ETHICAL CONCERNS OF BIOMEDICAL RESEARCH FUNDING

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By

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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The United States spends billions of dollars each year on health care. For example, every year, more than 795,000 Americans have a stroke, and in 2014-2015, stroke-related costs in the US were more than 46 billion dollars (CDC, 2020, p. 1). In 2017, stroke was the fifth leading cause of death in the United States (Murphy et al, 2018, p. 3). There are three main types of strokes: an ischemic stroke, a hemorrhagic stroke, and a transient ischemic attack, and an ischemic stroke, which comprises 87 percent of stroke incidences, occurs when there is a blockage in a blood vessel that is supplying the brain, resulting in cell death as oxygen and nutrients cannot reach brain cells (NIH, 2019, p. 1). The National Institutes of Health (NIH) funds a great portion of biomedical research, including strokes. The technical project focuses on a possible target for stroke therapy. While this investigation is underway, the ethical concerns of research funding have become an issue for labs across the country, and must be considered.

For decades the US has led the world in groundbreaking research and biomedical innovations, but in recent years, has lost its edge in discoveries to other countries. Following an analysis compiled by the Journal of American Medical Association, it was concluded that if trends continue, Europe and Asia could surpass the US in leadership (Michaud, 2015, p. 1). This decline threatens its ability to produce new therapies, as well could risk a business that provides over 300,000 jobs (Bluestone et al, 2018, p. 1). The inefficiencies of the federal funding may be the cause and, if so, the "biomedical science system needs major reform" (Malakoff, 2014, p. 1). This paper answers the question on how we can address the inefficiencies of how the NIH allocates research funds, and analyzes the proposed solutions using social and ethical frameworks. The Social Construction of Technology Theory (Bijker and Pinch, 1984, p. 1) is used in order to analyze the relevant social groups that influence the funding process. The paper further highlights how the 2020 global pandemic will affect how the NIH funds clinical research.

INEFFICIENCIES OF THE NATIONAL INSTITUTES OF HEALTH

While most research breakthroughs arise in academic-based or translational research funded by the government, only twenty two percent of biomedical research funding comes from the federal government. The US federal funding trend has been on the decline with a 19.2 percent decrease from 2003 in 2017 (Bluestone et al., 2018, p. 1). This decline has had two devastating effects, in which academic funding grants are not being accepted, and a decline in young people's faith in the NIH funding, decreasing the amount of young people entering the field. Additionally, one tenth of the NIH funds goes to their NIH employees. In recent years, the chance of breakthroughs originating from this intramural program has declined, due to unpredictable funding and a lack of attention to young, bold researchers, as shown by an independent study carried out by the NIH in 2014 (Bluestone et al., 2018, p. 1).

This continued issue of NIH funding more traditional researchers has become a concern within the biomedical field. For example, it has long been accepted in research communities that Amyloid-beta is somehow responsible for Alzheimer's disease, while this has never been proven. Recently, it has become evident the suppression of other hypotheses, and lack of variable funding, has held Alzheimer's research back for years (Begley, 2019, p. 1). This ethical concern must be amended in order to accelerate the US's ability to discover biomedical breakthroughs.

According to Sheth, research for cancer, stroke, and heart disease have all been paused or delayed by the lockdown caused in America due to the COVID-19 pandemic. Over 200,000 clinical trials across the United States were affected. Although the lockdown is necessary, the neglected disorders could likely cause a higher percentage of deaths, and clinical trials must resume (Sheth, 2020, p. 1). The NIH must be altered to more ethically allocate funds in order to

improve the US standing, but these alterations must consider the situation of the global pandemic.

ANALYSIS OF RELEVANT SOCIAL GROUPS

In order to successfully address the mentioned shortcomings of the NIH, it is important to consider the relevant stakeholders. The Social Construction of Technology (SCOT) (Bijker and Pinch, 1984, p. 1) refers to the theory that explains how a variety of social factors shape a technological development, or a technological change (Johnson, 2010, p. 1). According to SCOT, the technology refers to the NIH allocation system, or process, to research labs. The social groups that influence this system, and are in turn effected by the system, as seen in Figure 1, include: NIH or government officials who decide the budget, NIH employees who review and allocate funds to research labs, researchers or

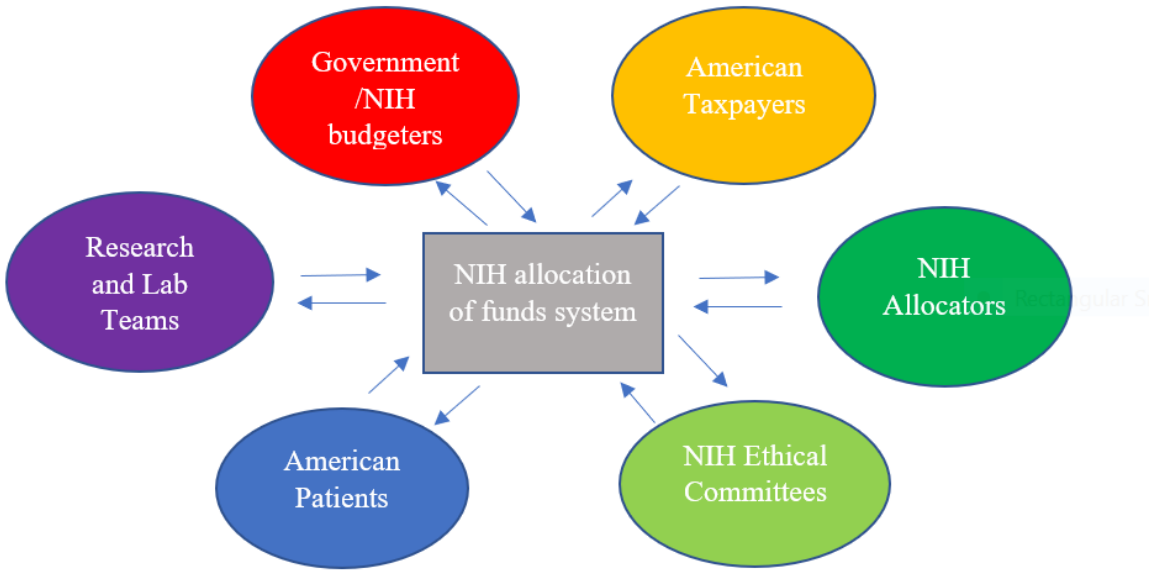

Figure 1: The Relevant Social Groups that Influence the NIH Fund Allocation System. This figure depicts how the six social groups, NIH or government officials who decide the budget, NIH employees who review and allocate funds to research labs, researchers or the lab teams themselves, ethical committees within the NIH that monitor how funds are used, American taxpayers, and the individuals throughout the world who benefit from the medical breakthroughs that result from the funding, influence the NIH system, and are directly affected by the system outcomes. The differing colors representing the distinct interests (Ford, 2020).

the lab teams themselves, ethical committees within the NIH, American taxpayers, and the individuals throughout the world who benefit from the medical breakthroughs. The government must propose a budget for the NIH, with the interests of the taxpayers and America's standing in biomedical research in mind. The NIH employs experts to review grant applications and appropriately allocate the budget. Their interests could be bias, as they may desire to allocate more funds to research that backs their own findings, such as in the previously stated Alzheimer's example. Research labs rely heavily on consistent funds in order to pay for their experimental expenses. Institute Ethical Committees monitor the research that resulted from the funds, in order to make sure it was used ethically (Mandal et al, 2012, p. 3). American taxpayers contribute the money to the NIH budget, and are interested in making sure their money is used properly. Finally, individuals who suffer from diseases all greatly benefit from biomedical breakthroughs. All of these social groups influence how the system operates, and are directly affected by the system outcomes. Not only do they interact with the NIH allocation process, they also interact and influence each other as seen in the revised handoff model depicted in Figure 2.

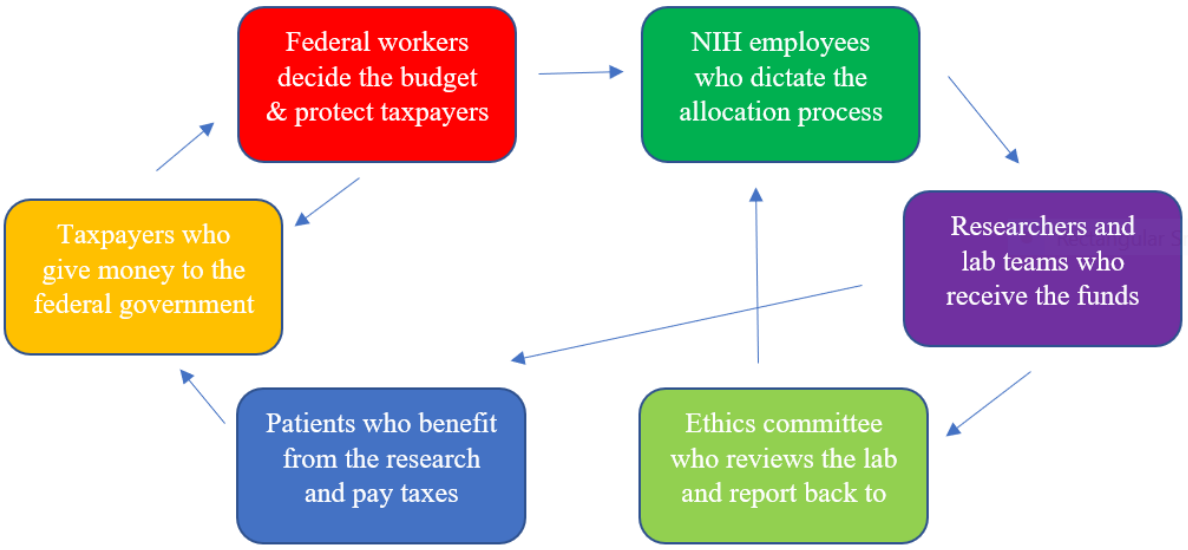

Figure 2: Revised Handoff Model. This revised handoff model shows how the relevant social groups not only influence the technology, but interact with other social groups (Ford, 2020).

PROPOSED SOLUTIONS FOR THE NIH FOLLWOWING SCOT ANALYSIS

According to Mandal et al., “the responsibility for ensuring that the funds and resources are utilized optimally without any misconduct rests on the shoulders of the researchers, as well as the respective institute ethics committees along with the funding organizations” (Mandal et al., 2012, p. 2). The first step is to ensure that ethical codes are abided by. In order to do this, the NIH needs to provide more power to these ethical committees. Their job is to be unbiased, so they should check and balance the power within the NIH.

The second recommendation considers the underrepresented portion of research labs promoting novel ideas and bold experiments. This section within the larger social group allows variability within the allocations, resulting in a greater chance of success. The intramural program structure should be reformed and NIH employees who review grants should be forced to consider smaller, new research groups. A quota should be met to delineate from the dominate theories. This ensures the taxpayers’ money is being used to improve American lives, not just to back certain scientists’ theories. It ensures the government is using the budget wisely and patients may now have a better chance of receiving successful therapy.

A third recommendation is a cultural change in perspective of biomedical research significance. The people of America greatly benefit from breakthroughs, and it also improves the country's status globally. Therefore, government leaders need to advocate for increased budgets for medical research. A better NIH budget provides jobs for hundreds of thousands of Americans, as well provides a business for pharmaceuticals, medical device companies, hospitals, and more (Bluestone et al., 2018, p. 1). It is an important aspect of our economy, and should be given more attention by taxpayers. Additionally, the government must continue to

advocate for trust in our biomedical research. Currently, the White House administration is struggling to promote trust in the COVID-19 vaccine among certain social groups, especially African American communities. Mistrust in the government stems from "government abuse of Black bodies in the name of science", such as the use of Henrietta Lacks' cells in science without her consent and "doctors allowed syphilis to run unchecked through Black test subjects in the Tuskegee experiments" for 40 years while penicillin was the known cure (Sellers et al., 2021, p. 1). President Joe Biden and his administration are making incredible strides in debunking myths related to vaccines, but more work must be put in to promote a healthy trust of research. If the people of the country trust and understand the work being done in the biomedical research field, this may in turn lead to a confidence throughout taxpayers. Government officials would increase budgets with less opposition and debate. For this reason, the federal government should continue to campaign in support of biomedical researchers.

Finally, the global pandemic has greatly shifted the focus of this issue. A great portion of the NIH budget now targets treating the COVID-19 virus. Although the NIH will benefit greatly from spending funds on research that will help to cure this virus, they must consider the impact of neglecting other diseases. The NIH should continue to restructure how clinical trials will be carried out in a social distant, and safe manner. NIH employees should think creatively on how to continue important research, such as the use of wearable trackers in remote clinical trials.

EVALUATION OF PROPOSED SOLUTIONS USING ETHICAL FRAMEWORKS

To further analyze these proposed solutions for improving the NIH, they can be considered using ethical frameworks. Ethical theory "seeks to provide a comprehensive perspective on morality that clarifies, organizes, and guides moral reflection" (Martin et al.,

2000, p. 48). These frameworks can help to make decisions that are morally right. The first to consider is rights ethics. According to Martin, rights ethics is distinctive from other ethical frameworks in that it upholds human rights, or a human's moral claims and entitlements above anything else (Martin et al., 2000, p. 48). Duty ethics is similar but it emphasizes an individual's duty to respect the liberty and autonomy of others (Martin et al., 2000, p. 52). Lastly, utilitarianism ethics emphasizes that the "sole standard of right action is good consequence", and that all individuals effected must be considered equally (Martin et al., 2000, p. 55). Using these frameworks can help to distinguish the morality of the proposed solutions.

The first solution proposed was to give more power to the ethical committees who are responsible for monitoring how the funds are used. Using duty ethics as an ethical framework, this solution is favorable. It follows that this team's duty is to ensure the funds are being used ethically and optimally. When considering this duty, there is no room for bias and partiality. These boards are made up of people whose one duty is to make sure all lab groups are acting in accordance with the guidelines set forth by the NIH.

The second recommendation considers the underrepresented portion of research labs promoting novel ideas and bold experiments. In the scope of rights ethics, supporters would agree with this solution. The rights of every researcher is given a chance to be heard and considered for funding. On the other hand, when utilitarianism ethics is considered, there may be some disagreement. To require the NIH a quota to fund smaller, novel groups may not necessarily always produce biomedical breakthroughs. In a perfect system, the groups with the most promise for a breakthrough would receive the funding everytime. This may be impossible to produce. Giving funding to the underrepresented groups can be favorable when considering rights ethics, but it may not necessarily produce the most good for the most people.

The third proposed solution is a cultural change in perspective of biomedical research significance. Both rights ethics and duty ethics would support this recommendation. Duty ethics emphasizes that the government has a duty to the public to provide all the information and transparency on what is happening in our country. Channels of communication must be available to all people of society. This duty will respect the rights' of people to make informed decisions about their life and their health. When considering rights ethics, this cultural change would also be supported. Every citizen in the United States has a liberty to make decisions and be active participants in our democracy. Campaigns to drive people to support biomedical research in this country allows participation of all people. Open debates and discussions must continue to happen in order to gain the trust of the public.

Finally, a consideration must be made on how the global pandemic will effect the NIH and clinical research in the future. The NIH should continue to restructure how clinical trials will be carried out in a socially distant, and safe manner. Utilitarianism ethics supporters would agree with this. The NIH needs to find way to make sure that, in the future, research can be carried out in socially distant manner in order to keep the most people safe, but ensure important research is still being carried out on time.

ALTERNATIVE SOLUTIONS FOR IMPROVING BIOMEDICAL RESEARCH OUTSIDE OF THE NIH FUNDING

This paper focuses on the issues plaguing the NIH in order to understand the shortcomings of American biomedical research. It is important to consider problems that are outside of the NIH's control. As stated previously, only twenty two percent of biomedical research funding comes from the federal government (Bluestone et al., 2018, p. 1). For this reason, "any realistic policy that addresses research priorities must come to terms with the fact

that private industry outspends the public sector" (Resnik, 2003, p. 1). Unsurprisingly, companies in the private sector invest their money with the motivation of economic gain. Due to this motivation, privately-funded companies tend to shy away from funding basic research, research on rare diseases, research on diseases with low consumer demand, and on drugs that will take a relatively long time to enter the market. In 2003, "90 percent of the money spent on biomedical [research and development] focuses on conditions responsible for only 10 percent of the world's burden of disease" (Resnik, 2003, p .1). This statistic emphasizes a major problem, in that biomedical research fails to promote interests of all people in society.

The obvious partiality in private-funded research is another area that should be improved to help increase the United States' status in biomedical research discoveries. Privately-funded companies are moral agents in the country's society, and should consider their social responsibility to all people. A possible solution to the issue should be to require major private companies to consider sponsoring rarer diseases, such as Huntington Disease. This may infringe on the freedom of private companies, but guidelines should be introduced to push for fairer representation in the research field. Additionally, the NIH should work more closely with the private sector in order to diversify research and consider all social groups. The inclusion of new voices and experiences can help to drive American biomedical research in the right direction, and prevent unneccessary waste of funds going to bigger, influential lab groups. This issue must be considered for both public and private companies, and the two groups should work together in solving this issue.

AMERICAN BIOMEDICAL RESEARCH MOVING FORWARD

This paper only broadly addresses and suggests solutions for the issues plaguing the NIH. The purpose is to draw attention to these concerns in order to improve our biomedical field and

return the US to its former prominence. Enhancements to the allocation system involving the ethical committees, underrepresented groups, and a cultural change are just a few ways the United States can advance the biomedical field. These improvements will also help American public health and the country's economy. Outside of the NIH, alternative solutions should be considered in the private sector of research. These two sectors should work together closely to make progress in biomedical research. Ethical and economic problems must be addressed in order to improve the NIH's system of allocating research funds in biomedical research labs across the country.

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