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Joanna K. Sax
California Western School of Law, jsax@cwsl.edu

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The Separation of Politics and Science

Joanna K. Sax, J.D. Ph.D.[1]

Abstract

This article proposes that scientific inquiry regarding questions of fact should have an autonomous zone that is protected from politics. Although many scholars promote the idea that science is politicized, little empirical data exists to support this conclusion. This article contains an empirical study that demonstrates that the public received inaccurate information in the debate over a highly politicized and controversial area of scientific inquiry, embryonic stem cell research.

This article utilizes the data from the empirical study and public choice theory to explain that there are process defects; this economic model can help explain, but cannot be used to resolve, the process defects. Instead, this article articulates reasons why scientific inquiry should have an autonomous zone and that political actors should play a limited role in oversight. This article proposes solutions to balance the roles of elected officials with the expertise of scientists.

[1] Associate Dean for Research and Faculty Development, Associate Professor of Law, and Co-Director Institute of Health Law Studies, California Western School of Law. Ph.D., Cell and Molecular Biology, University of Pennsylvania; JD., University of Pennsylvania.

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I. INTRODUCTION

Law and science have a complicated and highly dependent relationship. Innovation in science moves much faster than the law and for this reason, laws that regulate scientific achievements lag behind. An example of this is the development of *in vitro* fertilization techniques; this area of scientific inquiry advanced and the laws that regulate it were created after its existence.[2] The interaction of law and science also works in the opposite temporal direction; that is, legal policies create opportunities and incentives for scientific inquiry. An example of this is the allocation of resources to the National Institutes of Health (NIH) for basic science research. The interactions between law and science are temporal, dynamic, and evolving. The interplay between law and science can work well, but it can also have severe problems. An historical example of a problematic relationship between politics and science dates back to Galileo and the Roman Inquisition. While the law exists to incentivize and regulate science, problems can arise if the lawmakers and the scientists do not have boundaries respecting their individual spheres.

This article uses a contemporary example of a problematic political-scientific relationship – embryonic stem cell research – to suggest that politically charged actions can interfere with what should be an objective discussion regarding scientific inquiry. This article argues that due

[2] *See, e.g.*, LAWRENCE O. GOSTIN JUDITH AREEN, PATRICIA A. KING, STEVEN GOLDBERG, AND PETER D. JACOBSON, LAW, SCIENCE AND MEDICINE 1115-34 (3d ed. 2005).

to the nature of scientific inquiry, scientists should have a nonpolitical and autonomous zone for factual inquiry with political oversight in an important, but limited, fashion.

Perhaps one of the more controversial areas of basic biomedical science inquiry is the debate over federal funding for human embryonic stem cell research. Opponents object to embryonic stem cell research because the starting material is fertilized embryos and opponents argue that these embryos have the potential for human life and should not be destroyed for experimentation. Proponents argue that studies from embryonic stem cell research have potential to assuage human suffering from disease and save lives.[3] A political war waged over embryonic stem cell research and arguably hit a tipping point in 2001 when President Bush issued an Executive Order that banned federal funding for embryonic stem cell research for most practical purposes.[4] Although others argue that certain types of scientific inquiry are political, few empirical studies have been conducted to examine the interaction of politics and science.[5] This article contributes to the ongoing dialogue regarding the interaction of politics and science by including results of an empirical study to support the theory that politics influences scientific inquiry. Utilizing the data from the study, this article examines the interaction of politics and science and argues that a process defect exists when politicized information is used to set scientific inquiry objectives and then explores alternative mechanisms to maintain appropriate safeguards and separation.

This article is separated into multiple parts to provide the necessary background and framework for the analysis and relevance of the empirical study. Parts I and II provide introductory and background information on the relationship of law and biomedical science. Part III describes an empirical study demonstrating that the public received some factually unsupported information regarding the potential for embryonic stem cell research by comparing the statements made in the mainstream press with information from the scientific publications. This part utilizes the data to promote a central thesis to this article: there are process defects when political actors attempt to direct scientific inquiry.

Part IV describes the economic benefits of basis biomedical research and the process defects that may help explain when the political-scientific relationship becomes dysfunctional. In this part, the article utilizes public choice theory to explain the process defect. Contemporary law and economic theory helps explain the process defect, but principles from it cannot be used to resolve the defects.

In Part V, this article provides solutions to remove political actors from the minutia of deciding which scientific questions can and cannot be asked and instead creates ways that the political actors can maintain control at a higher level when there is egregious behavior or misuse of funding dollars. This article promotes several approaches. First, this article discusses the appropriate use of advisory committees within the NIH to guide scientific inquiry and questions the use of advisory committees with political agendas. Second, the article recognizes the need for greater communication and dissemination of factually supported information to the public

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[3] *See generally* Joanna K. Sax, *The States "Race" with the Federal Government for Stem Cell Research*, 15 ANNALS HEALTH L. 1, 5-13 (2006).

[4] *Id.* at 14-19.

[5] *See, e.g.*, CHRIS MOONEY, THE REPUBLICAN WAR ON SCIENCE (Basic Books 2005); Sidney A. Shapiro, *"Political" Science: Regulatory Science After the Bush Administration*, 4 DUKE J. CONST. L. & PUB. POL'Y 31 (2009); Union of Concerned Scientists, *Scientific Integrity in Policymaking: An Investigation into the Bush Administration's Misuse of Science*, (Mar. 2004), http://www.ucsusa.org/scientific_integrity/abuses_of_science/scientific-integrity-in.html; Union of Concerned Scientists, *2004 Scientist Statement on Restoring Scientific Integrity to Federal Policy Making*, (Feb. 2005), http://www.ucsusa.org/scientific_integrity/abuses_of_science/scientists-sign-on-statement.html.

and suggests mechanisms to be implemented. Third, this article suggests that non-partisan evaluation of scientific progress and merit can be accomplished through the creation of the Institute of Science,[6] similar to the nonpartisan analyses conducted by the Congressional Budget Office.[7] Fourth, this article notes that the scientific community has safeguards that can be promoted and improved. Finally, the article contends that a distinction should be respected between scientific and policy questions – the former governed primarily by the scientific process while the latter is governed by the democratic process.

This article addresses the important issues of ways to improve scientific advancement, innovation, and integrity so that society may experience the benefits of advances in the medical sciences. This article proposes a way to balance the integrity and objectivity of scientific inquiry with a proper limited government role in protecting the health and welfare of society at large.

II. BACKGROUND

Law has a unique interaction with the advancement of science. The federal government supports the lion's share of basic biomedical research. Our policymakers – the law side – allocate resources for scientific research. In this way, lawmakers have a direct impact on the decisions to support or not support scientific questions and innovation.

Our society depends on advances in science in many different ways. This article focuses on biomedical science, or the science related to the study of disease, and will mainly address this area. Our ability to treat and fight human ailments benefits society. In modern times, we generally live longer and healthier lives and this is due in large part to advances in biomedical research and medicine. Biomedical research is a significant building block of medical advances. For example, biomedical research is used to ask questions such as: what is the difference between a cancer cell and a normal cell, and how does HIV infect a cell? The answers to these questions are then used to create treatments and vaccines for cancer, HIV, and AIDS.

The federal government funds a large portion of biomedical research in this country.[8] The reason that biomedical research is funded by the government, as opposed to funded by the private sector, is because it is a public good and there is a lot of risk in making discoveries in basic biomedical research and the private sector is unwilling to invest in that risk.[9] Once discoveries are made, a market within the private sector is created and many biotech firms and pharmaceutical companies invest at that time. The United States government's dedication to funding biomedical research has economic advantages, including growing the economy through creation of jobs, advances in public health, and indirect positive economic consequences of scientific knowledge and advancement.

Each year, Congress allocates money to various departments to fund biomedical research. The NIH, which is part of the Department of Health and Human Services (HHS), receives the

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[6] This proposal has similarities to the Office of Technology and Assessment, which was defunded and essentially disbanded when Rep. Gingrich was Speaker of the House. *See* Union of Concerned Scientists, *Restoring the Office of Technology and Assessment*, (Feb. 24, 2010), http://www.ucsusa.org/scientific_integrity/solutions/big_picture_solutions/restoring-the-ota.html.

[7] Congressional Budget Office, http://www.cbo.gov/ (last visited July 11, 2013).

[8] Richard R. Nelson, *Reflections on "The Simple Economics of Basic Science Research": Looking Back and Looking Forward*, 15 INDUS. AND CORP. CHANGE 903, 912 (2006).

[9] *Cf. id*. at 905 ("I do highlight why it is generally better to do basic research in universities and public laboratories than in business laboratories[.]").

bulk of research dollars. In 2012, the NIH's budget was $30.9 billion.[10] The NIH then allocates this money to researchers throughout the country via a competitive grant process, which is described below.[11]

In general, the money given to the NIH is non-allocated, which means that the NIH decides how the money is spent.[12] Congress and the President, however, may include directives as to how they would like the money spent or even limit or eliminate certain research questions.[13] One example of this is a directive that encourages increased studies of breast cancer.[14] This creates incentives to study breast cancer, but can have the unintended consequence that other areas of inquiry will have reduced funding due to the allocation of funding via directives. Another example discussed in this article is the 2001 ban on the use of federal money to create new human embryonic stem cell lines. This directive eliminated any funding for a particular area of scientific inquiry. Studies have shown that these directives have a large impact on how the NIH allocates its budget.[15] These directives, which may be politically motivated, can interfere with the scientific process of determining which questions deserve funding. The scientific process uses peer review, building blocks, and consensus to determine the direction of scientific inquiry. As Presidents change or one political party garners control of Congress, the political directives change, which means that some scientific inquiry is subject to election cycles, instead of pure scientific process.

This article argues that there are process defects in the relationship between the elected government officials and the scientific community when the political process attempts to direct scientific research questions; questions of science should be protected from the political process and election cycle. This is because, in sum, the expertise of scientists should be respected to allow the scientific community to make decisions about scientific goals.

This analysis – regarding the separation of politics from scientific inquiry – does not mean to suggest that the scientific process for scientific inquiry, such as peer review, is a perfect system that is completely immune from politics within the scientific community. Problems within the scientific community in determining which scientific questions merit inquiry is beyond the scope of this paper. Instead, this analysis and proposal is limited to considering the role of elected officials in determining the types of questions the scientific community can ask.

The approach called for in this article is *idealistically* similar to the underlying reasons why Article III judges are protected from political influence through their tenure. It is true that some may argue that Article III judges are not shielded from the political process, but there is consensus that elected politicians should not be influencing judicial decisions by Article III judges.

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[10] NIH Budget, http://www.nih.gov/about/budget.htm (last visited Apr. 18, 2014),

[11] *See id.*; NIH Grants and Funding, http://grants1.nih.gov/grants/oer.htm (last visited Apr. 18, 2014).

[12] NIH Budget, http://www.nih.gov/about/budget.htm; H.R. 2055, The Consolidated Appropriations Act, 2012 Public Law 112-74 (Dec. 23, 2011), http://officeofbudget.od.nih.gov/pdfs/FY13/Appropriations%20Language-2012.pdf.

[13] *See, e.g.*, H.R. 2055 – The Consolidated Appropriations Act, 2012 Public Law 112-74 (Dec. 23, 2011), http://officeofbudget.od.nih.gov/pdfs/FY13/Appropriations%20Language-2012.pdf.

[14] Tara Parker-Pope, *Cancer Funding: Does it Add Up?*, N.Y. TIMES, (Mar. 6, 2008), http://well.blogs.nytimes.com/2008/03/06/cancer-funding-does-it-add-up/.

[15] Jocelyn Kaiser, *NIH Finding Shifts with Disease Lobbying, Study Suggests*, 338 SCIENCE 161, 181 (2012) ("Congress rarely earmarks funds for specific diseases in NIH's budget, so the reason why the agency adjusted its spending priorities aren't clear. . . . Factors might include congressional report language urging NIH to pay more attention to a disease and researchers shifting their attention to a new area in response to lobbying.").

The comparison to the protections afforded to Article III judges provides the normative framework for the thesis to this article – that science should have an autonomous zone with limited oversight by political actors. Changes in political leaders should not impact the ability of scientists to determine important scientific questions. By way of example, if political actors had control over scientific questions, we might still think the earth is the center of the universe, the earth is flat, or the earth is only 6000 years old.[16] We need scientific inquiry to have a separate space that is protected from politics.

Biomedical scientists have a rigorous process to determine which questions will move scientific understanding forward. This is mainly accomplished through the peer review system.[17] At the grant level, peer review is used to fund grant applications,[18] and it is also used for publishing articles in scientific journals.[19] To obtain funding at academic medical centers, the members of the faculty apply to the NIH for funding through a competitive grant process.[20] The NIH uses a peer review system to allocate its limited resources to fund and support extramural scientists.[21] This process is in line with the peer review system for building theory and consensus in the scientific community.[22] That is, it is the scientists, and not the politicians, who decide which research deserves funding because it is likely to seek and explain the truth about scientific phenomena. There are limitations and drawbacks to the established peer review system which need to be addressed. Even with this acknowledgement, the issues in the peer review system should be analyzed separately and not be conflated with the call in this article for a separation of politics from scientific inquiry.

In today's arena, biomedical science is political. Others have acknowledged the politicization of science in multiple areas beyond biomedical science, although little empirical data has been collected to support this conclusion in the biomedical area.[23] To demonstrate the politicization of biomedical science policy, this article contributes to the ongoing discussion by using an empirical study to provide support for the suggestion that there are process defects when political actors involve themselves in how science should progress and that this is not beneficial for scientific advancement and integrity. The results of the empirical study and scholarship in this area are used to propose solutions to allow scientific inquiry to be protected

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[16] FLAT EARTH (Mar. 6, 2013), http://en.wikipedia.org/wiki/Flat_Earth ("In the modern era, belief in a flat Earth has been expressed by isolated individuals and groups, but no scientists of note.").

[17] *Peer Review Process*, NATIONAL INSTITUTES OF HEALTH, http://grants.nih.gov/grants/peer_review_process.htm#PeerReview (last visited Apr. 18, 2014) ("The NIH dual peer review system is mandated by statute in accordance with section 492 of the Public Health Service Act and federal regulations governing "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects" (42 CFR Part 52h). NIH policy is intended to promote a process whereby grant applications submitted to the NIH are evaluated on the basis of a process that is fair, equitab

[18] *Id.*

[19] *See*, *e.g.*, General Information for Authors, http://www.sciencemag.org/site/feature/contribinfo/prep/gen_info.xhtml (last visited May 7, 2014) ("Research papers that are selected for in-depth review are evaluated by at least two outside referees. Reviewers are contacted before being sent a paper and asked to return comments within 1 to 2 weeks for most papers.").

[20] *Grants Process Overview*, NATIONAL INSTITUTES OF HEALTH, http://grants.nih.gov/grants/grants_process.htm (last visited Feb. 8, 2013).

[21] *Peer Review Process*, NATIONAL INSTITUTES OF HEALTH, http://grants.nih.gov/grants/peer_review_process.htm#PeerReview (last visited Apr. 18, 2014).

[22] *Id.*

[23] *See generally* CHRIS MOONEY, THE REPUBLICAN WAR ON SCIENCE 75-76 (Basic Books 2005); Jocelyn Kaiser, *NIH Finding Shifts with Disease Lobbying, Study Suggests*, 338 SCIENCE 161, 181 (2012).

by placing control within the scientific community with only a limited role for political actors in this arena.

III. EMPIRICAL STUDY

The empirical study described below addresses the funding for embryonic stem cell research. Embryonic stem cell research was chosen for study because the debate over funding played out in large part in the public sphere. Thus, this area of research provides a platform to analyze how politics may have impacted scientific inquiry in this area.

In 2001, President George W. Bush issued an executive order that technically allowed funding for some human embryonic stem cell research, but for all practical purposes, amounted to a ban.[24] The controversy surrounding embryonic stem cell research centers on the material used to create the cell lines, which are discarded embryos from fertility clinics.[25] Proponents of embryonic stem cell research argue that the therapeutic potential for treatments for many diseases including Alzheimer's, Parkinson's, heart disease, diabetes, and others is so great that we should attempt this type of research.[26] Opponents to embryonic stem cell research have a moral objection to the use of a discarded embryo from a fertility clinic (which is the starting material) because it represents a potential human life that is destroyed when it is used to create the cell line.[27] This battle has been waged for many years.

During President Bush's first term in office, tensions were high as the President took control of the funding issue.[28] Scientists and the Secretary of the HHS supported a policy to fund embryonic stem cell research,[29] while the Catholic Church, on the other hand, vehemently opposed funding for embryonic stem cell research.[30] Politicians and the public were divided on the issue.[31] Ultimately, President Bush issued an executive order that sounded like a compromise, but had the practical effect of hampering scientific inquiry. In the executive order, President Bush allowed funding for embryonic stem cell research on cell lines established prior

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[24] Joanna K. Sax, *The States "Race" with the Federal Government for Stem Cell Research*, 15 ANNALS HEALTH L. 1, 15 (2006).
[25] *Id.* at 6, 9-10.
[26] *Id.* at 6-7.
[27] *Id.*
[28] *Id.* at 14-15.
[29] *See, e.g.*, David Baltimore, *Stem-Cell Research: A Debate—Don't Impede Medical Progress*, WALL ST. J., July 30, 2001, at A18; Peter Gorner and Ronald Kotalak, *U.S. Scientists Critical of Stem-Cell Limits*, CHI. TRIB., Sept. 12, 2001, at N21.
[30] *See, e.g.*, Mike Allen, *Pope Tells Bush Views on Embryos; Pontiff Opposes Use for Research*, WASH. POST, July 24, 2001, at A1; Richard Boudreaux & James Gerstenzang, *Pope Urges Bush to Reject Human Embryo Research*, L.A. TIMES, July 24, 2001, at A1; Bill Broadway, *Faith Is a Force on Both Sides of Stem Cell Debate; Religious Communities Split Sharply on Permitting Embryonic Research*, WASH. POST, Aug. 4, 2001, at B9 (discussing position of Catholic Church and other religious groups on stem cell research); Sarah Delany, *Vatican Reiterates Stance on Embryos; Statement Condemns Any Use in Research*, WASH. POST, July 26, 2001, at A18; Antonio Regalado, et al., *Stem-Cell Issue Entangles Science and Policy*, WALL ST. J., Aug. 10, 2001, at A10 (noting Catholic Church's opposition to stem cell research).
[31] *See, e.g.*, Ceci Connolly, *Legislators See Opening on Stem Cell Studies; In a Divided Congress, Lawmakers Are Writing Bills, Scheduling Hearings and Lobbying President*, WASH. POST, July 17, 2001, at A4; Alison Mitchell & Sheryl Gay Strolberg, *Daschle Is 'Uncomfortable' with Cloning*, N.Y. TIMES, Aug. 2, 2001, at A16 (discussing positions of senators on cloning); Eric Pianin, *House Speaker Reveals Opposition to Stem Cell Research*, WASH. POST, July 30, 2001, at A2; Becky Waddingham, *GOP Senator, a Doctor, Backs Stem Cell Research*, CHI. TRIB., July 19, 2001, at 1.11.

to August 9, 2001.[32] It seemed that he was supporting research on existing embryonic stem cell lines, but not allowing any new cell lines to be established. This appeared to be a good compromise to the public. However, the cell lines established prior to 2001 were of little practical use to scientists for a number of reasons – including mouse feeder-cell contamination – and the scientific community had communicated this to President Bush.[33] Thus the policy had the practical effect of hindering advancement of science in the embryonic stem cell research arena because (1) the cell lines were not conducive to research and (2) few scientists were going to pursue stem cell research as their primary research because future funding was uncertain.[34] As a result of the 2001 executive order, the understanding and advancement in this area has been delayed in the United States, in large part because scientists have spent considerable resources trying to find experimental ways to sidestep the application of embryonic stem cells to answer scientific questions.[35]

One way that scientific policy is politicized is the dissemination of information – or even misinformation – to the public in order to bolster support for a particular course of action. For example, in opposing embryonic stem cell research because discarded fertilized eggs from fertility clinics made up the starting material to create embryonic stem cell lines,[36] opponents offered a number of reasons for their opposition – many of which were religious or cultural – but also promoted what they considered to be scientific reasons. Without scientific support, opponents promoted as a reason to oppose embryonic stem cell research the idea that research with adult stem cells offered the same or similar therapeutic potential as research with embryonic stem cells.[37] In this way, opponents claimed, scientists could avoid the ethical question of embryonic stem cell research and simply focus on adult stem cells instead, which did not pose the same ethical concerns.[38]

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[32] National Institutes of Health, *Human Embryonic Stem Cell Policy Under Former President Bush (Aug. 9, 2001 - March 9, 2009)*, STEM CELL INFORMATION (Mar. 10, 2009), http://stemcells.nih.gov/policy/pages/2001policy.aspx.

[33] *See, e.g.*, Sax, *supra* note 3, at 16 (noting scientific uncertainty as to usefulness of cell lines existing prior to August of 2001); Baltimore, *supra* note 29 (noting the need for new stem cell lines); Pianin, *supra* note 31; Rick Weiss, *For President, No Easy Solution to Stem Cell Debate*, WASH. POST, July 13, 2001, at A1; *see also*, Gretchen Vogel, *Bush Grapples with Stem Cells, Cloning*, 292 SCIENCE 2409, 2409 (2001) *available at*, http://www.sciencemag.org/content/292/5526/2409.full (noting scientific opinions on embryonic stem cells compared to adult stem cells for research use); Gretchen Vogel, *Can Adult Stem Cells Suffice?* 292 SCIENCE 1820, 1820-22 (2001), *available at* http://www.sciencemag.org/content/292/5523/1820.full (discussing limitations in use of adult stem cells over embryonic stem cells).

[34] *See, e.g.*, *Stem-cell Flap Sends Researcher Abroad*, CHI. TRIB., July 17, 2001, at N13 (discussing decision of major researcher to move to an overseas university); Quynh-Giang Tran, *Research: A Hard Life at the Bench*, CHI. TRIB., July 29, 2001, at 2.1 (noting possible loss of scientists to overseas research facilities as consequence of Bush policy on stem cells); Rick Weiss, *Promising More—And Less; Scientists See Growth in Field, Lament Limits*, WASH. POST, Aug. 10, 2001, at A1 (discussing insufficiency of current stem cell lines).

[35] *See, e.g.*, National Institutes of Health, *What Are the Similarities and Differences Between Embryonic and Adult Stem Cells,* STEM CELL INFORMATION (Jan. 20, 2011) http://stemcells.nih.gov/info/basics/pages/basics5.aspx (noting recency of phase I trials for tissues derived from embryonic stem cells).

[36] Sax, *supra* note 3, at 6-7.

[37] *See, e.g.*, Ceci Connolly, *Bush 'Agonizing' over Funding of Embryo Research*, WASH. POST, July 15, 2001, at A1 (reporting ethicists advice to President Bush on use of adult stem cells); Kathleen Parker, *Don't Rush Stem Cell Debate*, CHI. TRIB., July 18, 2001, at N21 (discussing possibility of adult stem cells in research); Sheryl Gay Stolberg, *Key Bush Ally Suggests a Deal on Cell Studies*, N.Y. TIMES, July 19, 2001, at A1 (noting opponent proposals to use adult stem cells in place of embryonic stem cells).

[38] Stolberg, *supra* note 37 (discussing opposition's reasons for stance on embryonic stem cell research).

The problem with the opponents' position – that adult stem cells offered the same or similar therapeutic potential as embryonic stem cells – was that it had no scientific basis.[39] Scientists at the time said that there was no way to know whether human adult stem cells could be used in lieu of human embryonic stem cells unless and until experiments on both types of cells were conducted.[40] Essentially, the opponents promoted a conclusion that was not and could not be scientifically supported. To a member of Congress or to the general public, the opponents' position may have sounded reasonable. And as the data below demonstrates, this position most likely had an effect on embryonic stem cell policy under the Bush Administration, as well as the public's response to that policy.

During the time period leading up to and shortly after President Bush's decision regarding funding of embryonic stem cell research, the scientific community pressed for funding for both embryonic and adult stem cell research in order to understand the therapeutic potential in this area.[41] That is, the scientific community formed a consensus that funding was needed in both areas in order to determine whether embryonic or adult stem cells could offer therapeutic benefits.[42] Opponents of embryonic stem cell research did not base their arguments on scientific data; rather, their arguments appear to have been a political tactic since their conclusions could not be supported.

To further explore the controversy that surrounded embryonic stem cell research, I conducted an empirical study to address whether there were different discussions about scientific information and innovation in the public realm versus the scientific realm.[43] As described in more detail below, the study analyzed articles in mainstream newspapers and in major scientific journals. The results of this study demonstrate that mainstream newspapers reported that scientific controversy existed over whether adult stem cells offered the same or similar therapeutic potential as embryonic stem cells. Publications in scientific journals, however, unequivocally formed a consensus that funding was needed for both embryonic and adult stem cells in order to know which type of starting material offered the greatest therapeutic potential.

To demonstrate the divide between the scientific and non-scientific community over funding for embryonic stem cell research, the study analyzed a sample of publications in non-scientific literature and scientific literature over a four-month period from June 1, 2001 to

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[39] *See, e.g.*, *id.* (mentioning National Institutes of Health report advising more research into possibilities of both types of stem cells); Anuj Gupta, *The Personal Sides of the Stem Cell Debates*, L.A. TIMES, July 18, 2001, at A10 (discussing National Institutes of Health report finding on limitations of adult stem cells); Laurie McGinley, *Influential GOP Sen. Frist Supports Stem-Cell Research*, WALL ST. J., July 18, 2001, at A20 (detailing National Institutes of Health report on limitations of adult stem cells); McQueen, *NIH Backs Greater Study of Stem Cell Potential*, CHI. TRIB., July 18, 2001, at N14.

[40] *See, e.g.*, Ceci Connolly, *Embryo Cells Promise Cited in NIH Study; Call for More Research Toughens Bush Choice*, WASH. POST July 18, 2001, at A1; Jeremy Manier & Ronald Kotulak*, Science Explores Stem Cell Options; As Debate Grows, Embryos Remain Most Promising*, CHI. TRIB., July 16, 2001, at N1 (reporting scientific uncertainty as to better type of stem cells); McQueen, *supra* note 39 (discussing NIH report advising more research into both types of cells); Sheryl Gay Stolberg, *Stem Cell Debate in House Has Two Faces, Both Young*, N.Y. TIMES, July 18, 2001, at A1 (detailing reactions to NIH report advising more research on both types of stem cells); Rick Weiss & Amy Goldstein, *Frist Backs Stem Cell Funding*, WASH. POST, July 19, 2001, at A1. (mentioning NIH report calling for more studies on both types of cells).

[41] *See, e.g.*, Connolly, *supra* note 40; McQueen, *supra* note 38; Weiss & Goldstein, *supra* note 40 (citing NIH study calling for more research in both types of stem cells).

[42] *See, e.g.*, Connolly, *supra* note 40; McQueen, *supra* note 38 (discussing NIH report calling for further study of both types of stem cells).

[43] *Cf.* MOONEY, *supra* note 5, at 252 (discussing an empirical study on articles discussing climate change and addressing whether the articles presented the scientific consensus or non-scientific views).

September 30, 2001 – the time frame surrounding President Bush's announcement of his executive order regarding funding for human embryonic stem cell research.

The hypothesis was that articles in non-scientific literature would be more likely than articles in the scientific literature to convey that adult stem cells could provide the same or similar results as embryonic stem cells. For the non-scientific literature, I conducted a search via Lexis Nexis of the following newspapers: *The Wall Street Journal*, *The New York Times*, *The Washington Post*, *Los Angeles Times*, and *Chicago Tribune*.[44] The key term was "embryonic stem cell" with the focus term "adult." This resulted in 151 articles. For the scientific articles, I conducted a search in the journal *Science* and in the journals published by *Nature Publishing Group* using a search for all of the following words in an article: embryonic, stem, cell, and adult. This resulted in 124 articles.[45] In sum, 275 articles appeared in the search results; only 268 articles, however, were ultimately analyzed. This is because some articles that appeared in the search results were duplicates, corrections to other articles, or a series of letters in response to a particular article that were appropriate for collective coding.[46] In sum, the study analyzed 148 newspaper articles and 120 scientific publications.

As noted, the publications were coded. A zero (0) was assigned if the article did not discuss a scientific relationship between human embryonic and human adult stem cells. A one (1) was assigned if the article said that therapeutic potential from human adult stem cells was almost equal to or equal to therapeutic potential from human embryonic stem cells. A two (2) was assigned if the article stated that therapeutic potential from human adult stem cells was not known to be equal to therapeutic potential from human embryonic stem cells.

Using STATA 12 software, I applied a Pearson's Chi Squared Test and confirmed the hypothesis that non-scientific literature is statistically more likely than scientific literature to say that adult stem cells can give the same or similar results as research with embryonic stem cells (Pv=0.000). Results of the coding as well as the P-value are shown in Table 1.

Table 1: Comparison of Non-Scientific and Scientific Literature Statements

	No mention of relationship (0)	ASC equal to or most likely equal to ESC (1)	ASC maybe not equal to ESC (2)	Total
Newspaper	69	26	53	148
Scientific Literature	104	0	16	120
Total	173	26	69	268

Key = Adult Stem Cells (ACS); Embryonic Stem Cells (ESC)
P-value = 0.000

The results provide for a number of interesting observations. For one, the articles in the scientific literature unequivocally stated that therapeutic potential with human adult stem cells has not been shown to be equal to therapeutic potential with human embryonic stem cells

[44] The articles within the non-scientific literature include publications by journalists as well as other articles, such as editorials, for example.
[45] The articles within the scientific literature include both peer-reviewed research articles and non-research articles, such as reviews, for example. The reason to include all types of articles in both the non-scientific literature and scientific literature is because all of these writing were published at this time and may have informed the discussion.
[46] The corrections had no effect on coding.

(n=16).[47] This is because the scientific community had not tested whether the two were interchangeable or whether one type of human stem cell was better for a particular therapy.[48] Until this hypothesis was tested, the scientific community could not make such a conclusion because no data existed with human cells to support such a conclusion.

The articles in the newspapers, however, reported that therapeutic potential from human adult stem cells was equal to or most likely equal to therapeutic potential from human embryonic stem cells – even though there was no scientific basis at the time for that fact (n=26). It appears that the newspaper reporting addressed the issue as if it were something that was up for debate in the scientific community, when clearly it was not. Rather, the scientific publications were *actually* reporting that the scientific community did not have enough evidence to know whether human adult stem cells were or were not equal to human embryonic stem cells (n=16).[49] It is unclear from where the newspapers that reported non-scientific conclusions were receiving their information, but it was clearly not coming from the scientific community.

It is of great interest that opponents of embryonic stem cell research were able to get this scientifically unsupported information into the mainstream media. There may be a number of reasons for this. For example, newspaper reporters may not have understood enough science to competently report scientific conclusions from non-scientific theories. Or, reporters may have had a personal bias that was reflected in their reporting. Or, to influence mainstream media reporting, the opponents of embryonic stem cell research may have used tactics reminiscent of those that tobacco companies used in an attempt to persuade the public that there were no health risks attached to second hand smoke.[50] Alternatively, newspapers may have felt compelled to tell "all sides" of a story. Newspapers *should*, however, report which side in the debate has scientific merit and which does not. Regardless of the reason behind the difference in reporting in the mainstream newspapers versus scientific journals, this study establishes that the articles that the public was more likely to read – newspaper articles – were reporting information that had no scientific basis.

Using data from this study, I also analyzed the frequency with which each of the mainstream newspapers reported whether or not adult stem cells offered the same or similar therapeutic potential as embryonic stem cells. Table 2 provides the results of the frequency tabulation.

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[47] One study article cited work with murine neural stem cells offering similar potential as murine embryonic stem cells. Thomas Schell, Giusepps Testa, Stefania Castagnetti, Berthold Rutz, Michi Hannus & Freddy Frischknecht, *Neuroscience from Different Angles*, 2 EMBO REPORTS 471, 472-3 (2001). Since murine cells are different than human cells, this study was not coded as a 1.

[48] *See, e.g.*, Connolly, *supra* note 40; Manier & Kotulak, *supra* note 40 (discussing scientific uncertainty as to better of the two types of stem cells); McQueen, *supra* note 40 (reporting on NIH study calling for further research on both types of stem cells).

[49] *See, e.g.*, Sally Temple, *Stem Cell Plasticity—Building the Brain of Our Dreams*, 2 NATURE REVIEWS NEUROSCIENCE 513, 513 (2001) (discussing areas of further research needed on adult stem cells); Vogel, *supra* note 33 (noting scientific uncertainty as to comparative advantages of adult and embryonic stem cells).

[50] Lisa Bero, Public Health Chronicles, *Tobacco Industry Manipulation of Research*, 120 PUB. HEALTH REP. 200, 204 (2005) ("The tobacco industry has been active in stimulating controversy in the lay print media about the health effects of secondhand smoke."); Jenny White & Lisa A. Bero, *Corporate Manipulation of Research: Strategies Are Similar Across Five Industries*, 21 STAN. L. & POL'Y REV. 105, 119-23 (2010) (discussing tactics of tobacco and other industries in manipulating public information).

Table 2: Frequency of Newspaper Reporting

	No mention of relationship (0)	ASC equal to or most likely equal to ESC (1)	ASC maybe not equal to ESC (2)	Total
Washington Post	17	6	10	33
Wall Street Journal	12	6	7	25
New York Times	21	7	14	42
Los Angeles Times	7	2	11	20
Chicago Tribune	12	5	11	28
Total	69	26	53	148

The frequency of reporting provides some interesting information. *The Wall Street Journal*, for example, reported that adult stem cells were equal, or likely equal, to embryonic stem cells (n=6) at nearly the same rate as it reported they were not (n=7). *The Wall Street Journal* is often considered one of the more conservative mainstream newspapers and the unfounded conclusion that adult stem cells offer the same or similar benefits as embryonic stem cells is associated with a conservative viewpoint.[51] *The New York Times* – often considered a liberal newspaper[52] – was twice as likely to report that adult stem cells are not equal to embryonic stem cells (n=14) versus the conclusion that adult stem cells offer the same or similar therapeutic benefits as embryonic stem cells (n=7). It must be noted, however, that the ostensibly liberal newspaper still reported the scientifically unsupported conclusion. Of the mainstream newspapers analyzed, *Los Angeles Times* appears to have had the most accurate reporting, with two articles reporting that adult stem cells are equal to or most likely equal to embryonic stem cells and eleven articles reporting the scientific consensus at the time. Moreover, one of the two articles in *Los Angeles Times* reporting that adult stem cells might offer the same therapeutic potential as embryonic stem cells was an excerpt of President Bush's speech on the subject, so this article can reasonably be discounted.[53] Both *The Washington Post* and *Chicago Tribune* were approximately twice as likely to report the accurate consensus in the scientific community as not, but both also reported that adult stem cells might offer the same or similar therapeutic potential. Overall, all of the mainstream newspapers analyzed in this study reported a non-scientifically supported conclusion, albeit with different frequencies.

Overall, the mainstream newspapers were twice as likely to report accurate information (n=53) versus inaccurate information (n=26). Still, many articles in mainstream newspapers reported information that was not only unsupported by the scientific community, but actually the opposite of what the scientific community was publishing.

This study is not without limitations. First, this study analyzes a small number of articles in a limited time frame, which places limitations on making broad conclusions about the politicization of biomedical policy. It does, however, provide a glimpse into a highly politicized area. Second, most of the scientific articles that did not address the stem cell debate controversy were research articles, which were unlikely to address the debate as stated in the hypothesis for

[51] *See, e.g.*, Laurie McGinley, *Sen. Lott Opposes Federal Funds for Embryonic Stem-Cell Study*, WALL ST. J., July 17, 2001, at A20 (discussing conservative opposition to stem cell research); Neil Weinberg*, NYT vs. WSJ: Liberal Bias vs. Conservative Bias*, FORBES,(Oct. 23, 2010), http://www.forbes.com/sites/neilweinberg/2010/10/23/nyt-vs-wsj-liberal-bias-vs-conservative-bias/ (discussing perceived bias of the Wall Street Journal).

[52] *See, e.g.*, Weinberg, *supra* note 51 (discussing perceived bias of New York Times).

[53] This article and text of speech is included in the coding because it is something that the public could read in the newspaper, just like the other articles.

the following reasons: (1) research articles tend not to address politics; (2) research articles are submitted months before the actual publication date, which may have been during a time when the adult versus embryonic battle was not as heated; and (3) the research articles often use mouse embryonic stem cells to create transgenic mice, which is why they were brought up under the search terms. Third, some of the newspaper articles that are coded (1) or (2) are letters or editorials, which means they are not authored by journalists who are expected to present information in an unbiased manner. These articles were included in the coding because the public had access to them, similar to articles authored by journalists. There were a number of letters and editorials on both sides of the issue. Fourth, some articles reported both arguments – that is, that opponents contended that adult stem cells offered the same or similar potential as embryonic stem cells and proponents contended they did not. If both sides of the debate were presented, the article received a code of (2), which means that the number of articles that presented the argument that adult stem cells are the same or similar to embryonic stem cells is under-coded in this study. The reason for this was to have a consistent rule for coding. Fifth, for the scientific research articles, only the introduction and discussion sections were analyzed for coding since they were the most likely sections to have any mention of the debate. Sixth, a possibility exists that journalists or politicians confused research on murine embryonic stem cells and adult stem cells with human embryonic and adult stem cells. Finally, this study provides only a starting point and this paper calls for expanded studies in the future.

The results of this study do suggest, though, that the public did not receive accurate information. A comparison of the information provided in major newspapers versus major scientific journals is alarming. Articles in major newspapers reported information that did not have scientific support. Whether this is a failure of journalistic reporting or a successful attempt by opponents of embryonic stem cell research to promote false and misleading information is unclear. But the public is not helped – and is actually harmed – by the misleading, biased, and incorrect information. As a consequence, the scientific inquiry into the potential of embryonic stem cell research was also impacted.

The process of promoting a scientifically unsound theory in the popular press as a means of raising opposition to a particular policy or confusing the public has been used before, by, for example and as mentioned above, the tobacco industry.[54] Other contemporary examples include climate change[55] and gun control.[56] This strategy works well – at least for a time – until it is debunked. The scientific community thus has to not only work hard to debunk the scientifically unsound theory, but also must spend energy and resources correcting the misinformation that has previously been disseminated.[57] The scientific community must spend energy to obtain funding in areas where funding has been denied. This can lead to confusion and unfair skepticism about

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[54] Bero, *supra* note 50, at 204 (discussing tobacco industry manipulation of public data).

[55] Coral Davenport, *The Coming GOP War over Climate Change*, NATIONAL JOURNAL (May 9, 2013), http://www.nationaljournal.com/magazine/the-coming-gop-civil-war-over-climate-change-20130509 ("Throughout the Republican presidential primaries, every candidate but one—former Utah Gov. Jon Huntsman, who was knocked out of the race at the start—questioned, denied, or outright mocked the science of climate change.").

[56] Alex Seitz-Wald, *The NRA's War on Gun Science*, SALON (July 25, 2012), http://www.salon.com/2012/07/25/the_nras_war_on_gun_science/ ("Dr. Arthur Kellermann, a prominent researcher whose 1993 CDC-funded study became a flashpoint in the debate over government funding of gun research, told Salon that the effects of the campaign against gun research have real consequences. 'In a nation dedicated to personal freedom and responsibility, it is ironic that policymakers and the public have been denied access to timely and objective research on this issue for 15 years and counting,' he said in an email.").

[57] *See, e.g.*, Bero, *supra* note 50, at 200 ("It is often to the benefit of interest groups to generate controversy about data because controversy is likely to slow or prevent regulation of a given product".).

the scientific process. In addition, it wastes public resources to spend time and money correcting misinformation. The results of the study above call for empirical inquiries into other areas that are of public interest as well as areas that might not be so public but nonetheless have great impacts on scientific inquiry.[58]

All of this is not to say that the ethics of a particular scientific process cannot be debated and evaluated. But it is to say that it must be debated *honestly*. That is, any process that governs scientific inquiry, progress, and innovation has to be based in fact, not in made-up, unsupported, or fictitious theories.

There appears to be a disconnect among the scientific community, the policymakers, and the public when discerning accurate scientific information to be used to make policy decisions. The small study described above demonstrates that information that had unequivocal scientific consensus was not accurately communicated to the general public. It is likely that this disconnect stems from multiple avenues that collide to lead to process defects in the system of scientific support and innovation.

The epilogue to the scientific consensus about whether adult stem cells offer the same or similar therapeutic potential remains unclear. During the Bush Administration, researchers made a lot of advances with adult stem cells. When President Obama took office, he lifted the ban and allowed federal funding for the creation of new embryonic stem cell lines, although with certain limitations.[59] Recently, scientists have created embryonic stem cell lines using Somatic Cell Nuclear Transfer (SCNT), a technique not allowed under federal funding rules.[60] Scientists continue to debate which derivation of stem cell lines will prove most therapeutically useful.[61]

IV. SUPPORT FOR BASIC SCIENCE AND THE PROBLEM OF PROCESS DEFECTS

The subject of the study described in this article is a particularly controversial and public example of the interaction of politics and science. Additional studies in other areas of research are needed to round out and fully mold the discussion on the interaction of (or separation of) politics and science.[62] But, by using such a controversial area, this study sheds light on, and begins the discussion about, the need to fully elucidate the consequences of using factually unsupported information to sway public opinion and ultimately to influence funding decisions. This article calls for an honest discussion between all the actors to make sound scientific policy. The story of embryonic stem cell research is informative to shed light on the process defects that undermine support for scientific inquiry.

That scientific innovation is subject to political pressures appears to create a process defect. This article proposes that there should be an autonomous zone of scientific inquiry that is not impacted by political influences that want to eliminate, alter, or suppress factual discoveries.

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[58] The author thanks a colleague for this important point.

[59] Exec. Order No. 13505, 3 C.F.R. 229 (2009).

[60] The debate over SCNT also appears politicized and an empirical study addressing this should and could be conducted in the future.

[61] Trisha Gura, *Does Cloning Produce Better Embryonic Stem Cells?*, 340 SCIENCE, 1390, 1390 (June 21, 2013).

[62] An example is the allocation of resources to breast cancer research compared to other types of cancer research or other types of research in disease in general. Breast cancer has garnered so much political support and it would be interesting to quantitatively study the impact on other areas of research.

Despite flaws in the scientific peer review system, it is a better system than subjection to cycles of elections that significantly alter how scientific inquiry can progress.[63]

To understand the relationship of law and science and how to appropriately create spheres of dependence and independence, the sections below examine the economics of basic science research, how the democratic process creates a process defect for scientific inquiry, and how the government does and should support scientific inquiry.

A. *The Economics of Basic Scientific Research*

The discussion regarding public funding of scientific inquiry is important not just for the sake of scientific inquiry, but because discoveries in scientific research are a public good, and an overview of this funding is necessary. Public funding of basic research is justified to correct a market failure.[64] That is, a market does not exist at the basic science level to create an optimal amount of private investment and the government, recognizing the long-term benefits of basic science, corrects the market failure by supplying funding at the basic science level.[65] Due to government funding, new economically valuable information becomes available through public disclosure, and this information may then be used to fuel the pharmaceutical, biotechnology, and other health-related markets.[66] Many economists study the value of this government funding of basic science research.

Research in basic science has obvious value for obtaining information or results that directly answer a proposed question – such as determining whether gene X is involved in colon cancer. But basic science research has additional social value. Small increments in knowledge are used to lay the foundation to answer different or more complicated questions. Science is an evolutionary process whereby small advancements lead to discoveries.[67] This is why it may take years, decades, or even longer to understand the origins and progression of disease. Allowing faculty at universities to compete, through the grant process, to propose new ways to discover knowledge, is the means of natural selection needed to increase knowledge.[68] Members of the faculty at universities publish results and share reagents, knowledge, and expertise. These interactions allow others to build on scientific results to attempt to resolve different or more difficult questions.[69] That is, the public and publicized nature of scientific discovery stimulates innovation and guides invention.[70] This free flow of information is different than the private sector, which is incentivized to keep its research and inventions secret until a patent is obtained.[71] The dynamics of the private sector do not lend it to rapid sharing of new knowledge. The tension between freely available work product and investment/incentive regimes plays out in

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[63] This article does not conclude that the peer review system works perfectly. There are defects in the peer review system. However, this article argues it is a better system to advance scientific inquiry than the political process.
[64] Ammon J. Salter and Ben R. Martin, *The Economic Benefits Of Publicly Funded Basic Research: A Critical Review*, 30 RESEARCH POL'Y 509, 510 (2001).
[65] *Id.*
[66] *See id.*
[67] Richard Nelson, *The Simple Economics of Basic Science Research*, 67 J. OF POL. ECON. 297, 297-99 (1959).
[68] Richard R. Nelson, *Reflections on "The Simple Economics of Basic Science Research": Looking Back and Looking Forward*, 15 INDUS. AND CORP. CHANGE 903, 906 (2006).
[69] *See id*. at 303.
[70] Richard R. Nelson, *The Market Economy, and Scientific Commons*, 33 RESEARCH POL'Y 455, 455 (2004).
[71] *Id*.

other technology driven areas such as software development and even the rise of covenants not to compete in the technology sector.[72]

While it is true, however, that the social value in funding basic science research must be evaluated with the awareness that because of this funding, other avenues will not receive funding due to limited resources, [73] social benefit is increased by the dissemination and publication of research results into the public domain.

B. *Process Defect - Public Choice Theory*

Despite that support for basic science creates a public good and that this is accomplished through political actors allocating government resources to fund the research, this same political process can also lead to a process defect in the area of scientific inquiry in specific areas. Public choice theory helps explain the process defect.

The public choice model applies the incentive structure of economic models to political institutions.[74] Public choice theory first gained traction in the political landscape by demonstrating how voting structures impact lawmakers. The public choice model responded to a critique of the political process that elections and majoritarian rule did not promote the public's best interest.[75] Advocates of what would be called public choice argued that the election cycles ultimately would lead to efficiency through rounds of voting where minorities may ascend to the majority in line with the public interest.[76] The debate centered on how to obtain a "combination of justice and efficiency under majority rule."[77]

Public choice uses economic analysis as applied to behavior to predict outcomes.[78] Public choice theory can be used to understand how bureaucracies grow and how interests that do not seem to be in the best interest of the public-at-large flourish.[79] Examples include pork-barrel politics and tax loopholes.[80] Under the public choice model, minorities will experience voting cycles and ascend to the majority.

Assuming *arguendo* that one accepts the theoretical model of public choice theory, it helps explain the problem of majoritarian rule in determining which questions scientists can ask. The problem exists on two major levels. First, just because a line of scientific inquiry is unpopular with the majority, it does not mean it should not exist. For example, there was a lot of political pressure against the theory of natural selection. If a majority of Congress did not want research conducted on natural selection, it is possible we would not have research in perhaps one of the least controversial areas within biology. Second, scientific innovation cannot progress if it is subject to election cycles and even repeating election cycles where the minority ascends to the majority. By way of example, embryonic stem cell research, or other controversial areas, cannot

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[72] *See, e.g.*, David S. Evans & Anne Layne-Farrar, *Software Patents and Open Source: The Battle Over Intellectual Property Rights*, 9 VA. J. OF L. & TECH. 1, 3-15 (2004); Ronald J. Gilson, *The Legal Infrastructure of High Technology Industrial Districts: Silicon Valley, Route 128, and Covenants Not to Compete*, 74 N.Y.U. L. REV. 575, 576 (1999) (discussing Alfred Marshall's writing that described industrial districts and his development of the concept of "agglomeration economies").
[73] Nelson, *supra* note 67 at 297.
[74] Daniel A. Farber and Philip P. Frickey, *Legislative Intent and Public Choice*, 74 VA. L. REV. 423, 424 (1988).
[75] James. M. Buchanan, *Public Choice, Politics Without Romance*, 19 POL'Y 13, 13-14 (2003).
[76] *Id*.
[77] *Id*. at 14.
[78] *Id*. at 17.
[79] *Id*. at 18.
[80] *Id*.

progress if it is subject to majority rule and election cycles. This is because scientists will not enter this area if funding is uncertain and subject to politics.[81] In the meantime, other countries will be conducting this research and surpassing the scientists in the United States.

In addition, political actors may employ political tactics. For example, an anti-science camp can challenge scientific reports by stating that scientists cannot come to a conclusion with 100% certainty.[82] This tactic, though a highly effective political tactic, fails to properly articulate the scientific process. Scientists build consensus through experimentation and peer review. Scientific theories do not require 100% certainty to be accepted in the scientific community. In fact, it is rare that any theory will have universal acceptance among scientists. Yet even the theory of evolution, one of the most accepted scientific theories to date and one which may not face any opposition within the scientific community, is still painfully attacked by political opponents on the basis that scientists may disagree on minor details within the theory of evolution. In any event, politicians play on the fact that scientific theories do not require 100% consensus in an attempt to discredit scientific theory, innovation, and exploration.

Application of the public choice model to social change, such as in discrimination, is analogous to the issues facing the scientific community. For example, it was the Supreme Court – the non-political branch of government – that decided *Brown v. Board of Education*, the landmark anti-discrimination case that held separate is not equal.[83] *Brown* was decided in 1954 and Congress and the President did not pass the Civil Rights Act until 10 years later.[84] Eventually, through repeated voting cycles, the legislative branch caught up to the public sentiment that discrimination is wrong. Public choice theory demonstrates that the rounds of voting may ultimately resolve critical and important issues, but it often takes too long.

Similarly, public choice theory explains why voting cycles cannot be relied upon to fix the problems in politicizing scientific inquiry. Scientific innovation moves in advance of the political process. As discussed in more detail in Part IV below, the elected government should have a role, but a limited role.

The application of public choice theory may or may not address other ways of influence that cannot be easily studied or analyzed, such as lobbying, campaign contributions, political favors, etc. And, it is for this very reason – that it is so hard to figure out the many ways that interest groups can exert influence on questions of scientific inquiry within the elected branches – that biomedical science should have an autonomous space that is not subject to the political winds.

Scientific innovation, goals, and progress do not occur on a schedule consistent with an election calendar. It may take decades to study and create a vaccine or treatment. For example, embryonic stem cell research can provide a promising approach to create treatments for muscular dystrophy and Parkinson's. This sort of scientific inquiry and advancement cannot progress if its support is subject to election cycles and the whims of the administration in charge.

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[81] Aaron D. Levine, *Policy Uncertainty and Conduct of Stem Cell Research*, 8 CELL STEM CELL 132, 132-35 (2011).
[82] CHRIS MOONEY, THE REPUBLICAN WAR ON SCIENCE 82 (Basic Books 2005).
[83] *Brown v. Board of Education*, 347 U.S. 483 (1954).
[84] The Civil Rights Act of 1964, Pub. L. No. 88–352, 78 Stat. 241 (1964).

V. CURRENT SAFEGUARDS AND ROOM FOR IMPROVEMENT

This article challenges the idea that political actors are needed to provide safeguards for scientific inquiry. In general, the two main arguments opposing limitations on political oversight are: (1) there should be some role for political actors to set the scientific agenda as well as ensure that research is conducted ethically and safely; and (2) elected political actors are involved in many areas of policy that require expertise, making science no different.

Regarding the first concern, there is undoubtedly an important place for political actors to ensure that government money is not being spent on meritless studies. Stated another way, scientific inquiry is not value-neutral.[85] This can be accomplished by balancing a respect for the job of political actors serving their role as public protectors with a respect for the need to provide scientists autonomy to conduct scientific inquiry. As discussed below, there are scientific processes in place to oversee this and to address the (non-) value-neutral issue. These processes include advisory committees and the peer review process. This article does not argue that there is no role for the democratic process in scientific inquiry; rather, it suggests that sometimes democratically elected officials overstep what should be appropriate boundaries and that these boundaries must be clarified and respected.

As it stands, elected officials do have a role in scientific inquiry. The President appoints the Secretary of HHS, who must be confirmed by Congress. Congress allocates the financial resources to the NIH, which is one way that the political process controls or restrains science.[86] Scientists must then prioritize funding opportunities. If the scientific community was found to be taking advantage of public resources, Congress has mechanisms to rein in the scientific community through reducing federal spending. In addition, Congress has the ability to impeach the Secretary of HHS or the Director of the NIH for abuse of government resources.[87]

The decisions about what factual questions scientists should ask, however, is not a place where democracy should govern, at least not in the technical aspects of scientific inquiry. Instead, scientific progress is more appropriately analogous to the judicial branch, which is not run via democracy.[88] Just as a strong judicial branch requires federal judges with expertise in their field who are resistant to political persuasion given their lifetime appointment,[89] progress in the scientific realm requires actors with expertise in their field and protections from the political process as well. The appropriate actors, then, are scientists, not politicians.

The second main area of opposition asks why science is different from other areas that elected officials regulate, such as transportation and farming. In fact, elected officials are not experts in many of the areas in which they play an important role. Even assuming *arguendo* that is the case, biomedical research is a unique situation because of the system of peer review, funding, collaboration, sharing reagents, publication, training, and the competitive grant process. All of these structural implements in the scientific community support the call for an autonomous zone.

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[85] The author thanks a colleague for this important point.

[86] Jeffrey Rosen, *The Court and Democracy*, PBS, http://www.pbs.org/wnet/supremecourt/democracy/history.html (last visited May 7, 2014).

[87] Articles of impeachment can be initiated against federal officials. *See, e.g.*, *Articles of Impeachment*, WATERGATE.INFO, http://watergate.info/impeachment/articles-of-impeachment (last visited Mar. 7, 2013) (articles of impeachment against Richard Nixon).

[88] Rosen, *supra* note 86.

[89] *Id*.

With the above discussion in mind, the below sections discuss some of the infrastructural safeguards as well as suggestions to improve and expand that structure to support a non-political approach to scientific inquiry.

A. *Advisory Committees*

The fear that less involvement by elected political actors in the minutia of scientific inquiry will lead to ethically questionable, or even horrific, scientific practices is overblown. Within the NIH, the processes governing scientific inquiry have grown and emphasize the importance of expertise in multiple disciplines in setting the requirements for scientific inquiry.

HHS and the NIH have numerous advisory committees.[90] The NIH Advisory committees include members of the scientific community and public at large.[91] These committees include outstanding scientists as well as experts in other fields such as economics, law, and public policy.[92] Committees are a vital component to the competitive grant process.[93]

Layers of committees exist to determine whether a proposal will be funded. Grant applications are initially reviewed by Initial/Integrated Review Groups (IRGs), also known as study sections, who score grant applications that they believe meet the criteria of significant and substantial merit.[94] Scored applications are then reviewed by members of the National Advisory Council (NAC), which includes scientists as well as experts in various fields.[95] By having experts in fields such as law, economics, management, and others, the NAC receives information from other fields to set its priorities and manage its goals.

Scientific and scientific-type advisory committees outside the HHS and NIH also exist, and some appear more political than others. The President has the authority to appoint people to advisory positions. For example, the President appoints his Council for Bioethics. The composition of advisory committee membership appears to have distinctive patterns, depending on who is the President. It is not surprising that a President wants to choose those providing advice. The problem that can arise, however, is that a President may want to appoint people who will tell the President what he wants to hear, not someone who will objectively advise the President. For example, Dr. Elizabeth Blackburn believes the George W. Bush Administration dismissed her from the President's Council on Bioethics because she disagreed with the administration's stem cell policy.[96]

An appropriate balance needs to be struck between the areas of scientific inquiry most appropriately governed by the effective use of advisory committees. Scientific inquiry cannot be run on election cycles, for reasons discussed above, and so deference should be given to the standing structures of the advisory committees within the HHS and NIH to provide and promote

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[90] OFFICE OF THE FEDERAL ADVISORY COMMITTEE POLICY, *Directory NIH Federal Advisory Committees and HHS Advisory Committees Managed by NIH Staff*, NIH, Nov. 2008, at 1.
[91] *Id.* at 2.
[92] *Id.* at 4.
[93] *Id*.
[94] *Id*.
[95] *Id*.
[96] *President's Council on Bioethics*, UNION OF CONCERN SCIENTISTS (July 2004), http://www.ucsusa.org/scientific_integrity/abuses_of_science/presidents-council-on.html; Sheryl Gay Stolberg and David E. Sanger, *Bush Aides Seek Compromise on Embryonic Cell Research*, N.Y. TIMES (Jul. 2, 2001), *available at* http://www.nytimes.com/2001/07/04/us/bush-aides-seek-compromise-on-embryonic-cell-research.html?pagewanted=2&pagewanted=print, ("They note that only about a dozen cell lines have been developed and say many more are needed to ensure that the cells have enough genetic diversity to be useful.").

mechanisms to allow scientific inquiry to progress in a non-politicized manner. To ensure that advisory committees to the HHS and NIH are performing the tasks and oversight as needed, studies can be conducted to assess whether these committees are meeting predetermined outcomes or whether changes are needed.[97]

B. *Scientific Societies Can Publish Scientific Reports*

One of the ways to manage the concerns that the public may have with a more autonomous process for scientific inquiry is to reevaluate how the public receives information. One suggestion is to have nonpartisan scientific societies, such as the National Academy of Science (NAS), disseminate reports to media outlets promoting and clarifying scientific information.[98] This was effective in the 1980s, for example, when a report by the National Academy of Science debunked the Reagan Administration's denial of acid rain.[99] *The New York Times* picked up the report and it reached a widespread audience.[100]

One problem with this system, however, is the slow pace at which the NAS writes scientific reports. One option is to create a fellowship program whereby junior scientists are tasked with researching and writing shorter scientific briefs in areas requiring clarification for elected officials and the public at large. This approach has multiple advantages. First, it allows junior scientists to participate in the process and gain exposure to the dynamics between law and science. Second, it may assist the careers of junior scientists through interaction with the senior scientist members of the NAS. Third, this proposal taps the fresh ideas and energy that are usually associated with junior scientists. Fourth, it may open up new funding opportunities for junior faculty. Finally, this option may allow junior scientists to interact with congressional and presidential staff in ways that bridge the gap between the political and scientific communities. All of these advantages benefit the public because the public will receive scientifically supported information.

It should also be noted that while the Institute of Medicine (IOM) issues reports on significant issues that are the result of intense collaboration and research and should be highly commended,[101] these objective and informative reports also require a lot of time and resources. Shorter reports on discrete issues could provide valuable and easily digestible information for public consumption.

C. *Creation of the Institute of Science*

The creation of a nonpartisan Institute of Science (IS) could also manage and oversee scientific inquiry.[102] Similar to the principles of the Congressional Budget Office (CBO), this office would not be loyal to any political party – rather, it would provide determinations based

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[97] The author thanks a colleague for this suggestion.
[98] *Mission*, THE NATIONAL ACADEMY OF SCIENCE, http://www.nasonline.org/about-nas/mission/ (last visited May 10, 2014) ("The National Academy of Science (NAS) is a private, non-profit society of distinguished scholars. Established by an Act of Congress, signed by President Abraham Lincoln in 1863, the NAS is charged with providing independent advice to the nation on matters related to science and technology. Scientists are elected by their peers to membership in the NAS for outstanding contributions to research.").
[99] CHRIS MOONEY, THE REPUBLICAN WAR ON SCIENCE 42 (Basic Books 2005).
[100] *Id*.
[101] *About the IOM*, INSTITUTE OF MEDICINE OF NATIONAL ACADEMICS (Jan. 18, 2012), http://www.iom.edu/About-IOM.aspx.
[102] *Cf.*, CHRIS MOONEY, THE REPUBLICAN WAR ON SCIENCE 249 (Basic Books 2005).

on scientific inquiry. The IS could respond to concerns that the NIH is making wrongheaded or biased decisions.[103] This type of office previously existed under the name Office of Technology Assessment (OTA).[104] That office, however, was dismantled and defunded under Newt Gingrich's leadership in Congress.[105] One difference between the OTA and the proposed Institute of Science is that the IS would be an institute within the NIH. In this way, the IS could receive funding through the NIH budget. One concern with this funding proposal is that it will stretch an already underfunded NIH budget, however. For this reason, a creative solution will be needed to ensure that the funding for the IS will not subtract from money allocated to funding basic science. Nonpartisan groups would appoint the leadership members of the IS. By way of example, the National Academy of Science could be responsible for the appointment of at least fifty percent of the IS members, while the American Medical Association and the American Association for the Advancement of Science could each appoint twenty-five percent. In this way, each group's members would have standing in the scientific community.[106]

Unlike the National Academy of Science, the IS would advise the President and members of Congress on discrete issues – thus addressing the concerns about politically appointed advisory committees. The National Academy of Science issues detailed reports on pressing issues, but this process takes time.[107] The IS would be able to move at a quicker pace to handle discrete issues.

The IS could also be charged with creating, implementing, monitoring, and revising enforceable policies to guide scientific inquiry. The IS would not determine which scientific questions should be asked, but rather would create and centralize policies that scientists must follow as they conduct research. In this way, an objective body would be in the position to monitor and study safety, ethics, workplace conditions, dissemination of results, collaboration, and more. One way to accomplish this would be to require academic medical centers and other institutions that receive federal funding to report on the activities of their institutional review boards, animal care facilities, lab safety, et cetera, so that the IS could serve as a centralization center to oversee safety of research and research subjects. Additionally, the IS could assist in creating guidelines for scientists to voluntarily follow.[108] Guidelines can have a powerful impact on the conduct of researchers while still allowing innovation and inquiry.

It is important that scientific advisors who have strong reputations and standing in the scientific community help guide our political leaders through scientific policy questions. As an example of this current need, the House of Representatives Committee on Science, Space and Technology recently announced new subcommittee chairpersons.[109] Subcommittee chairs Larry Bucshon (R-IN) and Cynthia Lummis (R-WY) are skeptics of human contributions to global

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[103] David B. Spence and Frank Cross, *A Public Choice for the Administrative State*, 89 GEO. L. J. 97, 120-121 (2000-01).
[104] Union of Concerned Scientists, *Restoring the Office of Technology and Assessment*, (Feb. 24, 2010), http://www.ucsusa.org/scientific_integrity/solutions/big_picture_solutions/restoring-the-ota.html.
[105] Union of Concerned Scientists, *Restoring the Office of Technology Assessment*, (Feb. 24, 2010), http://www.ucsusa.org/scientific_integrity/solutions/big_picture_solutions/restoring-the-ota.html ("Fortunately, the office itself was not abolished, just deprived of resources.").
[106] *Cf.* Robert Doubleday and James Wilsdon, *Beyond the Great and Good*, 485 NATURE 301, 302 (2012) (describing the British system of scientific advisors), www.nature.com/nature/journal/v485/n7398/pdf/485301a.pdf.
[107] Policy Studies and Reports, NATIONAL ACADEMY OF SCIENCES, http://www.nasonline.org/about-nas/policy-studies-and-reports/(last visited May 10, 2014).
[108] The author thanks a colleague for this suggestion.
[109] News of the Week, *A New Look for House Science Panel*, 339 SCIENCE 257 (January 2013).

climate change.[110] Since the scientific community has reached consensus that humans are contributing to climate change, there is a disconnect between congressional subcommittee chairs and prevailing scientific wisdom. Scientific advisors, with strong support and stature, are needed to ensure that accurate information is communicated to Congress when considering initiatives that impact scientific inquiry.[111] The IS could respond to these concerns.

D. *Scientific Community Safeguards Should be Respected*

The scientific community has safeguards in place to address egregious conduct or potentially harmful consequences of scientific discovery. For example, fabrication or falsification of data is taken very seriously.[112] Because scientific publications include the materials and methods of how the experiments were conducted, it is expected that the scientific community be able to replicate the experiments' results by following the same techniques. If replication is elusive, then an inquiry is made into the findings of the published paper.[113] This process uncovers scientists who have fabricated or falsified data.[114]

Another safeguard is that the advisory councils to the NIH contain many non-scientists. The National Advisory Council (NAC), for example, is composed of experts in other fields such as economics, law, management, and public policy.[115] The non-scientist experts are included to guide the implementation of scientific inquiry. By including these members, the NIH has the diversity needed to run balanced programs.[116] The non-scientific experts have their own expertise – in management for example – that provides balance and guidance in how to run an effective scientific endeavor. This system allows for the effective use of scientists' expertise and an efficient implementation of scientific inquiry in order to benefit the public.

The scientific community can also properly manage cases in which advances in science raise questions of security or global health. As an example, two labs recently took a flu virus that only infected birds and mutated the virus strain so that it could infect ferrets, which are mammals.[117] Prior to publishing the results in *Science* and *Nature*, the global scientific community raised concerns that a bioterrorist could utilize the published materials to mutate the virus so that it could infect humans and create a public health crisis.[118] The scientists who conduct this type of research issued a self-imposed moratorium to allow a worldwide consortium to address concerns about these flu strains.[119] The committee met for over a year and no papers containing the mutated flu strain were published during that time. Ultimately, with safeguards put in place, the committee decided that the papers could be published.[120]

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[110] *Id*.
[111] Conflicts of interest may cause great problems for members of advisory committees and vetting to avoid such conflicts should be a primary goal.
[112] *See, e.g.*, Jennifer Couzin, *MIT Terminates Researcher Over Data Fabrication*, 310 SCIENCE 758, 758 (2005).
[113] *See, e.g.*, D. Yvette Wohn and Dennis Normile, *Prosecutors Allege Elaborate Deception and Missing Funds*, 312 SCIENCE 980, 980-81 (2006).
[114] *See, e.g.*, Michael Hagmann, *Cancer Researcher Sacked for Alleged Fraud*, 287 SCIENCE 1901, 1901-02 (2000); Greg Miller, *Misconduct by Postdocs Leads to Retraction of Papers*, 329 SCIENCE 1583, 1583 (2010).
[115] OFFICE OF THE FEDERAL ADVISORY COMMITTEE POLICY, *Directory NIH Federal Advisory Committees and HHS Advisory Committees Managed by NIH Staff*, NIH, November 2008 at 4.
[116] *Id*.
[117] Declan Butler, *Work Resumes on Lethal Flu Strains*, 493 NATURE 460, 460 (2013).
[118] *Id.*; David Malakoff, *H5N1 Researchers Ready as Moratorium Nears End*, 339 SCIENCE 16, 16-17 (2013).
[119] Butler, *supra* note 117, at 460.
[120] *Id.*; Malakoff, *supra* note 118.

As another example, the scientific community in the 1970s worked together to resolve concerns about the use of recombinant DNA (rDNA) technology.[121] In short, rDNA technology allows a scientist to synthesize a piece of DNA in the laboratory, insert it into another organism, and then study it. When the technique was first reported, however, concerns arose about the possibility of using rDNA as a biohazard.[122] The scientific community responded to these concerns by creating committees and devising guidelines to be adopted by the scientific community.[123] The committees included scientists as well as experts in other fields such as public health, the environment, and law.[124] Working together, a set of guidelines was established and adopted by the NIH.[125] The rDNA technique revolutionized scientific experimentation and is used routinely and safely in biomedical laboratories.

The scientific process is admittedly an imperfect system,[126] but these cases provide examples of the scientific community adopting processes to address important concerns. Political actors, who are not scientists, simply do not have the expertise to discover and understand these types of problems. While political actors should play a part in these discussions, they should defer to the scientific experts to handle and manage scientific integrity.

E. *Distinguish Between Scientific and Policy Questions*

It is important to distinguish between scientific inquiry and the policy questions that necessarily follow from that inquiry. Policy decisions – the realm of politicians – should be based on fact and reality. But a failure to allow scientists the leeway to explore and discover leads to policy decisions that are based on fanciful guesswork. For example, it was properly the role of scientists, and not politicians, to discover that the earth was round. Had political actors been tasked with that discovery, it may never have been made. Once made, however, the question of what to do with that information becomes a policy question fit for political actors – for example, the decision to send ships into the ocean in search of more land to colonize. As another example, it is scientists' duty to determine whether rising global temperatures are due to human activities. With that information in hand, it then becomes the politicians' duty to determine what steps must be taken to combat that warming. In addressing these types of questions that can greatly affect society, it is crucial to remember – and respect – this distinction between questions of science and policy.

VI. CONCLUSION

The balance between the political process and scientific inquiry must be revisited. The political process should have a place in science, but it should be limited, much in the same way that it is limited in the federal judiciary system. The proposed solutions to address the process defects provide a balance that allows scientific inquiry to move forward and includes political safeguards.

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121 Bernard Talbot, *Introduction to Recombinant DNA Research, Development and Evolution of the NIH Guidelines, and Proposed Legislation*, 12 U. TOL. L. REV. 804, 806-09 (1980-81).
122 *See id*. at 807.
123 *Id*.
124 *Id*. at 814.
125 *Id*. at 807.
126 Ben Goldacre, *What Eight Years of Writing the Bad Science Column Has Taught Me*, THE GUARDIAN (Nov. 4, 2011), http://www.guardian.co.uk/commentisfree/2011/nov/04/bad-science-eight-years.