.

The Obama Administration asked for "$755 million in mandatory funds for new cancer-related research activities,"[120] with $680 million going to the NIH and $75 million to the FDA.[121] Though public remarks cite the increase as directly to the NIH, Health and Human Services breakdowns shows that the *only* individual Institute amongst the NIH's 27 to have been granted a larger piece of the pie in the President's budget was the NCI.[122] Disregarding the FDA component, the cancer moonshot can really be assessed by breaking down the requests for increased NCI appropriations.

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[119] CONGRESSIONAL JUSTIFICATION, *supra* note 104, at 12.

[120] Press Release, The White House, FACT SHEET: Investing in the National Cancer Moonshot, (Feb. 01, 2016) https://www.whitehouse.gov/the-press-office/2016/02/01/fact-sheet-investing-national-cancer-moonshot.

[121] *Budget in Brief*, DEP'T OF HEALTH AND HUMAN SERVICES, http://www.hhs.gov/about/budget/fy2017/budget-in-brief/nih/index.html.

[122] *See id.*

The NCI's research appropriations request is broken down into distinct categories: "understanding the mechanisms of cancer," "understanding the causes of cancer," "improve early detection and diagnosis," "develop effective and efficient treatments," "cancer prevention and control," "cancer centers," "research workforce development," and "buildings and facilities."[123] Far and away the three largest jumps are from, in descending order, understanding cancer's causes, developing treatments, and understanding mechanisms.[124]

A different way of looking at NIH appropriations may be in the number of individualized grants it funds. Though not a specific line-by-line grant appropriation, the Budget Request lays out just how the appropriations would be spent, i.e. the number of grants it would fund. For example, the proposed increase in research project grants—$322 million—would fund an additional 629 research grants; $3.6 million in additional research training appropriations funds 119 more grants.[125] In that way, NCI appropriations have a leg up on other large-scale efforts: tangible cause and effect.

iv. The Grant Application and Peer Review Process

To best explain the way the NCI funds scientists—and thus how the President's moonshot goes from the appropriations bill into a scientist's lab—it is best to first explain the way a scientist gets funding from these sources. To do so,

[123] CONGRESSIONAL JUSTIFICATION, *supra* note 104, at 10.

[124] *Id.* at 10. Funded at $181, $169 and $104 million, respectively. *Id.*

[125] *See generally* CONGRESSIONAL JUSTIFICATION, *supra* note 104.

it's best to follow the path of an individual scientist, asking how she can secure NCI funding for cancer research.

So, lets. Imagine scientist X is an established scientist[126] at an academic medical center. The first question to ask is what she is asking for: a new request for a yet unfunded project (Type 1), a continuation of a currently funded project (Type 2), a revision or administrative supplement (Type 3) or an extension (Type 4).[127]

Having determined the "Type," the scientist must look to which grants are applicable. To do so, she looks to both the NIH at large and the NCI.[128] The NIH makes "Parent Announcements," or overarching announcements for grant via an online clearinghouse.[129] The parent announcements are divided into overarching groups—research, training, career development, fellowship, administrative supplement, and post-award administrative action—to give the scientist a more targeted search. She then looks into the grant and sees if the specifications fit her needs.

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[126] This is an important qualification. For a new scientist without a distinct track record, there will be different levels of grants built to establish a record and resume. Because these are a distinctly lesser percentage of the NIH grants out for cancer research, I've instead chosen to focus on an established scientist without those strictures.

[127] *See Application, Development, Submission & Award*, NATIONAL CANCER INSTITUTE, http://www.cancer.gov/grants-training/grants-process/application/. There are 5 additional types of grants, including 4 that are administrative changes and one that requests to pay for further budget increments via Research Performance Progress Reports, but because these 5 are not central to the process, I will place them to the side in this explanation.

[128] There is an additional central clearinghouse of grants, but these include all grants for all federal agencies. *See Grants*, NIH, http://www.grants.gov. Thus, while applicable, *most* of the cancer research grants will be coming from the NIH and NCI. The notable exception is the Department of Defense, whose medical research generally would be an appropriate topic of its own briefing paper and is beyond the scope here.

[129] *See Parent Announcements (For Unsolicited or Investigator-Initiated Applications)*, NIH, http://grants.nih.gov/grants/guide/parent_announcements.htm.

Alternatively, the NCI solicits grants via three types: Program Announcement (PA), Program Announcement Reviewed in an Institute (PAR), or Requests for Applications (RFA).[130] A PA is a "formal statement about a new or ongoing extramural activity or program," a PAR is a PA with "special receipt, referral, and/or review considerations," and an RFA is an issued invitation for applications " applications in a well-defined scientific area to accomplish specific [Institute of Cancer] program objectives."[131] The scientist chooses the proper grant after scouring these invitations and or announcements, completes the grant application,[132] and submits.

Once she's submitted the grant application, there is a mandatory multi-level peer review system.[133] The first level is an initial review performed by the Initial Review Group, or IRG. The IRG has:

> six active specialized subcommittees for review of a variety of applications and scientific areas. . . . Following a discussion of each application, the IRG Chairperson will ask IRG members to record their merit scores on their individual scoring sheets. Temporary members, including consumers, also will vote a priority score on those applications in whose discussion they participated. Each application is scored in its own right and not in comparison to other applications under consideration. Reviewers will score the applications using a new scoring scale of 1 to 9 to list their final impact/priority score."[134]

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[130] *Application, Development, Submission & Award*, NATIONAL CANCER INSTITUTE, http://www.cancer.gov/grants-training/grants-process/application/.

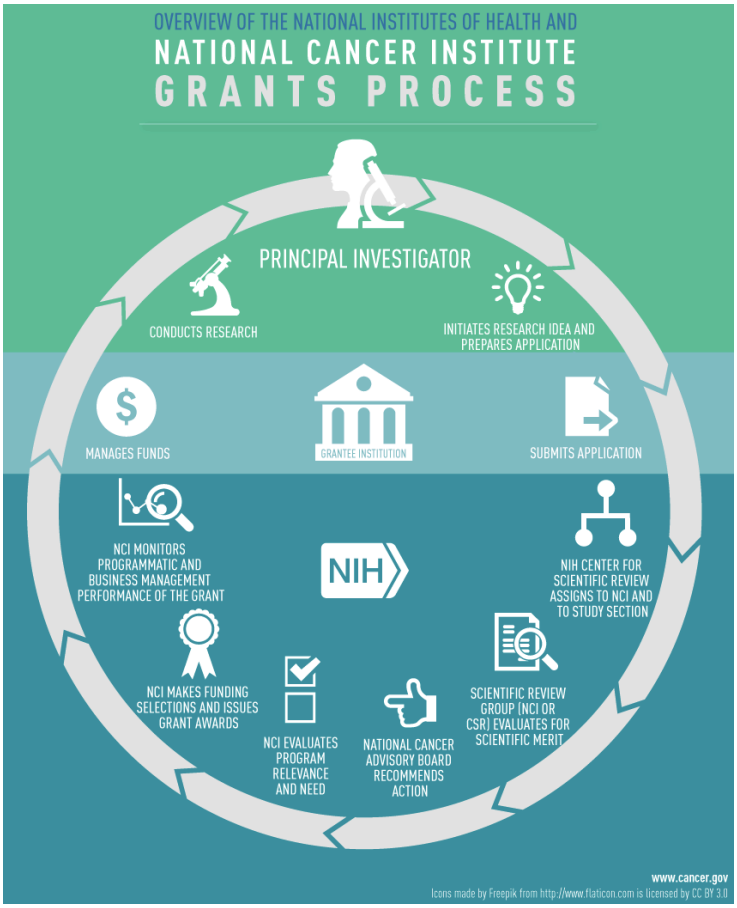
[131] *Id.*

[132] Which is its own albatross, as you'll come to understand in subsequent discussions of how the grant gets processed and accounted for.

[133] *See* Public Health Service Act of 1944 § 492, 42 U.S.C. § 489 (2012).

[134] *See* THE NCI CONSUMER'S GUIDE TO PEER REVIEW, DIVISION OF EXTRAMURAL ACTIVITIES: NATIONAL CANCER INSTITUTE 18, 28–29 (2009) http://deainfo.nci.nih.gov/PeerReview/GuideCompleteBook.pdf.

The core review criteria are the project's: significance, investigators, innovation, approach, and environment.[135] There are also additional review criteria, including the protections for animal or human subjects, minority inclusion or biohazards.[136]



Once these scores are compiled, a Summary Statement is prepared for the National Cancer Advisory Board, which comprises the second stage of the peer review process. The Summary Statement include contact information, impact score, summary of the discussion, reviewer critiques and individual criterion scores,

[135] ORIENTATION FOR THE NATIONAL CANCER ADVISORY BOARD, NATIONAL INSTITUTE OF HEALTH 35 (2013), http://deainfo.nci.nih.gov/advisory/ncab/orientationbook.pdf [hereinafter ORIENTATION BOOK]. Each question is undoubtedly subjective and thus prone to unfair influence, including the criteria of evaluating the investigators such as whether they are "well suited to the project," the strength of their previous accomplishments and leadership, and their organizational structure. *Id.*

[136] *Id.* at 35, 38.

committee recommendations concerning the budget.[137] The NCAB meets three times a year for multiple purposes, including grant approval. "Usually the Board concurs with the initial reviewers" recommendations; on occasion, however, the Board may vote to change the IRG recommendations," which could lead to another round of reviews, considered for an exception, or altogether denied.[138]

Interestingly, the NIH does not make public any practices revolving self-assessment. One could view the appointment process of new members to multiple advisory groups and boards as a mark of self-assessment, but no formal program is detailed.

In an odd idiosyncrasy of the grant process, however, "[m]any more grants are approved by the NCAB than can be financed from the NCI budget."[139] From there, a negotiation process begins to potentially trim some fat off of approved proposals and continue to slice the budget down further.[140] Thus, the Director of the NCI makes final funding decisions "based primarily on IRG percentile/impact score ratings of scientific merit, the Institute's program objectives, avoidance of duplicate effort, and other considerations."[141] Therefore, if the scientist's grant makes the cut,

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[137] *See* ORIENTATION BOOK, *supra* note 135, at 39.

[138] *See* ORIENTATION BOOK, *supra* note 135, at 51.

[139] ORIENTATION BOOK, *supra* note 135, at 52.

[140] *See* NATIONAL CANCER INSTITUTE, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, THE GRANT PROCESS: THE LIFECYCLE OF A GRANT 41–45 (2015). Unfortunately, no further information is provided as to what happens when negotiations insufficiently curtail spending.

[141] ORIENTATION BOOK, *supra* note 135, at 52.

she will be the recipient of NCI's newly augmented budget and a happy benefactor of the President's new moonshot.

Given the extraordinarily high bar placed on peer reviews and scientific rigor, the funding for scientific research stands alone in its funding structure.

v. Mandatory vs. Discretionary Spending

The final question at play is whether NCI's funding—or even NIH's funding at large—is mandatory or discretionary, or if it's a mandatory/discretionary hybrid appropriation.

The NIH's funding is *nearly* entirely discretionary. In FY2016, the NIH was appropriated $31,381 million as purely discretionary budget authority.[142] The only mandatory spending on the NIH at large is for Public Health Service Evaluation financing—$780 million[143]—and specialized type 1 diabetes research—$150 million.[144] Neither of these programs touches on the NCI directly, leaving NCI and its cancer research *purely* discretionary. The President's Proposed FY2017 budget proposes the $680 million "Cancer Initiative Mandatory Financing," which would be the only mandatory funding for the entire NCI. Because this has not yet passed, however, it is more appropriate to operate under the assumption that the NCI is still purely discretionary. This leaves two major questions for those trying to

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[142] Consolidated Appropriations Act, 2016, Pub. L. No. 114-113 (2016).

[143] Protecting Access to Medicare Act of 2014, Pub. L. No. 113-93, 128 Stat. 1040, U.S.C. § 1305. For more information regarding the PHS evaluations, see C. STEPHEN REDHEAD & AGATA DABROWSKA, CONGRESSIONAL RESEARCH SERVICE, PUBLIC HEALTH SERVICE AGENCIES: OVERVIEW AND FUNDING (FY2010-FY2016), (Oct. 13. 2015) https://www.fas.org/sgp/crs/misc/R43304.pdf.

[144] Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10, 129 Stat. 87, 42 U.S.C. § 1305 (2015).

understand how the taxpayer-funded cancer moonshot actually functions: how is it affected by budget cuts?, and what happens to research during any future government shutdowns?

Because NCI is *purely* discretionary, the Budget Control Act of 2011[145] could substantially impact it when the country is facing budget problems. Putting aside the contextual features and run-up to the law's enactment, the operative provision states that if budgets are not passed to hit a target reduction goal, automatic spending cuts are triggered across discretionary accounts.[146] The amount at which these discretionary accounts will be cut is determined by spreading the budget's shortfall across all accounts, including the NIH.[147]

Obviously for the cancer research community—not to mention those affected by the dreaded disease—that is far from ideal. It's for this obvious reason that the President's Proposed FY2017 Budget includes mandatory spending provisions not subject to these sorts of politics.

And what happens if politics obstructs the budgeting process again and the government shuts down? Frankly, there is not much of a manual for that, but the NIH's procedures during the 2013 government process may prove to be repeated. During the shutdown, a small portion of operations continued. Specifically,

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[145] Pub. L. No. 112-25, 125 Stat. 240, 2 U.S.C. § 901 (2011).

[146] *Id.* at § 302.

[147] *Id.* For more information on the Budget Control Act, see BILL HENIFF JR., ELIZABETH RYBICKI, & SHANNON M. MAHAN, THE BUDGET CONTROL ACT OF 2011, CONGRESSIONAL RESEARCH SERVICE, (Aug. 19, 2011) https://www.fas.org/sgp/crs/misc/R41965.pdf.

scientists operating under grants were permitted to continue their research.[148] Other NIH—and therefore NCI—functions, though, were cut: peer review and advisory council meetings, administrative support, and reporting administration were all cut off.[149] These functions, including certain ones that are time-specific, were resumed when a deal was struck under detailed guidelines.[150]

IV. Conclusion

The NIH is undoubtedly a complicated beast, but it is necessarily complex. In governing appropriations for expert, technical, crucial medical research, it arguably should not be so simple to fund and manage. It is interesting to note, however, that analogous scientific research and development programs throughout our nation's history have not been funded in the same "pipeline" style. The Manhattan Project—the U.S. government's top secret research project to create the world's first atomic bomb—was funded directly to the Department of Defense as part of an undisclosed

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[148] Press Release, National Institutes of Health, Information for the NIH Extramural Grantee Community During the Lapse of Federal Government Funding, (Oct. 1, 2013) http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-126.html.

[149] *Id.* Though not directly related to the NCI, one of the bigger problems with government shutdowns is the NIH's hospital facilities. During the 2013 crisis, NIH was turning away hundreds of patients a day for regular hospital procedures. *See NIH, CDC feeling government shutdown's effects*, CBS (Oct. 1, 2013) http://www.cbsnews.com/news/nih-cdc-feeling-government-shutdowns-effects/.

[150] Press Release, National Institutes of Health, Revised Guidance on Resumption of NIH Extramural Activities Following the Recent Lapse in Appropriations, (Oct. 22, 2013) http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-007.html; Press Release, National Institutes of Health, Guidance on Resumption of NIH Extramural Activities Following the Recent Lapse in Appropriations, (Oct. 18, 2013) http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-003.html.

increase in general appropriations.[151] The difference here is almost certainly due to secrecy concerns, as earmarking the project in a pipeline system would have given away too much intelligence to the Axis powers and to our "frenemies," the Soviet Union. The Space Race, on the other hand, was no secret, yet it was funded via direct congressional action as well.[152] That is likely due to the field's participants. As has been the case since the government sponsored research, a third party—in this case both pharmaceuticals and academia—had parallel participation. The same cannot be said for the Space Race, where private enterprise participants only played a part in component production; no one was themselves building a spacecraft to compete with the Apollo, Gemini and Mercury programs.[153] Thus, there was no need to apportion funding in a way other than directly.

There is a takeaway to be had regarding the timing of increased scientific investments. The Manhattan Project ran from approximately 1942-1946; the Space Race went on only a bit longer, spanning the 1960s. If we treat these two measures as *wartime* efforts designed to assert military or geopolitical superiority, it is interesting that one can see dramatic upticks in NCI—as well as the NIH—funding

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[151] For more information on the Manhattan Project's funding, both in specific dollar figures and structure, see THOMAS S. BLANTON, ATOMIC AUDIT: THE COSTS AND CONSEQUENCES OF U.S. NUCLEAR WEAPONS SINCE 1940 (Stephen I. Schwartz ed. 1998). For a visual depiction, see *infra* Appendix B.

[152] *See generally*, Jane Van Nimmen, Leonardo C. Bruno, & Robert L. Rosholt, 1 NASA HISTORICAL DATA BOOK, 1958-1968: NASA RESOURCES (1976), http://history.nasa.gov/SP-4012v1.pdf.

[153] *See* NASA, PROJECT APOLLO: A RETROSPECTIVE ANALYSIS, http://history.nasa.gov/Apollomon/Apollo.html; Stephen B. Johnson, The Political Economy of Spaceflight *in* SOCIETAL IMPACT OF SPACEFLIGHT 141, 152 (Steven J. Dick and Roger D. Launius eds., 2007) http://history.nasa.gov/sp4801-chapter9.pdf.

right *after* both of these measures. These funding upticks have occurred at either the tail end or the official termination of war: the first tick was post-WWII (and the Manhattan Project), the second at the tail end of Vietnam (post-Space Race). This most recent tick occurs as we draw down troop deployments abroad (though it must also be said that the NCI received its highest share of the federal budget in 2003 *before* the surge). Maybe these upticks are filling the void of military costs, a *quid pro quo* for returning money to domestic development after so much had been spent abroad.

There is also a takeaway to be had regarding the duration of scientific investments. Whether the Manhattan Project, the Space Race, or periods throughout the War on Cancer, these surges in scientific investment have been limited. The Manhattan Project and the Space Race were limited by having accomplished their goals, and lasted 4 and 10 years, respectively. The NCI's funding increases span approximately 10-year periods and then return back to lower levels, particularly the 1970s and the 2000s. It should make observers all the more curious about the earnestness of the "moonshot" and the mandatory/discretionary distinction in how the "moonshot" is achieved.

And while better understanding the pipeline and inner machinery of the funding structure is vital to evaluating the NIH from a lawmaker's policy perspective, it may also be worth noting the returns on investment scientific research has produced. For example, research has proven a positive "multiplier effect" on the economy, meaning that for every NASA-appropriated dollar, there

was a net economic benefit to the country.[154] More to the point, recent research has demonstrated the effect medical research has or could have to economy, having a return on investment in the trillions of dollars.[155] For this reason, though a cynic may reason that the President's moonshot for cancer research comes as a parting gift to a Vice President about whom he so deeply cares, objective analysis tells us that the rare case of bipartisanship is just sound political investment.

[154] *See* Roger H. Bezdek & Robert M. Wendling, *Sharing Out NASA's Spoils*, 355 NATURE 105, 105–06 (1992) ("The economic benefits of NASA's programmes are greater than generally recognized. The main beneficiaries may not even realize the source of their good fortune.").

[155] *See* Kevin M. Murphy & Robert H. Topel, *The Economic Value of Medical Research* in MEASURING THE GAINS FROM MEDICAL RESEARCH 41, 41–42 (Kevin M. Murphy & Robert H. Topel eds., 2003).

V. Tables and Appendices

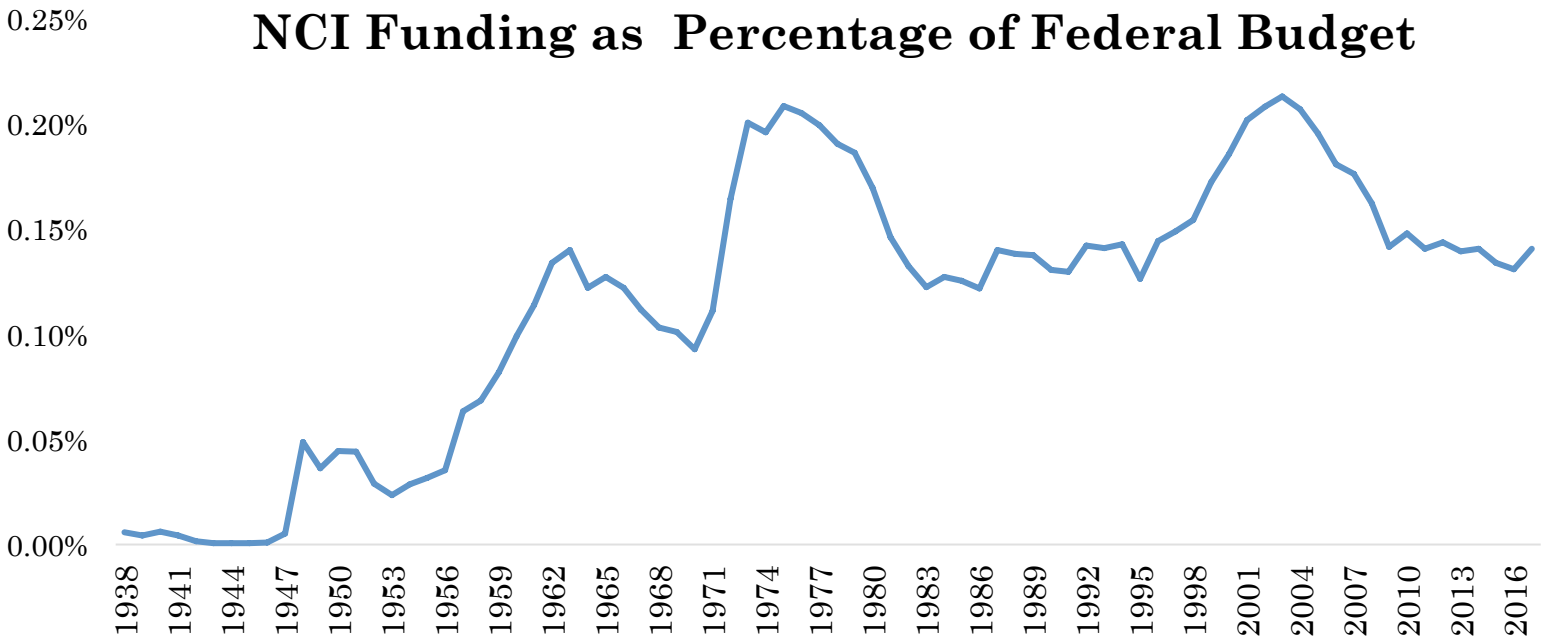
Table 1. NCI Budgets in Perspective[156]

Year	NCI Budget (Millions, Current USD)	NCI Budget (Millions, 2015 USD)	Percentage of Fed. Budget
1938	0.4	6.7	0.006%
1939	0.4	6.8	0.004%
1940	0.6	9.7	0.006%
1941	0.6	9.2	0.004%
1942	0.6	8.2	0.002%
1943	0.5	7.3	0.001%
1944	0.5	7.1	0.001%
1945	0.6	7.4	0.001%
1946	0.5	6.7	0.001%
1947	1.8	19.4	0.005%
1948	14.5	142.6	0.049%
1949	14.0	139.4	0.036%
1950	18.9	185.9	0.044%
1951	20.1	183.1	0.044%
1952	19.7	175.8	0.029%
1953	17.9	158.8	0.024%
1954	20.2	178.3	0.029%
1955	21.7	192.2	0.032%
1956	25.0	217.7	0.035%
1957	48.4	408.5	0.063%
1958	56.4	462.6	0.068%
1959	75.3	613.1	0.082%
1960	91.3	730.7	0.099%
1961	111.0	879.9	0.114%
1962	142.8	1121.0	0.134%
1963	155.7	1206.4	0.140%
1964	144.3	1103.6	0.122%
1965	150.0	1128.7	0.127%
1966	163.8	1198.0	0.122%
1967	175.7	1246.5	0.112%
1968	183.4	1248.8	0.103%
1969	185.2	1195.7	0.101%
1970	181.5	1108.5	0.093%
1971	233.2	1364.5	0.111%
1972	378.8	2147.8	0.164%

[156] *See* APPROPRIATIONS, NIH, http://www.nih.gov/about-nih/what-we-do/nih-almanac/appropriations-section-1; FISCAL YEAR 2016: HISTORICAL TABLES, OFFICE OF MANAGEMENT AND BUDGET, https://www.whitehouse.gov/sites/default/files/omb/budget/fy2016/assets/hist.pdf.

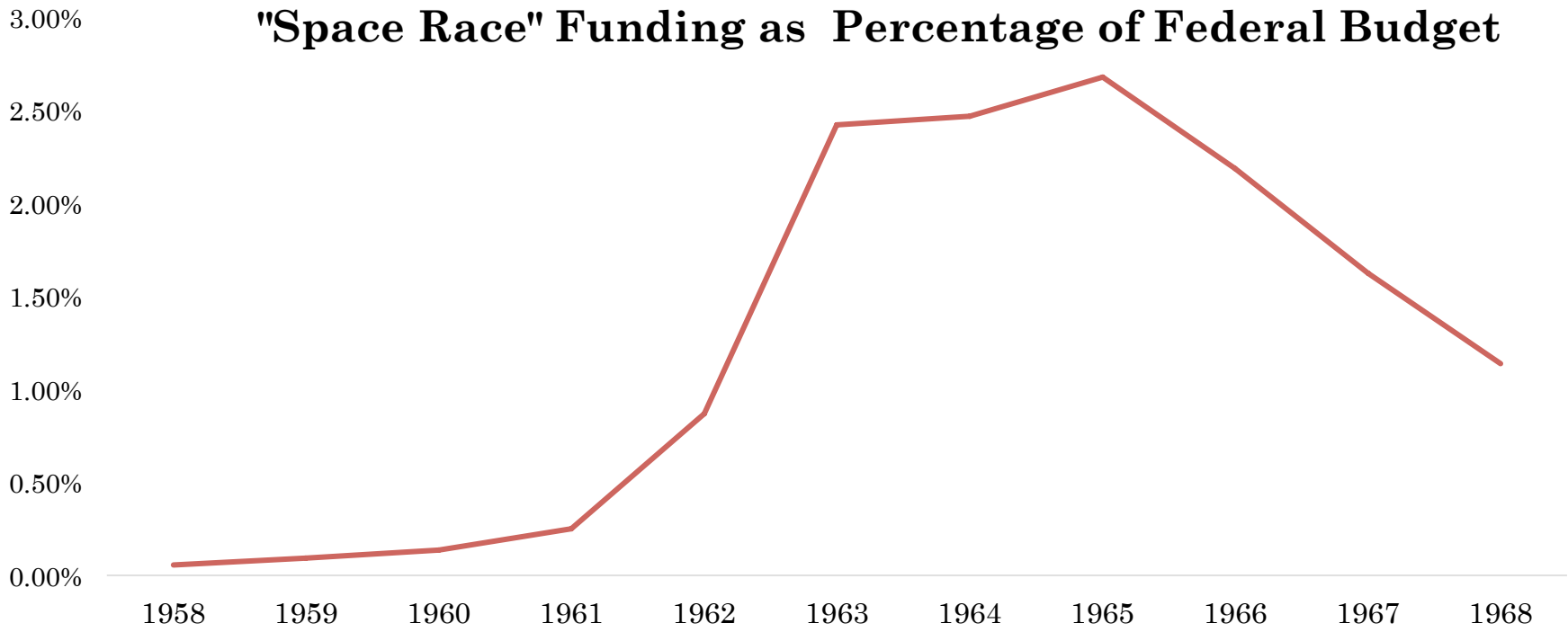
1973	492.2	2627.4	0.200%
1974	527.5	2536.2	0.196%
1975	691.7	3047.5	0.208%
1976	761.7	3173.4	0.205%
1977	815.0	3187.5	0.199%
1978	872.4	3171.1	0.190%
1979	937.1	3059.7	0.186%
1980	999.9	2875.6	0.169%
1981	989.4	2579.2	0.146%
1982	986.6	2423.1	0.132%
1983	987.6	2350.6	0.122%
1984	1081.6	2467.1	0.127%
1985	1183.8	2607.9	0.125%
1986	1203.4	2602.9	0.122%
1987	1402.8	2926.3	0.140%
1988	1469.3	2944.5	0.138%
1989	1570.3	3000.9	0.137%
1990	1634.3	2963.0	0.130%
1991	1714.8	2983.7	0.129%
1992	1962.6	3314.8	0.142%
1993	1981.4	3249.4	0.141%
1994	2082.3	3329.5	0.142%
1995	1913.8	2976.0	0.126%
1996	2248.0	3396.7	0.144%
1997	2381.1	3517.0	0.149%
1998	2547.3	3703.8	0.154%
1999	2925.2	4162.6	0.172%
2000	3314.6	4560.8	0.185%
2001	3754.5	5027.2	0.202%
2002	4181.2	5506.7	0.208%
2003	4592.3	5914.9	0.213%
2004	4739.3	5947.8	0.207%
2005	4825.3	5857.9	0.195%
2006	4793.4	5636.6	0.181%
2007	4797.6	5483.7	0.176%
2008	4830.6	5318.5	0.162%
2009	4969.0	5490.7	0.141%
2010	5103.4	5547.4	0.148%
2011	5058.6	5331.7	0.140%
2012	5072.2	5234.5	0.143%
2013	4807.5	4889.2	0.139%
2014	4923.2	4928.2	0.140%
2015	4931.0	4931.0	0.134%

Appendix A[157]



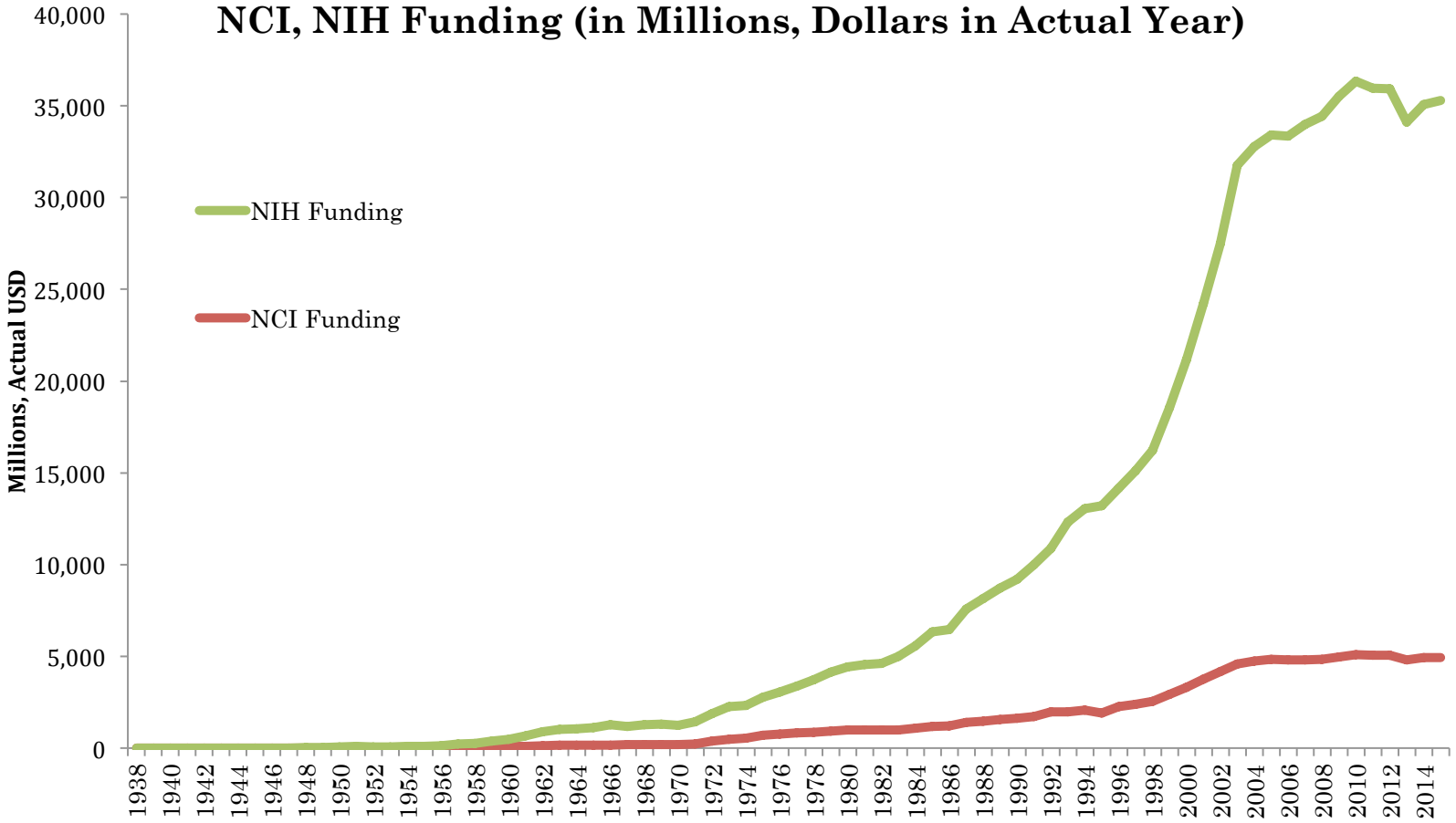
[157] APPROPRIATIONS, NIH, http://www.nih.gov/about-nih/what-we-do/nih-almanac/appropriations-section-1.

Appendix B[158]



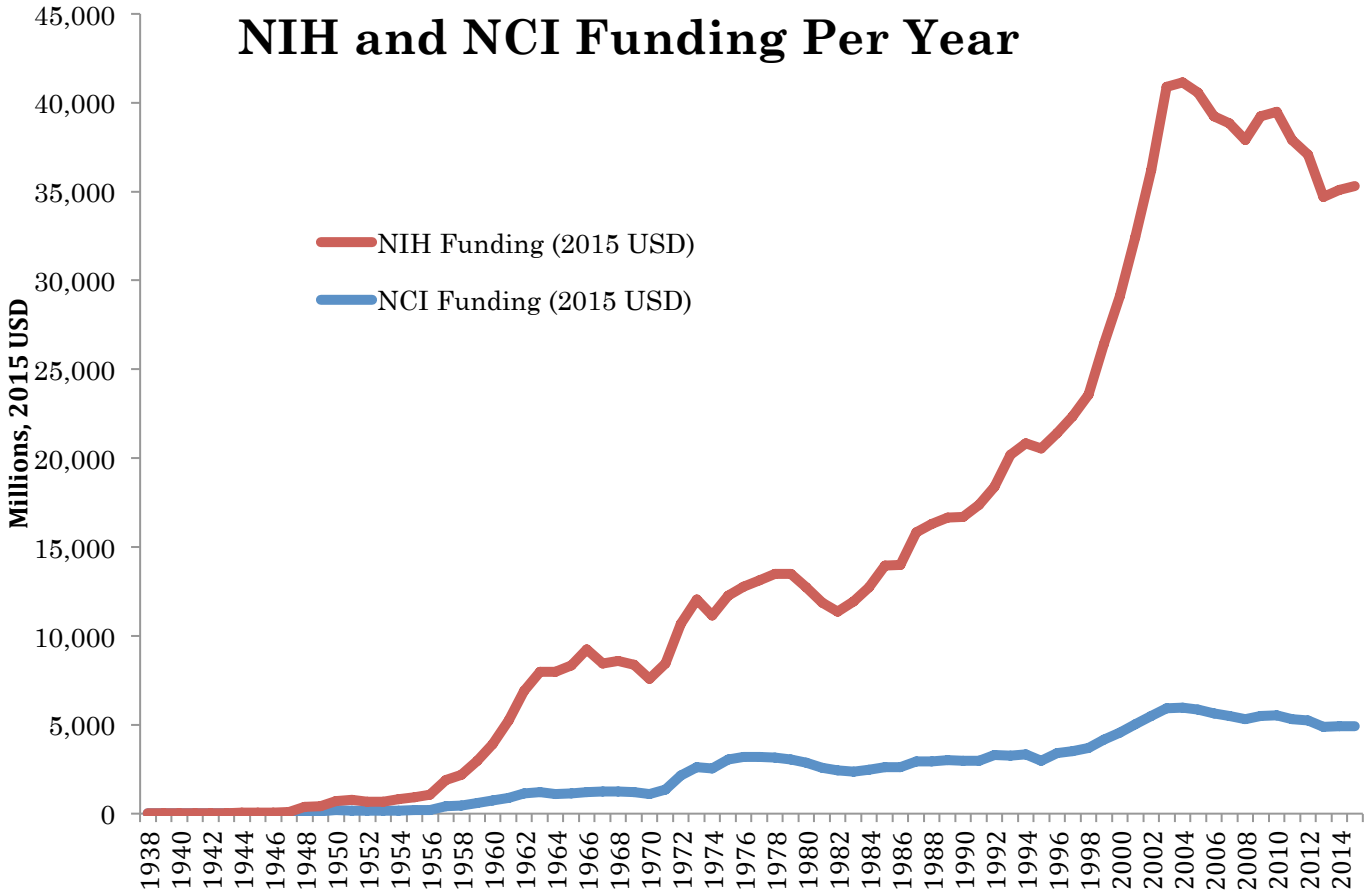
[158] LINDA NEUMAN EZELL, NASA HISTORICAL DATA BOOK VOLUME III PROGRAMS AND PROJECTS 1969-1978 (1988); LINDA NEUMAN EZELL, NASA HISTORICAL DATA BOOK VOLUME II PROGRAMS AND PROJECTS 1958-1968 (1988); DAVID J. SHAYLER, GEMINI STEPS TO THE MOON (2001); FISCAL YEAR 2016: HISTORICAL TABLES, OFFICE OF MANAGEMENT AND BUDGET, https://www.whitehouse.gov/sites/default/files/omb/budget/fy2016/assets/hist.pdf.

Appendix C[159]



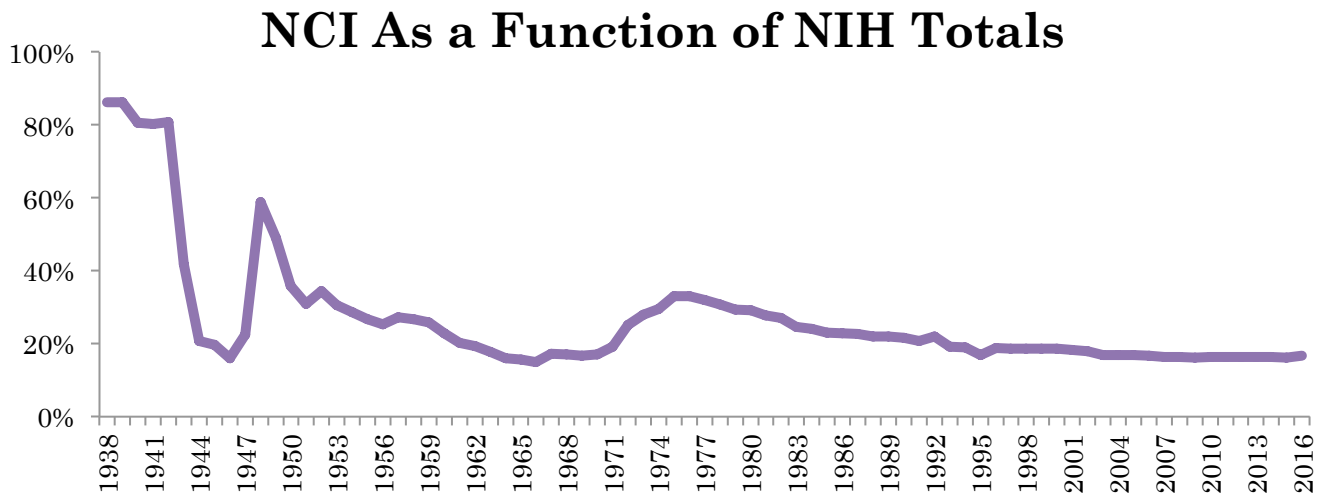
[159] *See* APPROPRIATIONS, NIH, http://www.nih.gov/about-nih/what-we-do/nih-almanac/appropriations-section-1.

Appendix B[160]



[160] *See* APPROPRIATIONS, NIH, http://www.nih.gov/about-nih/what-we-do/nih-almanac/appropriations-section-1.

Appendix C[161]



[161] *See* Appropriations, NIH, http://www.nih.gov/about-nih/what-we-do/nih-almanac/appropriations-section-1; WELCOME TO THE NIH OFFICE OF BUDGET, https://officeofbudget.od.nih.gov/.