POLICY BRIEF:

THE IMPACT OF RECENT WHITE HOUSE PROPOSALS ON CANCER RESEARCH

Tomas J. Philipson
Yier Ling
Ruiquan Chang

The University of Chicago

Executive Summary

In February 2022, the Biden Administration aimed to reignite the Cancer Moonshot through its proposed federal budget and stated that one of its objectives is to reduce cancer mortality by 50% over the next 25 years. Currently, there is already a very large amount of development activity for cancer treatments generated by the market and existing government policy. We find that about 49.2% of the total FDA pipeline is for new cancer treatments and 27.0% of new drug and biologics approvals are for cancer. Two of the Administration's major policy proposals affect this large amount of cancer R&D activity and new drugs going forward. The first is a proposed increase of public funding for cancer research and the second are proposed price controls on cancer treatments. If the increase in cancer research for the fiscal year 2023 was permanent, it would amount to an annual increase of about $1.9 billion, or 3.4% of the current overall public and private cancer R&D spending of $56.8 billion. In contrast, we find that the latest publicly proposed price controls reduce overall annual cancer R&D spending by about $18.1 billion, or 31.8%. Thus, the reduction in total R&D spending from proposed price controls is more than 9.4 times as large as the increase from the proposed budgetary expansion. Regardless of the level of R&D assumed needed to generate a new drug, the same proportional effects would apply to new drugs so that 9.4 times as many new drugs are lost due to price controls as gained from the budget expansion. We therefore conclude that the overall effect of the Administration's policies affecting cancer research is to greatly reduce, rather than raise, the large amount of development activity in cancer. This would ultimately raise, as opposed to lower, cancer mortality compared to the status quo and thus be counterproductive to the Cancer Moonshot objectives.

Section 1: Introduction

The Biden Administration has proposed new policies to promote more cancer research in the US. These proposals are in accordance with goals that the President enumerated in 2016 when he launched a non-profit called the Cancer Moonshot. The initiative was reignited by the White House in February 2022 with new objectives of reducing the cancer death rate by 50.0% over the next 25 years and improving the life experiences of people who survived or live with cancer (White House, 2022a). Making progress on cancer would be extremely valuable to the US – in 2020 it was the 2nd leading cause of death with an estimated total mortality of 600,000 per year (CDC, 2022).

Due to this high value of progress, cancer is by far the most active drug class in terms of medical innovation. For phase I – III drugs in the FDA pipeline, about 49.2% are new cancer treatments (PhRMA 2021). Moreover, 27.0% of new drug approvals from 2010 to 2019 were for cancer (Tufts CSDD, 2019). Cancer drugs are more likely to be given priority status than other drug classes and are thus approved faster. It follows that the Administration has made cancer research a priority at a time when research activity in the drug class is already highly incentivized by existing market conditions and public policies.

Two of the Administration's major policy proposals affect the amount of R&D and new drugs in cancer going forward. The first is a proposed increase of public R&D funding for cancer and the second are proposed price controls on cancer treatments.

For the first effort of raising public R&D funding, we find that public cancer research funding will increase by $2.0 billion in 2022 for Advanced Research Projects Agency for Health (ARPA-H) and National Cancer Institute (NCI) (White House, 2021; NCI, 2022), and by $1.8 billion in 2023 for ARPA-H, NCI and other cancer research institutions (White House, 2022d). These two years lead to an average annual increase of $1.9 billion and we consider the impact of making such an increase permanent. In addition to increased public R&D spending on cancer, the Moonshot contains other unfunded provisions that may also impact cancer, such as fellowships, access, and prevention provisions (White House, 2022d).

The second policy initiative to impact cancer research is the proposed price controls on cancer treatments. Philipson and Durie (2021) find that the proposed price controls enumerated in the House bill HR 5376 would reduce R&D spending by 18.5%, or $663 billion, from 2021 to 2039, which would lead to 135 fewer new drugs being approved in that period. Although any potentially passed bill may differ from that bill, we use it as benchmark because it is the last publicly available framework on the price controls considered. Regardless of the exact nature of the bill, given the large share of overall drug development that is taking place in cancer, the cancer class will be greatly affected by potential price controls.

Given that the two proposed policies have opposing effects, their respective quantitative magnitudes matter to determine their overall effect on total cancer R&D and new drugs. In 2021, we find that total cancer R&D spending was approximately $56.8 billion, with a public spending of $11.9 billion (*RePORT*, 2021), and a private spending of $44.8 billion (PhRMA, 2021 scaled by pipeline activity). We find that the proposed budget increase for cancer research of $1.9 billion is a 3.4% increase on this total R&D spending. In contrast, we find that the proposed price controls reduce that overall R&D spending by $18.1 billion or 31.8%.

It follows that reduction in total R&D spending from price controls is 9.4 times as large as the increase from the budgetary expansion. Regardless of the methods used to determine the R&D spending needed to generate a new drug, the total new cancer drugs lost to price controls is 9.4 times larger than the total new drugs gained from a budget expansion.

Overall, we therefore find that although the Administration has proposed increased federal funding for cancer related research, combined with its other proposals on cancer drug price controls, this combined approach will greatly reduce the large activity already taking place in the most active drug class. In turn, this will raise cancer mortality as opposed to lowering it.

Section 2: The Large Presence of Cancer Treatments in the FDA Pipeline

There is currently a large amount of R&D activity in cancer which will be increased by more federal cancer research funding but reduced in an overall manner from the negative effects of proposed price controls. This section reviews the evidence on the large presence of oncology in both the pipeline and approval at the FDA.

2.1 The Large Presence of Oncology in The FDA Pipeline

Oncology drugs are the most representative of any drug class in the FDA pipeline. According to Analysis Group (2021), cancer drugs represent 49.2% (6,137 out of 12,474) of the total drugs in clinical Phase I-III trials as of January 2021. This is more than any other drug class. Among Phase I drugs, cancer drugs amount to 2,686 of the total 4,927 (approximately 54.5%); for Phase II drugs, cancer drugs make up 2,931 of the total 5,940 (approximately 49.3%); among Phase III drugs, cancer drugs make up 520 of the total 1,607 (approximately 32.4%). No other drug classes have more drugs than oncology at any phase and, except for Phase III, cancer drugs represent around half of the total drugs.

There is also a large dominance of oncology drugs among first-in-class and orphan designated drugs. First-in-class drugs refer to drugs using innovative mechanisms distinctive from existing drugs of the same indications. Orphan drugs refer to drugs for rare diseases with less than 200,000 patients (Batta et al., 2020). Within first-in-class drugs, cancer drugs make up 4,189 of 8,644 Phase I-III drugs (approximately 48.5%), 2,173 of 3,900 Phase I drugs (approximately 55.7%), 1,812 of 3,972 Phase II drugs (approximately 45.6%), and 204 of 772 Phase III drugs (approximately 26.4%) (Analysis Group, 2021). Within orphan drugs, cancer drugs account for 504 of 1,085 Phase I-III drugs (approximately 46.5%), 109 of 222 Phase I drugs (approximately 49.1%), 266 of 548 Phase II drugs (approximately 48.5%) and 129 of 315 Phase III drugs (approximately 41%) (ibid). Similarly, no other drug class takes up more drugs than cancer drugs, and cancer drugs always account for around half of the drugs in each phase, except in Phase III. In addition, cancer drugs take up a higher percentage of Phase III orphan drugs than potential first-in-class drugs and drugs in general.

Two earlier pieces (Long, 2017; Long and Works, 2013) using the same data sources allow us to detect trends in oncology research. The numbers of drugs across the three reports are exhibited in Table 1-3. There is no desired information on the orphan drug project distribution in Long and Works (2013). Long (2017) demonstrates the distribution of oncology research in all Phase I-III drugs by August 2016. Around 42.6% of all Phase I-III drugs are in oncology, and from 2016 to 2021, 2,131 of the 3070 new drugs are in oncology (approximately 69.4%) (ibid; Analysis Group, 2021). By 2016, approximately 47.2% of Phase I drugs, 43.4% of Phase II drugs, and 26.2% of Phase III drugs are in oncology (Long, 2017). Between 2016 and 2021, oncology drugs represent around 77.2% of the increase in Phase I drugs, 66.7% of the increase in Phase II drugs, and 54.6% of the increase in Phase III drugs (ibid; Analysis Group, 2021). Long and Works (2013) show the distribution of drugs by December 2011, where oncology drugs take up around 38.8% of total drugs, 41.8% of Phase I drugs, 40% of Phase II drugs, and 26.2% of Phase III drugs. Oncology research also

represents about 62.4% of the increase in total drugs from 2011 to 2016 (ibid; Long, 2017). Breaking this down, oncology drugs represent 70.5% of the increase in Phase I drugs, 62.6% of the increase in Phase II drugs, and about 25.9% of the increase in Phase III drugs (ibid). Among all three reports, oncology has the most drugs in all phases and take up substantial proportions of the increases in drugs. These large proportions, especially in Phase I projects, suggest a steeply upward trend for oncology research at the FDA.

Among First-in-Class drugs, oncology remains the area with the most drugs across all phases and years. By 2016, oncology drugs make up about 45.9% of total drugs, 50.0% of Phase I drugs, 45.5% of Phase II drugs, and 28.8% of Phase III drugs (Long, 2017). Oncology drugs represent around 59.1% of the total increase in drugs from 2016 to 2021 (ibid; Analysis Group, 2021). They also represent 77.0% of the increase in Phase I drugs, 46.0% of the increase in Phase II drugs, and 10.9% of the increase in Phase III drugs (ibid). By 2011, oncology research is representative of approximately 41.2% of total drugs, 44.9% of Phase I drugs, 40.1% of Phase II drugs, and 29.9% of Phase III drugs (Long and Works, 2013). Additionally, oncology drugs represent 62.9% of the increase in total drugs from 2011 to 2016 (ibid; Long, 2017). They also represent 66.8% of the increase in Phase I drugs, 69.0% of the increase in Phase II drugs, and 25.4% of the increase in Phase III drugs (ibid). Thus, the conclusion remains that among First-in-Class drugs, oncology leads all drug classes in terms of quantity, which indicates the rising trend of research in producing oncology drugs.

Oncology continues to have the most drugs across all phases for orphan drugs in both reports. By 2016, oncology research represents around 49.4% of the total drugs, 49.4% of Phase I drugs, 51.4% of Phase II drugs, and 45.5% of Phase III drugs (Long, 2017). Between 2016 and 2021, oncology drugs represent 38.3% of total drug increases, 48.3% of Phase I drug increases, 38.9% of Phase II drug increases, and 32.1% of Phase III drug increases (ibid; Analysis Group, 2021).

Justifying the utilization of the Analysis Group reports and their data, we compared these results with a dataset from Informa. In Table 4, the numbers of drugs across phases from January 2000 to April 2022 are exhibited, considering the most advanced phases of drugs (for example, Phase II/III would be categorized as Phase III). As can be seen, oncology accounts for approximately 57.1% of Phase I drugs, 47.5% of Phase II drugs, 24.5% of Phase III drugs, and 42.3% of total drugs. Owing to the different time points in consideration, we allow for some discrepancies. It can be concluded that the Analysis Group (2021) data is largely compatible with Informa and should provide reliable insights.

2.2 The Large Presence of Oncology in FDA Approvals

Oncology drugs account for a large proportion of FDA drug approvals and are favored by the approval process. According to the Tufts CSDD Impact Report (2019), cancer drugs accounted for 27.0% of the new drug approvals from 2010 to 2019. As compared to non-cancer drugs, cancer drugs are also approved faster and more likely to be given priority rating and orphan drug status, both of which encourage oncology research with potentially accelerated approval pace and financial incentives. Such a conclusion is also corroborated in Batta et al. (2020), which indicates that cancer drugs account for the most fast-track, accelerated and priority approvals among all therapeutic areas. Furlow (2016) also suggests that cancer drugs are the largest recipient group of FDA expedited approvals, and Akhade et al. (2022) agrees that the accelerated approval systems are now most commonly used for cancer drugs. In 2015, oncology also received more approvals than any other therapeutic area. Among 46 novel drugs approved in 2017, 37.0% were given expedited development (Batta

et al., 2020). Thus, we conclude that expedited approval for cancer drugs has become a trend in recent years, and emphasis in medical research has been put on developing cancer drugs (Batta et al., 2020). In addition, Batta et al. (2020) suggest that cancer drugs take up 17.5% of drug approvals from 2010 to 2017, which may suggest a drastic increase in cancer drug approvals from 2018 to 2019, given data provided by the Tufts CSDD Impact Report (2019).

Section 3: White House Budget Proposals to Increase Cancer Research Spending

The Biden administration has proposed new budget increases to encourage cancer research.

3.1 ARPA-H

In their budget for fiscal year 2022, $6.5 billion of the $51 billion funding to the NIH was invested to launch the Advanced Research Projects Agency for Health (ARPA-H), whose mission lies in cultivating novel health breakthroughs with a focus on cancer (White House, 2021; Office of Science and Technology Policy, 2021). Examples of potential projects ARPA-H plans to take on include generating mRNA vaccines for cancer (Collins et al., 2021). For fiscal year 2023, another $5 billion would be invested in ARPA-H within the $49 billion funding to the NIH (White House, 2022d). Since cancer is part of its initial focus, we assume 25% of ARPA-H funding goes to cancer research.

3.2 Cancer Moonshot Initiative

First launched in 2016, the Cancer Moonshot initiative was re-ignited in 2022 to encourage cancer research under the goal to reduce cancer death rates by 50% over the next 25 years (White House, 2022a). For fiscal year 2022, compared to 2021, $6.5 billion was invested in ARPA-H and funding to NCI increased by $353 million, including $194 million for the Cancer Moonshot initiative (White House, 2021; NCI, 2022). Assuming cancer research takes up 25.0% of ARPA-H funding, this leads to a $2.0 billion increase in public cancer research funding from 2021 to 2022.

Compared to 2021, fiscal year 2023 allocated $5 billion to ARPA-H and increased NCI funding by $174 million (White House, 2022d). Apart from these direct funds for cancer research institutions, funds would also be directed to entities indirectly related to cancer research. An additional $80 million would be invested in the CDC, and an additional $20 million would be allocated to the FDA (White House, 2022d). $248 million would be allocated to the Department of Veterans Affairs, with $81 million for research and $167 million to enhance cancer care for veterans (White House, 2022d). $36 million would be invested in the Department of Defense (DOD)'s Murtha Cancer Center of Excellence to expand clinical trial networks and projects in DOD hospitals (White House, 2022d). Moreover, another $10 million would be allocated to the National Institute of Food and Agriculture for nutritional and dietary research against cancer (White House, 2022d). Summing over these increases, fiscal year 2023 increases cancer research funding by $1.8 billion compared to 2021. Combining both 2022 and 2023, the Biden administration has increased cancer research funding by $3.8 billion compared to 2021, equivalent to an average increase of $1.9 billion per year. If such an effect repeats from 2022 to 2039, $34.2 billion would be added to public funding on cancer research.

In addition to funding institutions, alternative non-pecuniary measures have also been taken to facilitate cancer research. Scholarships and fellowships would be created at the NCI in fiscal year 2023, aiming to generate a workforce in cancer research representative of the US population (White House, 2022b). A new cancer cabinet would be convened (White House, 2022c) and additional cancer screenings would be held to compensate for those missed during the pandemic (White House, 2022d). Collaboration with the UK is also established for a bilateral effort on cancer research (White House, 2022a).

In addition to cancer-oriented efforts, other R&D investments in institutions like the CDC, the FDA, the National Science Foundation (NSF), the Department of Energy (DOE), and the Department of Agriculture may also benefit cancer research with the positive externalities of their research despite cancer not being their focus (White House, 2022d).

Section 4: Policy Impact on Cancer Research

Price controls have been shown to reduce revenue and hence R&D spending and innovation (Philipson and Durie, 2021). Summarizing the evidence base from 2004 to 2015, they find that the literature finds that a 1.0% reduction in revenue leads to approximately 1.5% lower spending in R&D. According to Philipson and Durie (2021), this is likely to be underestimated given the differences in R&D sensitivity to revenue losses in different countries within the global market. When compared to a counterfactual without price control, they found HR5367 with its inflation rebates, negotiations, and Medicare Part D redesigns, to entail a total decline of 12.0% in global revenue through 2039.

Relating revenue to R&D activities, they find that this loss in revenue would lead to a reduction of $663 billion in R&D spending from 2022 through 2039, 135 fewer new drug approvals, and a 3.7% increase in alternative medical services.

Following Philipson and Durie (2021), we estimate the percentage loss of new cancer drugs to equal the percentage loss of cancer spending. We choose 2021 as the base year for comparison since both the White House initiatives increasing cancer research funding and estimated price controls take effect in 2022. To capture the cancer spending in 2021, we combine both estimates of public and private spending. The public spending data on cancer research can be found in the NIH's *RePORT*[1] system by filtering the disease area to be cancer. $11.9 billion was spent on cancer research in 2021, according to *RePORT.*

Due to the proprietary nature of cancer research in the private sector, we estimate the private spending on cancer research by multiplying the percentage of cancer phase I-III projects in all phase I-III projects by the total R&D spending in 2021. As discussed in previous sections in 2021, cancer research takes up 2,686 of 4,927 phase I projects, 2,931 of 5,940 phase II projects and 520 of 1,607 phase III projects, accounting for 49.2% of the total phase I-III projects. We then multiply this 49.2% by the total R&D spent in the private sector in 2021. Since the latest PhRMA membership survey only covers spending until 2020, we assume total R&D spent in 2021 to equal 2020 for PhRMA member companies, which gives $91.1 billion (PhRMA, 2021).

[1] https://report.nih.gov/funding/categorical-spending#/

Thus, we estimate the total private spending on cancer research in 2021 is given by approximately $44.8 billion. Consequently, the estimate for total 2021 spending in cancer research is $56.8 billion. Given the public spending increase of $1.9 billion per year, this marks a 3.4% increase in one year, which we assume increases the number of new cancer drugs produced proportionally by 3.4% per year.

4.1 Price Controls Effect on Cancer Drug Innovation

According to Philipson and Durie (2021), price controls would yield a $663 billion reduction in private R&D spending from 2022 to 2039, which is $36.8 billion per year on average. Similarly, we multiply the percentage of cancer phase I-III projects by the average reduction in R&D spending to arrive at the average loss of cancer research spending in the private sector. This gives an $18.1 billion reduction in private cancer research spending per year, a 31.8% decrease (compared to total cancer research spending). Correspondingly, the number of new cancer drugs produced in one year would be reduced by 31.8%. This is 9.4 times the effect brought by policies increasing public funding. If the estimated public funding increase continues through 2039 and yields a total increase of $34.2 billion, the price controls would reduce private funding in the same period by $326.2 billion, which is more than 9.4 times the public spending increase.

4.2 Aggregate Effect on Cancer Drug Innovation

Combining the effect of price controls and the budget proposals increasing public funding for cancer research, we estimate a net decrease of $16.2 billion per year, a 28.5% decrease given the total cancer research spending in 2021. This yields a 28.5% decrease in the number of new cancer drugs produced per year, more than 8.5 times the increase in public funding. Similarly, assuming a constant annual public funding increase of $1.9 billion through 2039, the aggregate effect on cancer research funding would result in a net $291.8 billion reduction, which is 8.4 times the total increase in public spending.

4.3 Sensitivity Analysis

4.3.1 Varying Proportion of Cancer Funding in ARPA-H

Instead of assuming that the percentage of cancer funding in ARPA-H would be 25.0%, we now estimate an upper bound for the possible percentage of cancer funding by assuming this percentage equals the 2021 percentage of cancer research in actual spending for cancer, Alzheimer's disease, and diabetes, which are some of the diseases mentioned in ARPA-H's focus (White House, 2021; Office of Science And Technology Policy, 2021). This would serve as an upper bound as there are other diseases mentioned in ARPA-H (for example, infectious diseases), and thus the total ARPA-H spending must cover more than cancer, Alzheimer's, and diabetes, enlarging the denominator. This estimate also takes into account the fact that cancer research is more costly than any other area (Wouters et al., 2020) by considering actual research spending. Similarly, we filter the disease area to be one of cancer, Alzheimer's, and diabetes in analyzing 2021 research spending in RePORT. It is estimated that $6.9 billion was spent on Alzheimer's and $1.2 billion was spent on diabetes in 2021, leading to a total public spending on cancer, Alzheimer's, and diabetes of $20.0 billion. Cancer takes up 59.7% of this spending.

Similarly, we now estimate the increase in public cancer research funding. In 2022, the increase is now $4.2 billion. For 2023, the increase becomes $3.5 billion, yielding an average of $3.9 billion per year. Compared to 2021, this marks a 6.9% increase, translating into 6.9% more new cancer drugs to be produced in one year.

However, this would still lead to a net reduction in total cancer research spending by $14.2 billion, a 25.0% decrease in one year. Consequently, 25.0% of new cancer drugs would be lost in one year. With such a 6.9% increase in public spending, the percentage reduction in private spending by price controls is more than 4.6 times the percentage increase in public spending. The percentage reduction in total cancer research funding is more than 3.6 times the percentage increase in public funding. Similarly, if the public spending increase continues through 2039, a total increase of $70.1 billion would be expected. Total private funding from 2022 to 2039 would be reduced more than 4.6 times the increase in public funding. Additionally, the total net effect would be reduced more than 3.6 times the increase in public funding.

4.3.2 Impact of Inflation

Given the recent increase in inflation, it is important to consider the impact of real spending levels rather than nominal ones. According to the Bureau of Labor Statistics (BLS, 2022), the all-item consumer price index (CPI) is 267.1 for 2021 and 289.1 for 2022 (April, latest). We assume CPI for 2023 will increase by the same amount as from 2021 to 2022, resulting in a 311.1 index. Thus, from our previous estimates for public cancer research funding increases of $2.0 billion for 2022 and $1.8 billion for 2023, the real increases would be $684 million for 2022 and $584 million for 2023, yielding an average annual real increase of $634 million. The real total spending on cancer research in 2021 would be $21.3 billion. Consequently, public funding for cancer research would increase by around 3.0% in real terms per year, yielding a total real increase of $11.5 billion through 2039 if such policies persist. If we apply the highest CPI of 311.1 to the annual R&D loss by price controls on cancer research, $5.8 billion would be lost in real terms in the private sector per year, leading to a net effect of $5.1 billion lost per year. This net decrease is around 24.3% of the real total spending on cancer research in 2021. In real terms per year, the reduction in private funding for cancer research is more than 9.1 times the increase in public funding, and the net decrease is more than 8.1 times the increase in public funding. If such a net effect repeats through 2039, a total of $93.3 billion in real terms would be lost in cancer research, and our conclusion holds that the increases in public funding cannot compensate for the loss from price controls.

Section 5: Limitations

There are several limitations of the analysis that we did not consider because we believe the evidence is too uncertain to be included but may nevertheless be considered in future analysis. The first is that the calibrated amount of private R&D spending used may under-estimate the impact of price controls on cancer research. We assumed cancer research is equally costly to other drug classes. However, Wouters et al. (2020) finds that cancer drugs are above average in terms of costs across all drug classes. As a result, the loss in cancer spending from price controls may be larger than we assumed.

The second limitation is that we have not considered is the crowding out of public R&D on private R&D. While the White House aims to boost cancer research with substantial public funding, previous research has found that there is substantial crowding out of such funding in the private sector. Thus, a given public spending increase translates into a lower total R&D spending increase. Wallsten (2000) finds such substitution is almost one-to-one in research by small businesses. While Ngo and Stanfield (2016) claim that public funding

sometimes crowd in rather than crowd out private funding, they also indicate that crowding in mostly happens to firms who profit on the government as a major source of revenue, while the other peer firms are crowded out, resulting in an overall reduction in research spending. Austin (2006) finds that crowding out in the pharmaceutical industry is more likely to happen when both public and private funding target similar areas of research and when public funding increases employment of specialists in the areas. Considering the specific focus on cancer research in public funding, in addition to programs like NCI fellowships cultivating scholars in cancer research, such crowding out is highly likely to happen. Apart from these cancer-specific policies highly susceptible to crowding out, CBO (2021) also implies that crowding out is more probable when the research area has apparently profitable commercial applications.

References

Akhade, A., B. Sirohi, and B. Gyawali (2022). Global consequences of the US FDA's accelerated approval of cancer drugs. *The Lancet Oncology 23*(2), 201–203.

American Cancer Society (2020). Cancer Facts Figures 2020. Technical report, Atlanta: American Cancer Society.

American Cancer Society (2021). Cancer Facts Figures 2021. Technical report, Atlanta: American Cancer Society.

American Cancer Society (2022). Cancer Facts Figures 2022. Technical report, Atlanta: American Cancer Society.

Analysis Group (2021). Innovation in the Biopharmaceutical Pipeline. Technical report, PhRMA.

Austin, D. H. (2006). Research and development in the pharmaceutical industry. Congress of the United States, Congressional Budget Office.

Batta, A., B. S. Kalra, and R. Khirasaria (2020). Trends in FDA drug approvals over last 2 decades: An observational study. Journal of Family Medicine and Primary Care 9(1), 105.

BLS (2022). Consumer Price Index News Release. https://www.bls.gov/news.release/cpi.htm [Accessed: 2022-05-11]

Book, R. A. (2002). Public Research Funding and Private Innovation: The Case of the Pharmaceutical Industry. Ph. D. thesis, Citeseer.

CBO (2021). Research and Development in the Pharmaceutical Industry. https://www.cbo.gov/publ ication/57126 [Accessed: 2022-04-17].

CDC (2022a). Deaths and Mortality. https://www.cdc.gov/nchs/fastats/deaths.htm [Accessed:2022-05-10].

CDC (2022b). Fiscal Year 2022 CDC President's Budget Detail Table. https://www.cdc.gov/budget /documents/fy2022/FY-2022-CDC-Budget-Detail.pdf [Accessed: 2022-05-10].

Collins, F. S., T. A. Schwetz, L. A. Tabak, and E. S. Lander (2021). Arpa-h: Accelerating biomedical breakthroughs. *Science 373*(6551), 165–167.

David, P. A., B. H. Hall, and A. A. Toole (2000). Is public r&d a complement or substitute for private r&d? a review of the econometric evidence. *Research policy 29*(4-5), 497–529.

FDA (2022). 2022 FDA Operating Plan. https://www.fda.gov/media/157738/download [Accessed: 2022-05-10].

Furlow, B. (2016). US FDA's safety monitoring of drugs with expedited approval. *The Lancet Oncology 17*(3), 281.

Gibney, M. and K. E. Figuracion (2021). Cancer drugs show big sales rise in 2020; AbbVie's Humira again tops list. https://www.spglobal.com/marketintelligence/en/news-insights/latest-news-headlines/cancer-drugs-show-big-sales-rise-in-2020-abbvie-s-humira-again-tops-l ist-63249898 [Accessed: 2022-04-30].

Long, G. (2017). The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development. Technical report, Analysis Group, Inc.

Long, G. and J. Works (2013). Innovation in the Biopharmaceutical Pipeline: A Multidimensional View. Technical report, Analysis Group, Inc.

NCI (2021). NCI Budget and Appropriations. https://www.cancer.gov/about-nci/budget/ [Accessed: 2022-04-25].

NCI (2022). NCI Budget and Appropriations. https://www.cancer.gov/about-nci/budget/ [Accessed: 2022-05-10].

Ngo, P. T. and J. Stanfield (2016). Does government spending crowd out r&d investment? evidence from government-dependent firms and their peers. *Journal of Financial and Quantitative Analysis*, 1–35.

NIH (2021). Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC). https://report.nih.gov/funding/categorical-spending#/ [Accessed: 2022-04-25].

Office of Science And Technology Policy (2021). Advanced Research Projects Agency for Health (ARPA-H). https://www.whitehouse.gov/ostp/advanced-research-projects-agency-for-health-arpa-h/ [Accessed: 2022-04-17].

Philipson, T. J. and T. Durie (2021). Issue brief: The impact of hr 5376 on biopharmaceutical innovation and patient health.

PhRMA (2021). 2021 PhRMA Annual Membership Survey. Technical report, PhRMA.

Prasad, V. and S. Mailankody (2017). Research and development spending to bring a single cancer drug to market and revenues after approval. *JAMA internal medicine 177*(11), 1569–1575.

Salas-Vega, S., O. Iliopoulos, and E. Mossialos (2017). Assessment of overall survival, quality of life, and safety benefits associated with new cancer medicines. *JAMA oncology 3*(3), 382–390.

The Council of Economic Advisers (2018). Reforming Biopharmaceutical Pricing at Home and Abroad. https://trumpwhitehouse.archives.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper -Final2.pdf/ [Accessed: 2022-04-30].

Tufts Centre for the Study of Drug Development (2019). Cancer Drug Approvals Grew from 4% of U.S. Total in the 1980s to 27% in 2010-18. *Tufts CSDD Impact Reports, 21(5).*

Wallsten, S. J. (2000). The effects of government-industry r&d programs on private r&d: the case of the small business innovation research program. *The RAND Journal of Economics*, 82–100.

White House (2021). Budget of the U.S. Government, Budget of the United States Government, FiscalYear 2022. https://www.whitehouse.gov/wp-content/uploads/2021/05/budget _fy22.pdf [Accessed: 2022-05-10].

White House (2022a). Fact Sheet: President Biden Reignites Cancer Moonshot to End Cancer as We Know It. https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/02/fact-sheet-president-biden-reignites-cancer-moonshot-to-end-cancer-as-we-know-it/ [Accessed: 2022-04-17].

White House (2022b). Fact Sheet: White House Announces Initial Steps for Reignited Cancer Moonshot. https://www.whitehouse.gov/ostp/news-updates/2022/03/17/fact-sheet-white-house-announces-initial-steps-for-reignited-cancer-moonshot/ [Accessed: 2022-04-17].

White House (2022c). Remarks by President Biden at an Event to Reignite the Cancer Moonshot. https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/02/02/remarks-by-president-biden-at-an-event-to-reignite-the-cancer-moonshot/ [Accessed: 2022-04-17].

White House (2022d). The Biden-Harris Administration FY 2023 Budget Makes Historic Investments in Science and Technology. https://www.whitehouse.gov/ostp/news-updates/2022/04/05/the-biden-harris-administration-fy-2023-budget-makes-historic-investments-in-science-and-technology/ [Accessed: 2022-04-17].

Wouters, O. J., M. McKee, and J. Luyten (2020). Estimated research and development investment needed to bring a new medicine to market, 2009-2018. *Jama 323*(9), 844–853.

Table 1: Oncology in Phase I-III Projects

Year	Phase I-Oncology	Phase I-Total	Phase II-Oncology	Phase II-Total	Phase III-Oncology	Phase III-Total	All Phases-Oncology	All Phases-Total
2021	2686	4927	2931	5940	520	1607	6137	12474
2016	1757	3723	1920	4424	329	1257	4006	9404
2011	1265	3025	1507	3764	288	1099	3060	7888

Table 2: Oncology in Potential First-in-Class Phase I-III Projects

Year	Phase I-Oncology	Phase I-Total	Phase II-Oncology	Phase II-Total	Phase III-Oncology	Phase III-Total	All Phases-Oncology	All Phases-Total
2021	2173	3900	1812	3972	204	772	4189	8644
2016	1536	3073	1459	3205	193	671	3188	6949
2011	1057	2356	1043	2602	149	498	2249	5456

Table 3: Oncology in Orphan Drug Phase I-III Projects

Year	Phase I-Oncology	Phase I-Total	Phase II-Oncology	Phase II-Total	Phase III-Oncology	Phase III-Total	All Phases-Oncology	All Phases-Total
2021	109	222	266	548	129	315	504	1085
2016	81	164	217	422	95	209	393	795

Table 4: Oncology Project Distribution 2000-2022 (Informa Data)

Phase	Projects-Total	Projects-Oncology
I	15241	8706
II	36869	17527
III	23645	5799
Total	75746	32032