# ETHICAL CONSIDERATIONS FOR INDUSTRY PARTNERSHIP ON RESEARCH TO HELP END THE OPIOID CRISIS

**DRAFT REPORT** 

March 2018

Working Group Report to the Advisory Committee to the Director, NIH

## Charge to the Working Group

To make recommendations about considerations and appropriate ethical boundaries for engaging with and accepting resources from opioid producers, to support research to redress the opioid crisis.

To inform its deliberations, the Working Group may: identify the risks (including ethical, governance, reputational, and relationship risks) and benefits of accepting such resources; examine options for funding and/or governance structures that might mitigate ethical risks, identify concerns and real or perceived conflicts-of-interest; and assess existing guidance for protecting the integrity of research funded by industries with real or perceived ethical conflicts.

The Working Group was constituted under the aegis of the National Institutes of Health (NIH) Advisory Committee to the Director (ACD) and, therefore, submits this report to that committee.

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### **Executive Summary**

The National Institutes of Health (NIH) has been intensely engaged for several months in planning stages with the Foundation for NIH (FNIH) and potential external partners to identify and outline options for collaboration to address the opioid crisis. Discussions have included dozens of companies, a few of which manufacture opioids and are the target of current litigation by several state Attorneys General and other entities. While there may be significant opportunity to advance addiction and treatment research with the financial, technical, and intellectual support of this substantial roster of private sector companies, the NIH must consider the ethics of accepting contributions from those companies that are perceived as having contributed to the crisis.

The Working Group recognizes the remarkable contributions made by pain and addiction researchers to advance these fields with NIH funding support and agrees that NIH's pursuit of a public-private partnership with biopharmaceutical and biotechnology industry partners (hereafter referred to as "industry"), the FDA, and others could work synergistically to accelerate the development of better pharmacological treatments for pain and opioid use disorder. Since there are certain ethical and reputational risks associated with accepting funds or scientific assets from companies that may have contributed to the opioid crisis, NIH needs to take appropriate steps to consider those ethical boundaries and to minimize those risks while aiming to benefit patients and public health. The Working Group identified parameters for accepting funds and assets from potential industry partners and strongly emphasized the need for increased transparency, carefully constructed governance, and stressed the importance of NIH's final decision making authority on all grant-making decisions and related oversight.

The Working Group offers the following recommendations for engaging in a public-private partnership with industry partners to address the opioid crisis:

1. To mitigate the risk of real or perceived conflict of interest, it would be preferable if only Federal funds were used to support the research efforts included in this public-private partnership.

2. For any public-private partnership to address the opioid crisis, NIH should not accept funding from companies involved in litigation of concern related to the crisis.

3. If a public-private partnership is established, any funding originating from industry partners (not precluded under Recommendation #2) that is to be provided to NIH, either directly or through FNIH, must be provided without conditions, other than being designated for the partnership, and must be received in full by NIH prior to NIH's announcement of any funding opportunity or other activity designated as part of the partnership.

4. Any company with assets (e.g., clinical and preclinical data, key chemical compounds) relevant to the research plan for a public-private partnership that NIH undertakes in response to the opioid crisis can contribute those assets to the partnership.

5. Any public-private partnership that NIH undertakes in its response to the opioid crisis should not involve governance participation from companies involved in litigation of concern related to the crisis.

6. In accordance with current practice, for projects that NIH funds using donations received under the partnership, NIH will solely govern the peer review process and have decision making authority with regard to the selection of projects, disbursement of funds, and monitoring and oversight of projects.

7. Governance structure(s) established to coordinate partners and to guide decision making about the overall strategy, direction, and goals of the public-private partnership should include a diverse group of stakeholders including public members.

8. NIH should augment its current vetting process for members of governance committee(s) to mitigate real and perceived conflict of interest.

9. Before moving forward with a public-private partnership, NIH should clarify and define a governance structure for each of the core initiatives of the proposed partnership or any subsequent core initiatives of collaboration.

10. NIH should clearly communicate to the public the full extent of its research agenda related to opioids and where the partnership fits within NIH's comprehensive research strategy.

11. NIH should publicly disclose the research plan for the partnership.

12. To ensure public trust and alleviate concerns about real or perceived conflicts, NIH should employ increased transparency measures in the governance of the partnership (e.g., posting meeting summaries from governance committees; posting conflict of interest declarations of committee members).

In addition, if NIH accepts funds from a partner that later comes under scrutiny as described in Recommendation #2, NIH must have a mechanism to return those financial resources to the extent possible by laws, regulations, and policies. While companies that have contributed to the opioid crisis may share assets with NIH as part of the partnership, they must transfer the assets to NIH without any conditions or claims arising from their ownership or IP on those assets, variants thereof, or future products that result from or are covered by the IP.

The Working Group also recommends that moving forward, NIH should develop criteria and guidelines for developing public-private partnerships and partner engagement that can be applied across the agency.

### Introduction

The current opioid crisis is an ongoing and increasing public health emergency. In 2014, almost 2 million Americans had an addiction to prescription or illicit opioids.<sup>1</sup> Approximately 25 million people suffer daily from chronic pain,<sup>2</sup> and about 21-29 percent of patients that are prescribed opioids for chronic pain misuse them,<sup>3</sup> with 8-12 percent developing an opioid use disorder.<sup>4,5,6</sup> According to the Centers for Disease Control and Prevention, from July 2016 to September 2017, drug overdose deaths increased 29.7% overall and 34.5% in 16 states with high prevalence of overdose mortality.<sup>7</sup> The crisis is getting worse; drug overdose deaths exceeded 64,000 in 2016,<sup>8</sup> representing 175 deaths a day. In recognition of the growing crisis, the President declared a national public health emergency on October 26, 2017,<sup>9</sup> and the President's Commission on Combating Drug Addiction and the Opioid Crisis released its report in November 2017.<sup>10</sup>

To address this crisis, NIH advocated an "all hands on deck" approach<sup>11</sup> with its partners to develop scientific tools to help end the crisis by accomplishing objectives that neither NIH nor the partners could do alone. As part of NIH's strategy to address the opioid crisis, the agency initiated discussions with the pharmaceutical industry and other partners to establish a partnership to investigate non-addictive pain medicines and new treatments for addiction and overdose. The proposed partnership would aim to develop safe and effective treatments for opioid use disorder and pain in an accelerated timeline by investing in four core initiatives over the next five years:

- 1) Develop new formulations and combinations of existing medications to treat opioid use disorder and to prevent or reverse overdose.
- 2) Share relevant clinical, preclinical, and pharmacokinetic data from past efforts in developing pain medications to inform and accelerate development of new pain treatments. Identify potential new uses for existing or abandoned medications that may be useful in treating addiction, overdose, or pain.
- 3) Develop new clinical endpoints for opioid use disorder treatments, and identify and validate biomarkers for more rapid discovery, development, and approval of new medications.
- 4) Establish a new clinical trial network that will provide infrastructure to test new pain medications.

<sup>6</sup> Carlson RG, Nahhas RW, Martins SS, Daniulaityte R. Drug Alcohol Depend. 2016;160:127-134. PMID: 26785634

<sup>&</sup>lt;sup>1</sup> Boscarino JA, Rukstalis M, Hoffman SN, et al. Addiction 2010;105:1776–82. PMID: 20712819

<sup>&</sup>lt;sup>2</sup> 2012 National Health Interview Survey. https://nccih.nih.gov/news/press/08112015

<sup>&</sup>lt;sup>3</sup> Vowles KE, McEntee ML, Julnes PS, Frohe T, Ney JP, van der Goes DN. *Pain*. 2015;156(4):569-576. <u>PMID</u>: <u>25785523</u>

<sup>&</sup>lt;sup>4</sup> Muhuri PK, Gfroerer JC, Davies MC. Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States. *CBHSQ Data Rev.* August 2013.

<sup>&</sup>lt;sup>5</sup> Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. JAMA Psychiatry. 2014;71(7):821-826. PMID: 24871348

<sup>&</sup>lt;sup>7</sup> Vivolo-Kantor AM, Seth P, Gladden RM, et al. MMWR Morb Mortal Wkly Rep 2018;67:279–285. DOI: http://dx.doi.org/10.15585/mmwr.mm6709e1

<sup>&</sup>lt;sup>8</sup> Seth P, Rudd R, Noonan, R, Haegerich, T. *Am J Public Health*. March 2018;108(4),e1-e3. DOI:/10.2105/AJPH.2017.304265

<sup>&</sup>lt;sup>9</sup> <u>https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-taking-action-drug-addiction-opioid-crisis/</u>

<sup>&</sup>lt;sup>10</sup> https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final\_Report\_Draft\_11-1-2017.pdf

<sup>&</sup>lt;sup>11</sup> Volkow ND, Collins FS. N Engl J Med 2017 Jul 27; 377:391-394. (Epub 2017 May 31) PMID: 28564549

The proposed partnership would involve sharing expertise and providing funding to expand the range and success of NIH's programs, supporting high impact studies to advance development and FDA approval of effective compounds to prevent and reverse overdose and treat opioid use disorder. The partnership would also create and share tools and infrastructure to accelerate current therapeutic development efforts for treating pain. Given the severity of the opioid crisis, the proposed partnership would bring together the resources of patients, government agencies, industry, and academic research institutions to respond to the crisis. To guide the formation of such a partnership, this report begins with recommendations regarding accepting funds and assets from all or some of the interested industry partners. The report then addresses considerations for governance structure(s) for the partnership, aiming to mitigate ethical risks. Finally, the report addresses recommendations for transparency and strategies for maintaining public trust.

### Process of Deliberations

The Working Group held two teleconferences and one in-person meeting over a period of four weeks. Additional communication between and among Working Group members took place between meetings. The Working Group discussed the charge at the initial teleconference meeting and held an in-person meeting over a day and a half to hear presentations from academic and non-profit leaders involved in addiction and pain research and policy. Following the presentations, the working group developed initial recommendations. During a follow-up teleconference, Working Group members discussed the final recommendations and the report. The Working Group's deliberations were based on publicly available information and resources related to the topic at hand, a draft version of the white paper provided by the FNIH, and insights from invited speakers.

### Summary of Recommendations

For many years, NIH has partnered successfully with industry, including biopharmaceutical companies, biotechnology companies, and others. NIH engages in public-private partnerships to accomplish agency goals that would otherwise be impossible, less efficient, or incomplete if conducted by NIH alone. Such partnerships have provided considerable benefits to biomedical research, to patients, and to the public. Industry adds value to NIH efforts to develop new treatments through its financial, intellectual, and material support. However, partnerships to address the opioid crisis present unique challenges due to the alleged involvement of certain companies in practices that contributed to the crisis that resulted in harms incurred by patients. These allegations include improperly marketing opioids, misrepresenting the risks and benefits of the use of opioids, encouraging physicians to over-prescribe opioid products, and supplying distributors increasingly excessive amounts of pills without notifying authorities of suspicious orders.<sup>12,13</sup> Thus, a partnership to address the opioid crisis requires additional scrutiny and risk mitigation, in addition to the usual rigorous norms. NIH must be aware at all times that undue influence can occur in many different ways. NIH must ensure that appropriate guidelines and mechanisms are in place to prevent undue influence or the perception of undue influence that could

<sup>13</sup> See e.g., In re Nat'l Prescription Opiate Litig., MDL No. 2804, 2017 WL 6031547 (J.P.M.L., Dec. 05, 2017); Assurance of Discontinuance under Executive Law Section 63, Subdivision 15, In the Matter of Purdue Pharma L.P., Assurance No. 15-151, N.Y. Att'y Gen. (Aug. 19, 2015), available at <a href="http://www.ag.ny.gov/pdfs/Purdue-AOD-Executed.pdf">http://www.ag.ny.gov/pdfs/Purdue-AOD-Executed.pdf</a>; Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations, U.S. Dep't of Justice (July 11, 2017), <a href="https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders">https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders</a>.

<sup>&</sup>lt;sup>12</sup> This document is not intended to reflect legal advice or the views and positions of the U.S. Government with respect to these or other allegations.

diminish public trust in the integrity of the research. If rigorous standards and mechanisms are in place to mitigate these and other potential risks, then a public-private partnership to achieve goals that NIH cannot accomplish on its own that includes sharing of expertise and strategies among partners could help accelerate efforts to address the opioid epidemic.

The recommendations below outline the ethical boundaries and additional processes that the Working Group deemed necessary for NIH to consider when determining how to engage in a public-private partnership to support research efforts to address the opioid crisis.

### Funding and Assets

# <u>Recommendation 1</u>: To mitigate the risk of real or perceived conflict of interest, it would be preferable if only Federal funds were used to support the research efforts included in this public-private partnership.

Due to the high level of real and perceived conflict of interest in this potential partnership, the best risk mitigation strategy would use only Federal funds to support research efforts. This would eliminate the perception that the research could be biased in any way. The Working Group recognizes that this condition could be limiting, however, and offers additional parameters if funding from industry partners is accepted.

## <u>Recommendation #2</u>: For any public-private partnership to address the opioid crisis, NIH should not accept funding from companies involved in litigation of concern related to the crisis.

Companies previously or currently involved in litigation related to the opioid crisis have expressed interest in a potential public-private partnership with NIH. However, the ethical and reputational risks to NIH if the agency accepts funds from these companies, either directly or through the Foundation for NIH (FNIH) are too great to balance the potential benefit of accepting financial contributions. In determining which companies fall under the purview of this recommendation, NIH should clearly and transparently define what level of litigation (e.g., class-action suits, suits by city/state/tribal/federal government against a company) rises to the level of "litigation of concern."

In addition, if any company in the public-private partnership that is not currently involved in litigation comes under such scrutiny or credible evidence comes to light, NIH must have a mechanism in place to return all financial resources from those companies, to the extent possible under applicable laws, regulations, and policies, as well as to bar future participation in funding or governance of the public-private partnership. This recommendation not to accept funds from these companies guards against the companies' potential use of the partnership to generate positive media or to garner leverage in litigation. NIH also should not accept funds that are generated as a "tax" on all member companies of a third-party or trade organization if the companies excluded from contributing funds to the public-private partnership as described in this recommendation would be included as contributors to the "tax."

If funds are made available through a negotiated or court-ordered settlement with these companies, the Working Group believes it is ethically acceptable for NIH to accept those funds for research.

<u>Recommendation 3</u>: If a public-private partnership is established, any funding originating from industry partners (not precluded under Recommendation #2) that is to be provided to NIH, either

directly or through FNIH, must be provided without conditions, other than being designated for the partnership, and must be received in full by NIH prior to NIH's announcement of any funding opportunity or other activity designated as part of the partnership.

Accepting funding from industry partners at the outset of the partnership will mitigate the risk of undue influence or of having insufficient funds to complete the project if a partner is unable to or decides not to make all payments in the future. For an NIH-managed project, this would require the agency to add supplemental funds for completion. The condition requiring all industry-supplied funds upfront is also a measure of assurance in the autonomy of NIH's decision-making; for example, it is another safeguard to ensure that a project would continue at NIH's discretion even if the partners later diverge ideologically or develop different priorities. Potential industry partners should be made aware of this condition with as much notice as possible to enable such a transfer of funds.

# <u>Recommendation 4</u>: Any company with assets (e.g., clinical and preclinical data, key chemical compounds) relevant to the research plan for a public-private partnership that NIH undertakes in response to the opioid crisis can contribute those assets to the partnership.

Companies involved in discussions to develop the proposed public-private partnership have indicated that they have data and other material assets that could help accelerate research in new medication development, biomarker discovery, or other aspects of the partnership. NIH should encourage all companies with such assets to share them within the partnership to advance research goals. Companies excluded from providing funding (Recommendation #2) or participating in governance (Recommendation #5) should be allowed to share relevant assets.

All companies must share assets freely, without any conditions or restraints on the use of the materials. If companies share assets with intellectual property (IP) (e.g., the assets are covered by a patent), then they must transfer the assets to NIH without any conditions or claims arising from their ownership or IP on those assets, variants thereof, or future products that result from or are covered by the IP. When accepting such assets to use in support of the public-private partnership, NIH should provide a mechanism for validating the assets as well as a plan for mitigating the risk of overvaluation of those assets by the companies that hold them.

### **Governance**

# <u>Recommendation 5</u>: Any public-private partnership that NIH undertakes in its response to the opioid crisis should not involve governance participation from companies involved in litigation of concern related to the crisis.

In keeping with Recommendation 2, to restrict funding from companies accused or confirmed to have contributed to the opioid crisis, NIH should also exclude those companies from participation in governance of the partnership. By excluding these companies, NIH prevents the possibility of undue influence on partnership decision making. The involvement of these companies would create unresolvable conflict of interest issues that could threaten the perceived integrity of the entire partnership and any research results generated from the activities of the partnership. These companies could share data and assets in accordance with Recommendation #4, including appropriate validation of such assets.

<u>Recommendation 6</u>: In accordance with current practice, for projects that NIH funds using donations received under the partnership, NIH will solely govern the peer review process and have decision making authority with regard to the selection of projects, disbursement of funds, and monitoring and oversight of projects.

NIH's longstanding two-tiered peer review process strives to be fair, equitable, and free of bias. Mandated by statute and governed by federal regulations, a group of non-federal scientists with relevant research expertise conducts the first level of review based on scientific merit. Institute and Center (IC) National Advisory Councils or Boards, which include both scientific and public representatives, perform a second level of review that takes into account public health relevance and the overall balance of the IC's research portfolio. IC Directors make the final funding decisions. NIH will employ this process for any applicable projects that the agency manages under the proposed publicprivate partnership. After NIH makes a funding award, the agency's post-award monitoring and report processes ensure responsible use of funds.

Industry partners will not participate in the review, selection, or oversight of grants or cooperative agreements included within the public-private partnership. NIH has sole purview over these responsibilities, and the absence of industry partners in this process will help mitigate conflict of interest with regard to project selection and research progression.

# <u>Recommendation 7</u>: Governance structure(s) established to coordinate partners and to guide decision making about the overall strategy, direction, and goals of the public-private partnership should include a diverse group of stakeholders including public members.

To ensure broad representation of perspectives in the partnership coordination and decision making, NIH must include stakeholders from a variety of sectors, including members of the public. These public members could include patients recovering from opioid addiction, patients afflicted with chronic pain, affected family members, and/or advocates for pain or addiction research and policy. Members of the public provide a critical voice for NIH to consider in its stewardship of federal funds.

## <u>Recommendation 8</u>: NIH should augment its current vetting process for members of governance committee(s) to mitigate real and perceived conflict of interest.

NIH has policies to address conflict of interest for its advisory committee members and employees. However, given the additional ethical considerations that NIH must apply to this partnership, the agency needs a more stringent and transparent vetting process to identify and manage real and perceived conflict of interest for members of governance bodies engaged in decision making for the public-private partnership. In particular, scientists, medical professionals/clinicians, and members of the public who have direct or indirect relationships with the companies of concern should fully and transparently disclose those relationships and other potential conflicts, and NIH should employ strategies to appropriately manage such conflicts. If a conflict of interest (even if disclosed) cannot be fully managed, then NIH should exclude that party from the public-private partnership governance.

<u>Recommendation 9</u>: Before moving forward with a public-private partnership, NIH should clarify and define a governance structure for each of the core initiatives of the proposed partnership or any subsequent core initiatives of collaboration.

Each of the four core initiatives that could become part of the public-private partnership will require different mechanisms to ensure appropriate oversight and guidance of the partnership. The governance mechanisms most appropriate for each initiative should be outlined in detail before that aspect of the partnership moves forward. NIH will need to address the appropriate level of industry involvement (if any) in the governance for each initiative. For example, one initiative might involve a continuation of current NIH programs that could benefit from industry funding, but have all decision making retained by NIH. Another initiative in the precompetitive space might require valuable industry intellectual input and data contribution throughout the life of the partnership. Any governance plans outlined in accordance with this recommendation should not include companies excluded from governance participation pursuant to Recommendation #5.

### **Transparency**

# <u>Recommendation 10</u>: NIH should clearly communicate to the public the full extent of its research agenda related to opioids and where the partnership fits within NIH's comprehensive research strategy.

The proposed aim and scope of the public-private partnership should capitalize on areas where industry partners are best poised to work with NIH and other partners to advance particular areas of research to help address the opioid crisis. It is important, however, for stakeholders and the public to understand the scope of NIH's ongoing and wide-ranging research to address opioid misuse and addiction and to develop non-addictive approaches for pain management. For instance, large-scale epidemiological studies are underway to understand patterns and risk factors of addiction, and NIH supports development and testing of prevention interventions for both general and high-risk populations. In addition, implementation research, such as a study on how to effectively screen for drug use in primary care settings to intervene with patients who are misusing opioids, could yield effective strategies to prevent addiction. The National Institute on Drug Abuse (NIDA) also engages in education and outreach initiatives for clinicians and patients, with the goal of reducing prescription opioid misuse.

Realizing the need for new options in treatment of both acute and chronic pain, NIH supports research to develop medications with diminished misuse potential, including both opioid and non-opioid medications, as well as non-pharmacological treatment options (e.g., transcranial magnetic stimulation, biopsychosocial interventions). NIH also focuses on the youngest victims of the opioid epidemic, filling a critical knowledge gap by launching a new study to evaluate treatment options for newborns with opioid withdrawal syndrome as a result of exposure to opioids during pregnancy. These are just a few examples from NIH's broader research portfolio related to opioid misuse and addiction.

A public-private partnership to accelerate development of new and innovative medications, biologics, and devices to treat opioid addiction and pain as well as to prevent or reverse opioid overdose would complement NIH's other efforts to address the opioid crisis, but it is best understood in the context of the comprehensive research agenda. Increased communication around this point will increase transparency and help the public understand all related NIH research activities.

#### *<u>Recommendation 11</u>:* NIH should publicly disclose the research plan for the partnership.

The research plan for the proposed public-private partnership was developed with input from more than 100 experts in the fields of opioid misuse and addiction, pain, behavioral health, imaging, and neurobiology. Representatives from NIH, the FNIH, the Food and Drug Administration (FDA), the

Pharmaceutical Research and Manufacturers of America (PhRMA), key academic researchers, and more than 30 biopharmaceutical companies were involved in discussions that resulted in a proposed partnership that includes two primary focus areas encompassing four core initiatives. To ensure transparency, NIH should disclose the research plan and the discussion participants to the public for their information. The plan is the product of extensive consultation with a range of expertise and perspectives, and is in itself a valuable resource developed partially with public funds.

### <u>Recommendation 12</u>: To ensure public trust and alleviate concerns about real or perceived conflicts, NIH should employ increased transparency measures in the governance of the partnership (e.g., posting meeting summaries from governance committees; posting conflict of interest declarations of committee members).

In addition to augmented conflict of interest policies for governing bodies of the public-private partnership (Recommendation #8), a guiding principle must include increased transparency measures in all aspects of the partnership. In particular, NIH must document partnership governance thoroughly and in a form that is accessible to the public. This includes information about committee members and all decisions and plans that guide the partnership.

### **Concluding Observations**

The recommendations presented here apply to this particular potential partnership that presents distinctive ethical challenges. However, NIH-wide standards for public-private partnership development could aid such deliberations in the future. Thus, the Working Group recommends that moving forward, NIH should develop well-considered criteria and guidelines for developing public-private partnerships and partner engagement to apply across the agency and ensure public confidence in the integrity of the research to the fullest extent possible.

### Appendix

### Agenda for the ACD Working Group on Ethical Considerations for Industry Partnership on Research to Help End the Opioid Crisis

Date: March 8-9, 2018 Location: NIH Main Campus, Building 1 1 Center Drive, Bethesda MD Teleconference Number: 866-692-3582 Passcode: 2136309#

**Working Group Charge:** To make recommendations about considerations and appropriate ethical boundaries for engaging with and accepting resources from opioid producers, to support research to redress the opioid crisis.

### March 8, 2018 Agenda

	Location: NIH Main Campus, Building 1, Wilson Hall (3 <sup>rd</sup> floor)
9:00 am	Welcome - Working Group Co-Chairs
9:05 am	Introduction of Working Group Members
9:10 am	Declaration of Conflicts of Interest
9:15 am	<b>Stephen I. Katz, M.D., Ph.D.</b> Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases
9:45 am	<b>Jennifer Miller, Ph.D.</b> Assistant Professor, NYU School of Medicine, and Founder, Bioethics International and the Good Pharma Scorecard
10:15 am	Break
10:30 am	Adriane Fugh-Berman, M.D. Professor of Pharmacology and Physiology, Georgetown University
11:15 am	Francis Collins, M.D., Ph.D. Director, National Institutes of Health

12:15 pm Working Lunch

1:00 pm	Jessica Hulsey Nickel Founder, President and CEO, Addiction Policy Forum
1:45 pm	Bernard Lo, M.D. President and CEO, Greenwall Foundation
2:30 pm	Break
2:45 pm	<b>Peter Adams, Ph.D.</b> Professor, School of Population Health and Associate Director, Centre for Addiction Research, University of Auckland, New Zealand
3:30 pm	<b>John Burklow</b> Associate Director for Communications and Public Liaison, National Institutes of Health
	<b>Adrienne Hallett</b> Associate Director for Legislative Policy and Analysis, National Institutes of Health
4:30 pm	Discussion
5:30 pm	Break
6:30 pm	Adjourn

### March 9, 2018 Agenda

Location: NIH Main Campus, Building 1, Room 151

- 8:00 am Maria Freire, Ph.D. President and Executive Director, Foundation for NIH
- 9:00 am Discussion
- 10:15 am Break
- 10:30 am Discussion
- 1:00 pm Adjourn