

## Helping to End Addiction Long-term (HEAL) Initiative\* Investigator Meeting Hyatt Regency Bethesda Bethesda, Maryland January 16–17, 2020

The Helping to End Addiction Long-term<sup>SM</sup> Initiative, or NIH HEAL Initiative<sup>SM</sup>, is an aggressive, trans-NIH effort to speed scientific solutions to stem the national opioid public health crisis. Launched in April 2018, the initiative is focused on improving prevention and treatment strategies for opioid misuse and addiction and enhancing pain management. For more information, visit <https://heal.nih.gov>.

### Overview

The NIH HEAL Initiative convened this meeting to bring together more than 350 investigators who represent the full scope of scientific research through which HEAL is tackling the opioid crisis. Participants included basic, translational, clinical, and implementation scientists working on research to address every facet of pain and opioid addiction, along with leaders and experts from across the U.S. Department of Health and Human Services.

The goals of the meeting were to:

- Establish the HEAL investigator network and make it a place to build collaborations, share lessons learned, and advance everyone's research toward a collective goal.
- Raise awareness of the geographic, thematic, and programmatic scope of the initiative.
- Explore commonalities and enhance individual programs to optimize successes of the NIH HEAL Initiative.
- Consider priorities for HEAL research moving forward.

### January 16

#### Welcome and Introductory Remarks

Francis S. Collins, M.D., Ph.D., Director, National Institutes of Health (NIH) called the meeting to order, emphasizing that “all hands on deck” will be needed to improve treatment for opioid addiction and provide better treatment options for managing pain. Research toward these two goals will be required to turn the corner on the national opioid overdose crisis, and the unique structure of HEAL offers the promise of a united effort that will advance scientific progress further than would be possible otherwise. Dr. Collins highlighted the severity of the crisis: in 2017, more than 70,000 Americans died from drug overdoses; nearly 70% of these deaths involved an opioid. On the other side of the equation, more than 20 million Americans suffer from high-impact chronic pain. HEAL is addressing problems that do not currently have evidence-based solutions, including: most people with OUD do not receive the effective treatments that already exist; those who do receive treatment are not always retained in care; current tools for pain management are often insufficient; and it remains unknown how best to address the needs of infants with prenatal opioid exposure. HEAL research is specifically targeting these critical areas of need.

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\* NIH HEAL Initiative and Helping to End Addiction Long-term are service marks of the U.S. Department of Health and Human Services.”

## The NIH HEAL Initiative and Meeting Overview

NIH HEAL Initiative Director, Rebecca Baker, Ph.D., gave remarks highlighting the comprehensive scope of the [projects funded by HEAL](#), designed to be a research response that matches the opioid crisis in urgency and magnitude. HEAL is awarding \$500 million per year over five years to support research, and so far has supported more than 400 investigators across 41 states. This research is organized into a framework that is based on the twofold goal of enhancing pain management and improving treatments for opioid misuse and addiction. Dr. Baker presented the broad range of HEAL programs, including:

- [Development of novel medication options for OUD and overdose](#)
- [The Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome \(ACT NOW\) study and the HEALthy Brain and Child Development \(HBCD\) Study](#)
- [Developing New Prevention And Treatment Strategies, including:](#)
  - [Prevention of OUD Among At-Risk Adolescents](#)
  - [Managing Opioid Misuse and Low-Severity OUD](#)
  - [Understanding the Role of Sleep Dysfunction in Addiction And Recovery](#)
  - [Determining the Optimal Duration of Medication Treatment](#)
  - [Optimizing Care for People with OUD along With Other Mental Health Conditions](#)
- Translation of Research to Practice for the Treatment of Opioid Addiction, including:
  - [The HEALing Communities Study](#)
  - [The Justice Community Opioid Innovation Network](#)
  - [Enhancement of the National Drug Abuse Treatment Clinical Trials Network](#)
- Clinical Research in Pain Management, including:
  - [The Early Phase Pain Investigation Clinical Network \(EPPIC-Net\)](#)
  - [The Acute to Chronic Pain Signatures Program](#)
  - [Back Pain Consortium Research Program](#)
  - [The Pain Management Effectiveness Research Network](#)
  - [Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing \(PRISM\)](#)
  - [An Integrated Approach To Pain and Opioid Use in Hemodialysis Patients](#)
- [Preclinical and Translational Research in Pain Management, including:](#)
  - [Discovery and Validation of Novel Targets for Safe and Effective Treatment of Pain](#)
  - [A Preclinical Screening Platform for Pain](#)
  - [Development of Novel Drugs and Human Cell-Based Screening Platforms to Treat Pain and Opioid Use Disorder](#)
  - [Optimizing Non-Addictive Therapies to Treat Pain](#)
  - [Translating Discoveries into Effective Devices to Treat Pain](#)
  - [Discovery and Validation of Biomarkers, Endpoints, and Signatures for Pain Conditions](#)

Dr. Baker also described crosscutting features spanning the broad spectrum HEAL Initiative projects, including a strong commitment to meaningful interactions with research participants, patients, and stakeholders, and a very progressive approach to sharing of and access to study data.

## Plenary Panel Discussion:

### Helping to End Addiction Long-Term: Understanding and Addressing Pain

**Moderator:** Walter J. Koroshetz, M.D., Director, National Institute of Neurological Disorders and Stroke (NINDS)

**Panelists:** Daniela Salvemini, Ph.D., Saint Louis University; Lynn L. DeBar, Ph.D., M.P.H., Kaiser Permanente Washington Health Research Institute; Dupelia Numa, Person with pain ; and Srinivasa N. Raja, M.B.B.S., Johns Hopkins University

## Introductions

In his introductory remarks, Dr. Koroshetz described the contribution of opioid prescribing to the current crisis. He highlighted the [NIH Pain Consortium](#), and described new HEAL pain research focus areas including: developing and validating new targets for pain therapeutics; developing

biomarkers for pain conditions; large-scale compound screening using human cells; establishing a nationwide clinical trials network for pain; pragmatic and implementation studies for pain management; and understanding the transition from acute to chronic pain. Dr. Koroshetz introduced the panelists, who spoke briefly about their involvement in the NIH HEAL Initiative:

- Dr. Salvemini described her interest in cellular mechanisms that drive the transition from acute to chronic pain states. She asserted that validation of targets will be the key to bringing new molecules forward, and the ability to test new molecules in well-defined patient populations through HEAL has the potential to exponentially catalyze the drug development process.
- Dr. DeBar spoke about the implementation research opportunities available through collaborations in a large health care system. She highlighted the complexities of pain patients and those with OUD, noting that both groups often have many comorbidities, making treatment challenging. Dr. DeBar emphasized that working across domains will help both health care providers and patients.
- Ms. Numa spoke about her experience as a patient with a pain condition and other health problems. She mentioned the complexity in trying new treatments, and expressed interest in participating in research studies, an option that should be communicated to patients.
- Dr. Raja described his work as a clinician-scientist running clinical trials and leading efforts to establish guideline therapy for neuropathic pain. He compared HEAL's systematic program to other sweeping research programs addressing questions that could not be answered by single-site studies.

## **Discussion**

The moderator opened up discussion with the panelists and with the audience about the challenges of pain treatment. Physicians were once encouraged to prescribe liberally but now feel hesitant to prescribe. Consequently, some patients in need of pain relief may be undertreated.

One of the challenges for pain management is balancing concerns about pain with concerns about addiction. Patients often fear the return of severe acute pain, and this can drive a perceived need for medication and can lead to opioid misuse. Stigma around addiction treatment can also stand in the way of patients requesting help to taper pain medications. There is a lack of effective screening tools and methods for provider-patient discussions about addiction risk. Developing these, along with risk profiles to aid clinicians, is a promising area of research.

Opioids are highly effective short-term analgesics, but for many pain conditions, opioids are not very effective, and lower-risk nonpharmacologic treatments are more effective for helping people regain function. There is a great need to develop new, safer and more targeted pain medications. Some molecules have gone into Phase 3 trials, but the results are not reported; to drive progress, it would help to make these data available. Multi-target drugs that might control pain and reduce the potential for addiction are also an important area to explore.

Other areas of future research identified by panelists include:

- Developing objective pain biomarkers to help guide physicians, including MRI screening
- Research on social determinants of health in the area of pain and addiction, including food and housing insecurity; development of a pharmacoeconomics data base
- Research on the transition from acute to chronic pain
- Preventive strategies, including research on children to determine if lifestyle habits can modify lifetime risk for injury and pain

## Plenary Panel Discussion: Helping to End Addiction Long-Term: Understanding and Addressing Opioid Use Disorder

**Moderator:** Nora D. Volkow, M.D., Director, National Institute on Drug Abuse (NIDA)

**Panelists:** Yasmin Hurd, Ph.D., Icahn School of Medicine at Mount Sinai; Jose Szapocznik, Ph.D., University of Miami; Diane J. Abatemarco, Ph.D., M.S.W., Thomas Jefferson University; and Gary Mendell, Shatterproof

Dr. Volkow observed that the tragedy of the addiction crisis has captured the nation's attention. The opioid crisis is the result of serious issues that arose from a fragmented system of health care, a misunderstanding of addiction and its treatment, and lack of knowledge about pain management. The NIH HEAL Initiative is an opportunity to strengthen diverse collaborative partnerships across NIH and with other agencies. By integrating many efforts under the HEAL umbrella, science can provide requisite knowledge and novel interventions can be made available. Dr. Volkow introduced the panelists who commented on their work to address the opioid crisis:

- Dr. Hurd described her interest in the molecular neurobiology of opioid and cannabinoid use. She stated that tetrahydrocannabinol (THC) affects opioid addiction vulnerability in a negative way, but cannabidiol (CBD) appears to do the opposite on animal models. Through the HEAL Initiative, she will conduct pilot studies to see whether these findings translate into humans.
- Dr. Szapocznik is developing clinical trials with communities and families, engaging family therapists and family therapy researchers. He said that many cost-effective interventions prevent or delay drug use, and pointed to a NIDA publication on [Preventing Drug Use among Children and Adolescents](#), and the National Academies of Science, Engineering, and Medicine [Collaborative on Healthy Parenting in Primary Care](#), and [Forum for Children's Well-Being](#).
- Mr. Mendell developed [Shatterproof](#), a national nonprofit organization dedicated to reducing stigma and helping people access treatment, following his son's death from overdose. Shatterproof has documented [eight national principles of care](#) for patients and providers.
- Dr. Abatemarco directs the [Maternal Addiction Treatment Education and Research \(MATER\)](#) which focuses on maternal addiction treatment and provides support for women to help sustain recovery. She emphasized the strength of women who seek treatment and the role poverty and stigma play as barriers to treatment for addiction.

### Discussion

The moderator opened by remarking that many models of prevention and treatment do not take socioeconomic determinants into account and noted that it will be important that HEAL do so. Panelists discussed the importance of considering psychosocial functioning, family education to support sustained recovery, and systems of skill-building for families. It was noted that mindfulness has been shown to reduce stress levels and help build relationships, and that this may be relevant for researchers in interactions with study participants.

Participants also discussed the need to build an evidence base from neurobiology for assessment of susceptibility to addiction. As the NIH HEAL Initiative is fostering collaborations across organizations and across disciplines, it would be helpful to foster an interest in neurobiology among all stakeholders, including patients. Changes in policy, education, and language will be key to helping people understand that addiction is a disease, and one that is treatable.

The necessity of evidence-based addiction treatment demands the ability to measure treatment quality, such as the [quality measurement system](#) that Shatterproof developed. There is also the potential for HEAL to address issues associated with a fragmented health care system.

## **Plenary Presentation: Data Sharing and Harmonization Across HEAL: Current and Future Plans**

Lawrence A. Tabak, D.D.S, Ph.D., Principal Deputy Director, NIH

Dr. Tabak shared with the audience the devastating effects of heroin he has witnessed in his own community, and as an endodontist and as Acting Director of NIDCR he is also aware of how pain affects people. As part of its response to the crisis, NIH intends to maximize the availability of publications and the sharing of underlying data for NIH-Supported NIH HEAL Initiative Research Projects. Dr. Tabak noted that data sharing is central to the NIH HEAL Initiative and listed the top three reasons researchers are reluctant: (1) “My data are too complicated, too sensitive, or too private”; (2) “Sharing costs too much time and money”; and (3) “It’s *my* data!” Dr. Tabak expressed confidence that working together, HEAL investigators will overcome these objections to data sharing.

## **NIH’s Strategic Vision for Data Science: Enabling a FAIR Data Ecosystem for HEAL**

Susan Gregurick, Ph.D., Associate Director for Data Science, and Director, Office of Data Science Strategy, NIH

Dr. Gregurick stated that HEAL clinical researchers reported the following data needs: (1) Access to standardized, cross-study data; (2) Information about other HEAL research projects in their region to avoid overlap between cohorts; (3) The ability to build synthetic cohorts across studies; (4) Data for studying comorbidity; and (5) Fully searchable and discoverable database for all HEAL data. She emphasized that HEAL data should be shared across studies and standardized to allow sharing across disciplines.

Dr. Gregurick outlined the FAIR principles to make data findable, accessible, interoperable, and reusable. She highlighted many options for sharing HEAL data. General repositories include [NIH Figshare](#) and HEAL repositories. HEAL will leverage FHIR® (Fast Healthcare Interoperability Resources) for genotypic and clinical research data. Other platforms are available for sharing data that require greater security controls. She explained that HEAL data will be standardized in the data management centers and made available to all stakeholders, including the research community, patients, and advocates.

## **Discussion**

In response to audience questions, the speaker explained that harmonizing and accessing data from projects funded by other federal agencies is a long-term goal. She also explained that NIH will develop language around data storage and sharing, confidentiality, and privacy of data for consent documents that ensures that potential participants will not be discouraged. She added that the National Library of Medicine is working on common data elements and leveraging FHIR to generate usable datasets so that data are usable across disciplines.

## **Group Discussions: Data Sharing and Harmonization Across HEAL: Implementation Challenges**

During this discussion session, meeting participants divided into four groups: (1) Therapeutics Development; (2) Basic Science of Pain and Opioid Use Disorder; (3) Clinical Trial: Phase 2 and Effectiveness Trials; and (4) Clinical Research: Implementation and Sustainability. The groups’ discussion points were presented during the second day of the meeting.

## **Cross-cutting Topic Breakout Sessions**

During the breakout session, meeting participants divided into five groups. The groups’ discussion points were presented at the end of day two of the meeting.

## **Plenary Panel Discussion: Reporting from the Front Lines on Pain and Addiction: Perspectives from National Reporters**

**Moderator:** John T. Burklow, Associate Director for Communications and Public Liaison, NIH

**Panelists:** Lenny Bernstein, The Washington Post; Jon Hamilton, National Public Radio (NPR); and Lauran Neergaard, The Associated Press (AP)

Mr. Burklow introduced the panelists and said the goal of the session was to learn about the stories the reporters are working on and how they are dealing with the rapidly changing world of journalism.

- Ms. Neergaard said she had worked on several intriguing stories in the past year on pain and addiction. She spoke about the challenges a teenager faced in getting doctors to pay attention when she was in pain, and a [story](#) about an app to detect overdose.
- Mr. Hamilton discussed a story he did about the incomplete science of pain and another story that focused on the intersection of the pain community and the addiction community.
- Mr. Bernstein has covered the opioid crisis since 2015, beginning when economists [Anne Case and Angus Deaton](#) published their paper on “diseases of despair.” Mr. Bernstein has written about opioids from many perspectives and those stories led him study the topic of chronic pain.

### **Discussion**

The panel discussion highlighted the important role the media has played in the opioid crisis, including revealing the story of overprescribing of opioids as one of its drivers. The media helps communicate messages that otherwise would not be heard.

Panelists from media outlets noted that the bar for reporting on research is high and going higher. The press is seeking stories about research that can change readers’ lives, so AP reporters are interested in research that affects the general public.

The media often focus on the sad side of addiction. Stories about how research is revealing how the brain functions and how people work their way through the disease may be more inspiring. Reporters can try to find new angles, including the NIH HEAL Initiative and stories of success in research and in recovery.

For their part, scientists should consider the importance of engaging effectively with the media. When researchers engage with reporters, it is important to let them know about facts or context that would help readers understand or engage with the story. Researchers should also speak in plain English so their quotes can be included. The panelists also emphasized the importance of visual images, and stated that professional photographers, videographers, and producers manage the imagery. It is helpful when researchers provide excited images or videos, especially for lab-based research.

Researchers can also help reporters use accurate, non-stigmatizing language, since terminology preferences are constantly changing. The AP stylebook editor is also receptive to suggestions from scientific experts.

January 17

## Plenary Panel Discussion :

### Collaborating for Success: Federal Partners in HEAL

**Moderator:** Francis S. Collins, M.D., Ph.D., Director, NIH

**Panelists:** Elinore F. McCance-Katz, M.D., Ph.D., Assistant Secretary for Mental Health and Substance Use, SAMHSA; Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, FDA; Kimberly Brandt, J.D., Principal Deputy Administrator for Operations, CMS; and Debra Houry, M.D., M.P.H., Director, National Center for Injury Prevention and Control, CDC

Dr. Collins said that this session is a chance for the HEAL investigators to hear from leaders in the federal government about what their agencies are doing to address the opioid crisis.

- Dr. McCance-Katz described SAMHSA's primary mission to address the nation's substance misuse and mental health issues, ensuring that states are utilizing evidence-based approaches. Its work includes: epidemiology, prevention, treatment, recovery support services, training, stigma reduction, and public education. SAMHSA is also partnering with NIH on the HEALing Communities Study. She thanked everyone for their support of this important work.
- Dr. Woodcock said the FDA commissioned a [report](#) on evidence-based prescribing from the National Academies of Science, Engineering, and Medicine (NASEM). FDA will include information from that report in guidelines for prescribing opioids for common conditions and guideline for addressing both acute and chronic pain. Based on FDA guidance, better information about tapering was added to drug labels to help people avoid withdrawal symptoms. FDA also released [guidance](#) for developing new depot buprenorphine and is establishing an opioid data warehouse.
- Ms. Brandt said that CMS uses all the great work accomplished by federal agencies to determine how CMS — the world's largest health insurer — can make sure that people have access to the best possible alternatives to help prevent and treat OUD. CMS is focusing on three main areas: preventing OUD, expanding access to OUD treatment, and using the large volume of CMS data to target prevention and treatment. Effective October 1, 2020, states will be required to cover medication-based treatment for OUD. Ms. Brandt invited the HEAL investigators to navigate to [Data.CMS.gov](#) and [ResDAC.org](#) to access CMS data, including from Medicare, Medicaid, and Medicare Advantage.
- Dr. Houry stated that CDC focuses on public health, prevention, and the intersection with clinical medicine. CDC has [five main strategies](#) for its opioid work: (1) Conducting surveillance and collecting timely data to support action; (2) Building state, local, and tribal capacity to address OUD; (3) Supporting providers, health systems, and payers; (4) Partnering with public safety; (5) Empowering consumers. CDC's collaboration with the NIH HEAL Initiative has great potential and additional priorities include prevention efforts and expanded surveillance to include all drug overdoses.

### *Overarching Goals for Treatment and Prevention*

Dr. Collins asked the panelists about their vision for the future. Dr. McCance-Katz said that SAMHSA has a major focus in educating stakeholders and recently updated its treatment locator ([FindTreatment.gov](#)). Drs. McCance-Kate and Collins urged HEAL investigators to inform their state government officials about the necessity of medications to treat opioid use disorder.

### *Guidelines on Opioid Prescribing Practices*

Dr. Houry said that CDC issues guidelines for clinicians. They are not regulations but are based on the Agency for Healthcare Research and Quality's (AHRQ) systematic reviews that pool evidence. As CDC looks to expand and update its guidelines. Ms. Brandt said that CMS cannot

regulate, but can strongly encourage, guide, and direct the ways that it wants to see states use their resources.

### ***Approval and Reimbursement for Nonpharmacologic Interventions***

Dr. Collins said that the NIH HEAL Initiative has much invested in coming up with alternatives to opioid treatment for pain. He asked the panelists about alternatives to opioids and the path to approval and reimbursement. Dr. Woodcock said that for alternative interventions to be approved, FDA requires studies with endpoints tracked over time. Dr. Collins noted that one of the HEAL projects involves working with CMS on a study of acupuncture for chronic low back pain.

### **Discussion**

The issue arose of organizations that claim to provide medications for OUD, but that do not provide FDA approved medications, or do not provide them in an evidence-based manner. While SAMHSA does not think these facilities should qualify as providing medications for OUD, individual states, not SAMHSA, contract with individual providers. Groups that do not provide medications themselves cannot receive SAMHSA funding unless they are partnered with a program that does. Coverage for contingency management was mentioned: the Office of the Inspector General has said that small amounts of goods and services or cash under \$75 a year for contingency management protocols is acceptable, and SAMHSA allows states to use contingency management with their block grant funds.

### **Plenary Panel Discussion:**

#### **Understanding Stigma and the Impact on Public Health**

**Moderator:** Joshua A. Gordon, M.D., Ph.D., Director, National Institute of Mental Health

**Keynote Speaker:** Vice Admiral Jerome M. Adams, M.D., M.P.H., Surgeon General of the United States

**Panelists:** Travis N. Rieder, Ph.D., Johns Hopkins University; and Valerie A. Earnshaw, Ph.D., University of Delaware

#### ***Keynote Address***

The opioid crisis is a very important and personal topic for VADM Adams whose younger brother is in prison for crimes he committed to support his addiction. For years, Phillip had unrecognized and untreated mental illness. Phillip faced stigma about his mental illness and, to self-medicate, he turned to a variety of substances, including opioids. VADM Adams shared this story to show that any family can be touched by addiction; in his case, the same household raised both a Surgeon General and a person with OUD. VADM Adams said that the NIH HEAL Initiative will make an impact by reducing stigma.

#### ***Valerie A. Earnshaw, Ph.D., University of Delaware***

Dr. Earnshaw said that stigma can undermine prevention efforts and she highlighted three shortcuts to incorporating stigma science into the NIH HEAL Initiative: Use (1) existing stigma theory to understand how bias affects care providers and creates barriers to treatment initiation; (2) scientifically and theoretically validated measures of stigma; and (3) a stigma intervention toolkit. She also pointed to NIH's special [collection](#) of crosscutting approaches to stigma research.

#### ***Travis N. Rieder, Ph.D., Johns Hopkins University***

Dr. Rieder spoke from the perspective of a bioethicist experienced in stigma around addiction and pain. Following a motorcycle accident, Dr. Reider received prescriptions for opioids and became dependent. His health care providers did not know how to help him taper and advised him to stop abruptly. While going through withdrawal, Dr. Rieder then experienced stigma from his physicians. By telling his story, he aims to help people understand that OUD is a disorder.

### **Discussion**

The keynote speaker said that aggressive action needs to be taken now to end stigma, noting that stories can help people understand that addiction is not a moral failing or a choice.



Panelists affirmed that story sharing is a type of contact-based intervention that can help end stereotypes—resources for story sharing in stigma reduction can be found at this [website](#).

People living with SUDs often are not suffering from a single source of stigma, but several. Intersectionality theory highlights how co-occurrence of stigmas leads to different experiences and different effects on people's health. For HEAL research purposes, analytic strategies exist to deal with intersectional stigma in interventions. Using nonsigmatizing language is crucial, although it can be hard to change habits, including in community justice and criminal justice partners. Another challenge is that interventions to prevent stigma carry a high risk of promoting and exacerbating disparities.

### **Data Sharing Discussion Summary**

Dr. Baker summarized the previous day's small-group discussions on data sharing, saying that several important points emerged: (1) A portfolio analysis will likely reveal commonalities among trials and identify overlaps; (2) Data standardization should integrate measures from both pain and OUD research communities; (3) A need exists for uniform guidance for data collection across HEAL studies; and (4) Focus groups could address data harmonization challenges.

### **Crosscutting Topic Breakout Session Summary**

#### ***Translating from Basic to Clinical Research***

**Moderator:** Walter J. Koroshetz, M.D., Director, NINDS

Jack B. Stein, Ph.D., M.S.W., Director, Office of Science Policy and Communications at NIDA and NIDA Chief of Staff, presented major themes identified by the group: (1) NIH should provide more technical assistance to help researchers transition a compound from experimental stages, through IND approval, to NIH clinical trials; (2) There is a need for broader understanding of the science of translation, and the participants had concerns about the relevance of model systems to humans; and (3) Information about failed trials should be made available through data sharing.

#### ***Overcoming Challenges in Therapeutics Development***

**Moderator:** Donald C. Lo, Ph.D., Director, Therapeutic Development Branch, NCATS

Linda Porter, Ph.D., Director, NINDS Office of Pain Policy, said the group expressed difficulties scaling up research for the next stage of development and noted that HEAL investigators could benefit from: (1) Rapid screening of small molecules in small-scale studies; (2) Assistance with IND procedures; (3) Access to the NIH's drug development programs to provide resources in the medicinal chemistry space to help HEAL investigators conduct studies at lower cost; and (4) Better screening using relevant high-throughput or behavioral models; (5) Specific preclinical models that are predictive of particular types of pain and SUDs; (6) Development of pharmacogenomic strategies and biomarkers.

#### ***Integrating Co-Occurring Conditions into HEAL Research***

**Moderator:** Helene M. Langevin, M.D., C.M., Director, National Center for Complementary and Integrative Health (NCCIH)

Dr. Langevin reported that the breakout group shared information about their collaborations and interest in a rich array of co-occurring conditions. They discussed using an array of multimodal interventions that address more than one component, contributing to our knowledge of how conditions progress together.

#### ***Assessing Pain and Risk for Opioid Use Disorder***

**Moderator:** Robert H. Carter, M.D., Acting Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

Dr. Baker presented the highlights of the breakout group's discussion, which reflected the larger dialogue about integrating pain research with addiction research and the progression from opioid use to misuse to addiction. Addiction researchers could benefit from asking questions about pain, and vice versa. Valid methods are needed, and data sharing will be helpful.

### ***Incorporating Stakeholder Input***

**Moderator:** Diana W. Bianchi, M.D., Director, *Eunice Kennedy Shriver* National Institute of Child Health and Development (NICHD)

Dr. Bianchi shared the group's thoughts on working with different types of stakeholders. Some challenges for HEAL researchers include: (1) Ensuring that consent forms are understandable to people with low literacy; (2) Overcoming potential challenges related to gathering disparate groups together; and (3) Consistently using thoughtful language to reduce stigma. Solutions might include providing online resources that would allow people to share their experiences and connect with researchers.

### **Meeting Summary: Future Challenges and Priority Areas**

Rebecca Baker, Ph.D., Director, NIH HEAL Initiative, Office of the Director, NIH

Dr. Baker presented a list of HEAL expert workshops scheduled during the spring and summer of 2020 and noted that NIH has issued a new set of HEAL [funding opportunity announcements](#). In closing, she asked for suggestions about future meeting topics and thanked the meeting organizers, and NIH HEAL Initiative teams, and the HEAL investigators.

### **HHS Response to the Opioid Crisis**

Alex M. Azar II, Secretary, U.S. Department of Health and Human Services (HHS)

Dr. Collins introduced Secretary Azar as a proven leader with a commitment to and a personal interest in the opioid crisis and the NIH HEAL Initiative. Secretary Azar expressed his gratitude to attendees and the NIH HEAL Initiative which faces the challenge of providing Americans with solutions to pain and the opioid crisis. He relayed that President Trump is committed to ending the opioid crisis and HHS is focusing on financing of care, deriving better value from that care, and tackling specific, impactable health challenges. He assured the HEAL investigators that their work will save lives.

### **Closing Remarks**

Francis S. Collins, M.D., Ph.D., Director, NIH

Dr. Collins expressed his confidence that the HEAL investigators can meet the challenge presented by Secretary Azar and save American lives. This research initiative is unprecedented in terms of the size of the team and the timetable for getting projects funded and underway. The NIH team stands ready to serve as advocates and supporters of the researchers. The meeting ended with a song: "If not now, tell me when" ([hyperlink to video](#))