

***Eunice Kennedy Shriver* National Institute of Child Health and Human Development
Division of Intramural Research
BOARD OF SCIENTIFIC COUNSELORS
MINUTES
June 7, 2019
Building 31, Room 2A48**

Members Present: Dr. Scott A. Rivkees (chair), Dr. Kate Ackerman, Dr. Elizabeth Bonney, Dr. Serdar Bulun, Dr. Frances Jensen, Dr. Ursula Kaiser (nominee), Dr. Kojo A. Mensa-Wilmot, Dr. Yoel Sadovsky, Dr. Eric Vilain, and Dr. Martha Werler.

Federal Employees Present: Dr. Constantine A. Stratakis, Dr. Garcia-Perez, Dr. Chris McBain, Mrs. Francie Kitzen, and at various times additional members of the NICHD staff participated in the meeting.

OPEN SESSION

The meeting convened at 8:00 a.m. Dr. Stratakis started by saying that the agenda for this meeting would be different than previous meetings, as Dr. Bianchi, Director, NICHD, would not be able to join the meeting in person, however she recorded a video message for the group.

Dr. Stratakis welcomed new BSC member to the group, Dr. Kaiser. He presented outgoing member, Dr. Sadovsky, with a certificate and thanked him for his years of service on both the BSC and as a member of the 2012-2013 Blue Ribbon Panel. This would have also been the last meeting for Dr. Susan Taylor, who unfortunately wasn't able to be present.

Dr. Stratakis introduced Dr. Bianchi's video message.

Director's Report

Dr. Bianchi noted that she was not able to attend the meeting as she was at the Trisomy 21 Research Society meeting representing NIH and the INCLUDE project as well as her lab, where they were presenting five posters. She provided an outline of her talk which included updates on the FY2020 appropriations, the NICHD Strategic Planning, NICHD and trans-NIH research initiatives, and on NICHD and NIH staff.

Dr. Bianchi testified at the FY2020 House appropriations hearing along with Drs. Francis Collins, Tony Fauci (NIAID), Gary Gibbons (NHLBI), Douglas Lowy (NCI), and Nora Volkow (NIDA). During the hearing, she fielded questions about maternal mortality, the Task Force on Research Specific to Pregnant and Lactating Women, newborn screening, postpartum depression, and on what NIH is doing regarding pediatric research. Dr. Bianchi noted that there is strong bipartisan support expressed for NIH funding. The House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies marked up a bill that included \$41.1 billion

for NIH, an increase of ~\$2 billion over the FY2019 budget; \$1.580 billion for NICHD, representing an ~\$80 million over FY 2019's budget; and \$12.6 million for Gabriella Miller Kids First program. The House Appropriations full committee markup occurred on May 8, and the Senate schedule had yet to be determined.

The NICHD has been involved in its strategic planning process for the last year and a half. The goals are to identify where NICHD should lead, where NICHD should partner and participate, and to inform future investments in research, training, and infrastructure. At the core of the process have been the principles of transparency, decisions informed by evidence, and stakeholder participation. Input has been sought from the NACHHD (Advisory) Council, Friends of NICHD, and a Working Group of NICHD staff and external experts. Decisions have been informed by evidence that included a portfolio analysis, a review of prior NICHD/NIH strategic plans, internal scientific research plans, and a bibliometric analysis of the portfolio. Following all of that input, themes were drafted and released for public comment in early 2019. NICHD staff is working to refine the themes and incorporate the feedback, in preparation to submit the final strategic plan in fall 2019. The strategic plan can be thought of as a weaving, with “warps” corresponding to scientific priority areas and “wefts” referring to concepts that are woven or embedded in all priority areas, such as global health, health disparities, infectious diseases, nutrition, prevention, and inclusion of NICHD's focus populations. The themes proposed in the Request for Information (RFI) included understanding early human development, setting the foundation for a healthy pregnancy and lifelong wellness, promoting gynecological, andrological, and reproductive health, identifying sensitive time periods to optimize health interventions, improving health during the transition from adolescence to adulthood, and ensuring safe and effective therapeutics and devices. NICHD considered the feedback and is refining the themes to provide clearer explanations for a number of items in the final plan. This information will be shared internally and with the Advisory Council before the institute moves to an implementation phase over the summer. Revised mission and vision statements will also be presented. The final strategic plan will be published by September 2019.

Dr. Bianchi shifted to NICHD and trans-NIH research initiatives. Dr. Bianchi along with Drs. Stratakis and Forbes Porter, NICHD Clinical Director, have been visiting local institutions to explore collaboration opportunities. Recently they toured the Children's National Health System Research and Innovation campus, which is under construction on the site of the old Walter Reed and Armed Forces Pathology Institute. The campus is envisioned as an innovation hub for the development of pediatric devices and the site of the pediatric genomic and precision medicine group. They also visited the Howard University Hospital to explore potential collaborations in maternal and neonatal health and in pediatrics. As a result of that visit, Dr. Tatiana Sanses, the Director of Public Medicine and Reconstructive Surgery at Howard, now has an adjunct appointment with the DIR's gynecology program to explore opportunities to expand the research aspects of pelvic floor disorders in the NIH Clinical Center. Drs. Bianchi, Stratakis, and Porter also visited the Inova Fairfax Hospital.

Helping to End Addition Long-term (HEAL) is a trans-NIH initiative launched in April 2018 to provide scientific solutions for the opioid crisis by improving prevention and treatment strategies for opioid misuse and addiction and enhancing pain management. There are 12 NIH ICs leading 26 HEAL projects involving 20 collaborating institutes, centers, and offices spanning from

prevention to basic and translational research, clinical trials, and implementation science. The initiative has a budget of \$500M/year and over \$850M will be obligated in FY19. More than 40 funding announcements will be released in FY19, with NICHD involved in more than half. There are six major focus areas, with clinical research in pain management and enhanced treatments for affected newborns being of particular interest for NICHD. Advancing Clinical Trials in Neonatal Opioid Withdrawal, ACT NOW, will include two clinical trials studying medical treatments for infants with NOWs as well as non-pharmacologic approaches as well as a multi-center prospective cohort study of infants exposed to opioids in utero compared to unexposed infants. Other programs NICHD is involved in include the back-pain consortium (BACPAC); the Pragmatic and Implementation Studies for the Management of Pain (PRISM); efforts to discover and validate biomarkers, endpoints, and signatures for pain conditions that affect our populations; and the Pain Management Effectiveness Research Networks and Trials, which are phase 3 trials for an array of pain conditions.

Another public health crisis NICHD is focused on is maternal mortality. A recent CDC analysis published in May 2019 showed that about 60 percent of the approximately 700 maternal deaths per year in the U.S. are preventable and the data confirmed that there are persistent racial disparities. Obstetric emergencies were the cause of most of the deaths at delivery. Heart disease and stroke accounted for more than one-third of maternal deaths, and cardiomyopathy is the leading cause of death from one week to one year postpartum. The CDC has been emphasizing that maternal death can occur up to a year following delivery which is extremely important since approximately half of pregnancies in the U.S. are supported by state Medicaid programs, with coverage ending 60 days after delivery. NICHD is sponsoring a series of meetings aimed at updating the research agenda on maternal mortality. On April 8, 2019, the *Community Engagement Forum on Improving Maternal Health* was held in which community-based and healthcare provider groups discussed community engagement strategies to improve maternal health, with more than 400 participants. That meeting was followed on May 2-3 by a workshop on *Maternal Mortality in the United States: Future Research Directions* to develop a research agenda to address maternal mortality. Discussions included data quality and trends, disparities, social determinants, and clinical causes. In addition, NICHD is sponsoring a study by the National Academies of Sciences, Engineering, and Medicine on choice of birth settings including risk factors, social determinants that influence risk, and maternal health outcomes, with recommendations expected in 2020. Another workshop will be held in 2020 to discuss a research agenda for how to deal with the comorbid conditions, such as obesity, hypertension, and diabetes, that increase a woman's risk of serious morbidity or death.

The Medication Taken by Pregnant and Lactating Women (PRGLAC) Task Force submitted their recommendations to the Department of Health and Human Services (DHHS) in September 2018. There were 15 recommendations including: changing the existing culture which has limited scientific knowledge of therapeutic product safety, effectiveness, and dosing for pregnant and lactating women, thus protecting women through research rather than from it, and removing pregnant women as a vulnerable population through the Common Rule; expanding the workforce of clinicians and researchers with expertise in obstetric and lactation pharmacology and therapeutics; and removing regulatory barriers. The charter was extended until March 2021 and working groups have been established to make recommendations on how to implement the plans.

The INCLUDE project (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE), is a new trans-NIH initiative which was included in FY18 budget legislation to investigate conditions that affect individuals with Down syndrome and the general population. The project will address key quality of life issues through (1) targeted high-risk, high-reward basic science studies on chromosome 21; (2) assembling a large study population of individuals with Down syndrome; and (3) including individuals with Down syndrome in existing clinical trials. The idea is to provide a unique double benefit to understanding both Down syndrome and shared common conditions that either provide risks or resiliencies. NIH awarded \$22.2M in FY18 and NICHD issued four FOAs in FY19, with awards expected in September. NICHD is currently developing workshops related to these goals and will be leveraging the existing NICHD Pediatric Trials Network to establish infrastructure for Down syndrome clinical trials as well as developing training programs on effective ways for practitioners to work with populations of people who have intellectual or developmental disabilities.

The Gabriella Miller Kids First Program was launched in 2015 and is co-supported by NICHD, NHLBI, and NHGRI as a largescale data resource to help researchers uncover new insights into the biology of childhood cancer and structural birth defects. Whole genome sequencing of cohorts is provided by Kids First sequencing centers and these well-curated clinical and genetic sequencing data are a publicly available.

NICHD is very committed to making resources publicly available. The Data and Specimen Hub (DASH) is a centralized resource for researchers to store de-identified data and to access data and associated biospecimens from NICHD-supported studies. To date, 133 studies have been uploaded on 35 different study topics, including eight offering biospecimen. DASH has received 136 data requests, resulting in 15 publications from this secondary analysis so far.

Dr. Bianchi concluded her presentation with a couple of staff updates. Dr. Elizabeth Baden joined the NICHD Office of the Director as Chief of Staff from the NIH Office of Science Policy and is already involved in a number of trans-NIH and trans-NICHD initiatives. Dr. Debara Tucci has been named Director of the National Institute on Deafness and Other Communication Disorders (NIDCD). With the addition of Dr. Tucci, 10 out of 27 of the IC directors are now women. Several other IC director recruitments are ongoing.

Dr. Bianchi thanked the BSC for their time and for listening to this presentation. BSC members were invited to write down any questions they had for Dr. Bianchi to address by email. A propos of the budget proposal in Congress to provide ~\$80M increase in FY20 to NICHD, Dr. Stratakis noted that it is just hypothetical at this point and the institute is also preparing for the possibility of being on a continuing resolution at the start of FY20. However, if NICHD does receive increased funding in FY20, both extramural and intramural are likely to benefit as they did with the increase in FY19.

Scientific Director's Presentation

Dr. Stratakis began his comments by noting that this is his 10th year reporting to the BSC as Scientific Director and thanked the members of the committee for their hard work and dedication to our staff and mission. Dr. Stratakis expressed his gratitude for the support he is receiving from the BSC and said that he is looking forward to working with the BSC for years to come.

Two members of the BSC are rotating off: **Dr. Yoel Sadovsky** and **Dr. Susan Taylor**. New members have been recruited: Dr. Stratakis welcomed **Dr. Ursula Kaiser**, Chief of the Division of Endocrinology, Diabetes, & Hypertension and Co-Director of the Brigham Research Institute at Brigham and Women's Hospital. Four new members will join the December 2019 BSC meeting: **Dr. Hugo Bellen**, Professor of Molecular and Human Genetics and Neuroscience at Baylor College of Medicine; **Dr. Nancy Carrasco**, CNH Long Professor of Cellular and Molecular Physiology at Yale School of Medicine; **Dr. Ellen Grant**, Director of the Fetal-Neonatal Neuroimaging and Developmental Science Center at Boston Children's Hospital; and **Dr. Errol Norwitz**, Chair and Louis E. Phaneuf Professor of Obstetrics and Gynecology at Tufts University School of Medicine.

Dr. Stratakis reviewed the tasks of the BSC, including the main one which is to evaluate the research of NICHD DIR, our investigators, cores, and programs, and advise institute leadership on programmatic decisions and resource allocations. Dr. Stratakis stated that the goal of the intramural program is to promote high-risk, high-impact laboratory and clinical investigations, especially those that could not be readily supported in the extramural environment. The BSC meets twice a year, each June and December, to review site visits and advises us on the career course of our tenure-track investigators on an ongoing basis. The review policy is outlined in the NICHD DIR Guidelines for Site Visit Reviews.

Dr. Stratakis reviewed the NICHD DIR's organizational structure. Investigators are organized into six building hubs based on areas of science. This was possible following a years-long effort concluding in 2019 to consolidate investigators from 14 buildings down to six, providing new or renovated space to more than 80% of the labs. All investigators are organized in 13 self-selected intellectual affinity groups. With the reorganization in October 2015, investigators now report directly to the Scientific Director for budgetary and other issues. An important group for how the NICHD DIR functions is the Group of Senior Advisors (GSA). This group consists of Associate Scientific Directors (ASDs), most of whom head one of the building hubs. In addition, the GSA includes **Dr. Mary Dasso**, who serves as the ASD for Budget and Administration; **Dr. Tracey Rouault**, the ASD for Recruitment, Retention, and Diversity; **Dr. Chris McBain**, Deputy Scientific Director; **Dr. Forbes Porter**, Clinical Director of NICHD; **Ms. Francie Kitzmiller**, Deputy Director for Administration & Budget; and **Ms. Sara King**, Chief of Staff of the Office of the Scientific Director. Memberships of the GSA and affinity groups were presented. ASDs may serve up to two consecutive four-year terms and all of the ASDs are approaching the end of their first term so Dr. Stratakis noted that he would be reaching out to the BSC for their input on the renewals. NIH is also working on a policy that will affect branch/laboratory chiefs and their equivalents so we will be working to ensure the ASD terms and renewal process are in line with the new policy.

In FY18, the DIR represented 14% of NICHD's total budget. Of the approximately \$194M the DIR received for FY19, approximately 26% is allocated for lab consumables, 31% toward personnel, 20% toward the NIH Office of Research Services to cover buildings, maintenance, etc., and 16% was paid in support of the NIH Clinical Center. Smaller portions of the budget go to central support of animal care, capital equipment, IT support, renovations, and various contract agreements. In addition to the discussed DIR allocation, DIPHR has a budget of approximately \$9.8M. The space and renovation costs in FY19 are now much lower at approximately \$1M, as the years-long effort that began in 2012 to provide labs with new or completely renovated space winds down. The total effort cost approximately \$18M. Assessments for the Clinical Center and NIH Office of Research Services have been increasing from approximately \$63.6M in FY16 to \$70.3M in FY19. The Perinatal Research Branch, headed by Dr. Roberto Romero, is supported by a \$15.5M contract to Wayne State University in Detroit, MI, which will be up for renewal in 2022. The DIR is projecting to support approximately \$2M in capital equipment requests in FY19 but may be able to support more capital equipment if additional funds become available at the end of the FY.

The total number of DIR staff is 906, with 296 FTEs, and 610 non-FTEs which includes trainees and contractors. Hiring controls for FTEs across NIH remain in effect, reflected in the decline of the DIR's personnel. The trainee population, which is not affected by the controls, includes 191 postdocs, 76 postbacs, 51 summer students projected for 2019, 14 of graduate students, and 22 clinical fellows.

Dr. Veronica Gomez-Lobo has been recruited as a senior clinician to develop and head a Pediatric and Adolescent Gynecology Program as well as to help support the gynecological consult service at the Clinical Research Center (CRC). She is expected to start on July 1, 2019 and will present to the BSC later in the agenda. Dr. Fady Hannah-Shmouni has been recruited and will start June 24, 2019 as the new Co-chief for Internal Medicine and NICHD's Associate Program for the Inter-Institute Endocrinology Training Program. Dr. Hannah-Shmouni, graduated from the NIH Inter-Institute Endocrinology Training Program in 2017 and has since worked at Sick Kids at Toronto, with experience in genetics, endocrinology, pediatrics, and internal medicine. Dr. Marissa Lightbourne has been recruited as a staff clinician and Co-chief for Internal Medicine, starting in July 2019. Dr. Lightbourne is graduating from the Pediatric Endocrinology Training Program at the end of the month and is also trained in both pediatrics and internal medicine.

NICHD continues to support the Lasker Clinical Research Scholars Program. The goal of the program is to grow the diminishing pool of talented clinical/translational researchers. Candidates of the program are early stage clinical researchers with the ability to conduct independent research. Lasker Scholars are able to come to the intramural program to conduct research for up to five years, and then may be funded for an additional three years either in the intramural program or at their home institution. At the end of the program, Scholars may be recruited by the NIH Intramural Program as senior investigators.

Recent honors were highlighted. Dr. Meg Keil, Associate Director for Nursing and Protocol Navigation was selected for Fellowship in the American Academy of Nursing. Dr. Juan Bonifacio was elected to the American Society for Cell Biology and Dr. Forbes Porter was elected to the Association for American Physicians. Dr. Stratakis noted that a reunion of staff from the NICHD

Developmental Endocrinology Branch (DEB) in the 1980s-1990s took place during the 2019 Endocrine Society meeting in March 2019 to honor Dr. Lynn D. Loriaux, ex-DEB Chief who recently retired from University of Oregon (OHSU) after serving as their Chair of Medicine for more than 20 years.

NICHD DIR investigators continue to be successful in competing for funding. NICHD is the lead institute for the U-01 program, an effort to open up the NIH CRC to extramural investigators through collaborations with intramural researchers, about to enter its sixth cycle. BSC members were encouraged to advertise this program at their own institutions in an effort to have more extramural investigators take advantage of this program.

The NICHD DIR Director's Awards are in its third cycle. This competitive award was established following the recommendation from the 2013 Blue Ribbon Panel Report to foster new collaborations and support new research ideas. Applications are based on an R-21 and reviewed by a panel of NIH extramural reviewers, with successful awards receiving two years of funding. Approximately \$3.2M in awards were made to investigators in FY18-19, and the 12 successful applications were presented.

Investigators were also successful in competing for funding from the Office of AIDS Research (OAR). The OAR Strategic Funding provides funds to the highest priority, most meritorious, research aligned with the current NIH HIV/AIDS research priorities. Three DIR investigators received a total of more than \$1.1M in FY19: Drs. Leonid Chernomordik, Leonid Margolis, and Joshua Zimmerberg. OAR's Innovation Funding supports innovative, unanticipated, or unfunded applications that align with the NIH HIV/AIDS research priorities. A total of \$374K was awarded to three investigators in FY19: Drs. Anirban Banerjee, Henry Levin, and Leonid Margolis.

The NICHD Office of the Director also allowed intramural investigators to apply for funding through a couple of its initiatives. The Human Placenta Project seeks to improve current methods, and develop new technologies, for real-time monitoring of human placental development and function across pregnancy and to apply these technologies to understand and monitor, in real time, human placental development and function in normal and abnormal pregnancies. Three investigators from DIR and DIPHR received a total of \$229K in FY19 for studies with the potential to advance these goals: Drs. Amir Gandjbakhche, Todd Macfarlan, and Edwina Yeung. The Zika virus research award support studies with the potential to advance our understanding of Zika virus-related morbidity and how virus infection affects reproduction, pregnancy, and the developing fetus. A total of \$150K was awarded to three investigators in FY19: Drs. Leonid Chernomordik, Constantine Stratakis, and Joshua Zimmerberg.

NICHD continues to support its postdoctoral fellows in applying for K99 awards. This year, three fellows were successful: Dr. Marina Venero Galanternik (Weinstein lab), Dr. Amber Stratman (Weinstein lab), and Dr. Sarah Cohen (Lippincott-Schwartz/Bonifacino lab).

Dr. Stratakis then reviewed the activities of the Office of Education under the direction of Dr. Yvette Pittman. The Office of Education continues to support trainees at all levels through a variety of activities, including a monthly newsletter and an Annual Fellows Retreat.

The Office of Education, along with the Scientific Director, supports a number of initiatives to increase diversity. The Developing Talent Scholars program supported three recruitments at the postbaccalaureate level in 2019. Three new alumni from the program will start professional school in the fall with full scholarships. As part of the summer program, 10 centrally-funded students from groups traditionally underrepresented in science or from disadvantaged backgrounds were supported in 2019. The Fellows Recruitment Incentive Award, which supports fellows at the postdoctoral level, supported the recruitment of Dr. Velencia Witherspoon (Basser lab). NICHD also has four students supported by the NIH Academy Enrichment Program (NAEP) which supports trainees at the postbac level from diverse backgrounds to perform biomedical research while actively learning how to engage in eliminating health disparities. NAEP scholars participate in a customized curriculum as part of the NIH Academy as well as a leadership development plan. In addition, NICHD has a number of international collaborations for training including the NICHD-Inserm Exchange Program and the Future Researchers Program which supports medical students from the Santa Casa de São Paulo School of Medical Sciences (Brazil) to train with NICHD investigators. Postbaccalaureate fellow medical and graduate school acceptances were presented.

The Office of Education is continuing initiatives aimed at public speaking, teaching, and grantsmanship, and career counseling. The annual Three-minute Talks (TmT) Competition will be held on June 27, 2019 to promote the effective communication of science, with five institutes now competing. NICHD continues to monitor trainees through the online annual progress report system. The Intramural Research Fellowship is an award opportunity for NICHD DIR postdocs and clinical fellows which will provide training on how to write an NIH grant. Awards will be for \$30K for one year and applications are reviewed by the BSC. Finally, NICHD will be launching an online exit survey in October 2019 to track career outcomes for fellows and provide a comprehensive view of their training experiences.

Questions followed. A propos of how outcomes of the various funding opportunities are monitored, Dr. Stratakis noted that publications are monitored, and investigators are asked to include outcomes in their site visits.

Following a short break, Dr. Stratakis introduced Dr. Enrique Schisterman, to provide an update on DIPHR. Dr. Schisterman is Chief of DIPHR's Epidemiology Branch and was presenting in place of Dr. Una Grewal who could not be at the meeting.

Presentation on DIPHR

Enrique Schisterman, PhD, Chief, Epidemiology Branch, Division of Intramural Population Health Research, NICHD

Dr. Schisterman started by saying that this presentation on DIPHR would focus more on how the division functions internally than previous presentations to the BSC which focused on its research. He reviewed the mission of DIPHR, to conduct research leading to the promotion of population health and wellbeing. The division's vision is to be the leader for population health research focusing on successful reproduction, the health and well-being of pregnant women and their infants, and the optimal growth and development of children and adolescents across the lifespan.

They also work to realize the elimination of health disparities. DIPHR has 30 FTEs members organized into three branches and one program: the Epidemiology Branch, the Biostatistics and Bioinformatics Branch, the Social & Behavioral Sciences Branch, and the Contraceptive Development Program. The organizational structure was presented.

DIPHR's FY19 operating budget is approximately \$9.8M. The budget has remained relatively stable in recent years, though there was a notable increase in FY18 as a result of the expansion of the division to include the Contraceptive Development Program headed by Dr. Diana Blithe, which was previously part of NICHD's extramural program. In addition, DIPHR has a R&D budget of approximately \$14M which supports data collection and protocol implementation through contracts to extramural partners. Nearly half of that budget is for indirect costs.

Dr. Schisterman highlighted a number of historical discoveries made within the division since its establishment 52 years ago, including its contribution of a new method to calculate sample sizes for cohort and case-control studies in 1974. A study in 2005 provided evidence supporting misoprostol as an effective, safe, and acceptable medical treatment for miscarriage. More recently, in 2014, findings from the Upstate Kids Study concluded that infertility treatment is not associated with differences in children's growth or development through 3 years of age. The following year, the NICHD Fetal Growth Studies developed contemporary standards of fetal growth, and, in the process, confirmed variations in growth across race/ethnic groups, even for low-risk healthy pregnant women. Ongoing research studies were also presented which vary in scale, ranging from 259 women in the BioCycle study to over a quarter of a million for the Consortium on Safe Labor, and reflect substantial and crucial partnerships that DIPHR has established with the extramural community.

In contrast to the lab-based model of DIR, DIPHR's has a unique approach to research that emphasizes team science and team governance. DIPHR investigators do not have individual budgets but must compete internally for funding which incentivizes collaborative research where multiple PIs and trainees from across the branches are working on multiple questions within a study. To implement this team governance, an internal peer-review process is in place which is designed to evaluate new research and to ensure that only the strongest science goes forward. Any investigator can propose a new study either as an individual or a group, which is peer reviewed by the whole branch and then the whole division. Based on those comments, senior leadership and the DIPHR director set research priorities for the division, balancing the anticipated impact of the science with considerations of equity across PIs. The division has a number of core resources including a DCC contract to provide data management and data sharing support, core statistical programming and analysis, core biomedical analysis contract, and beginning in 2018 a contract for a multi-site population laboratory to build infrastructure for collective recruitment efforts.

Dr. Schisterman then presented on the impact of the divisions work, noting that productivity has increased over time. More than 650 articles were published by the group of 14 PIs between 2011 and 2016 covering a wide array of topics, with 22% of those articles in the top 10% in terms of citations. A propos of the BSC's previous recommendation that junior faculty focus on quality over quantity, Dr. Schisterman pointed out that four of the seven tenure-track investigators at DIPHR when the recommendation was made, had already gone on to successfully receive tenure. Another measure of impact is media dissemination. The 33 press releases during 2015-2019 have

a combined total of nearly 8 billion views. Awards, editorial board memberships, and society board memberships of division staff were presented, showing their impacts to their larger fields.

In 2017, DIPHR completed a division-wide strategic planning process. The institute's mission provided the overarching framework that resulted in the identification of four strategic goals: to (1) investigate the developmental origins of health and disease from preconception through adulthood including associated health disparities; (2) develop interventional research to promote health and disease prevention; (3) develop methods for leveraging existing cohorts; and (4) train and build a diverse team of population scientists. Dr. Schisterman used obesity as an example to demonstrate how these goals are reflected in the division's work. In addressing the etiology of this issue, they adopted a cohesive conceptual framework, thinking about obesity from both an inputs perspective (nutrition, behavior) and a physiological perspective (inflammation). DIPHR investigators have taken the lead in studying different aspects of this framework at each developmental stage over the life course, for example studying the impact of obesity and inflammation on the length of time to become pregnant at preconception, the effect of maternal obesity on fetal growth during pregnancy, the effect of parental obesity on early childhood development, and to adolescence and the pre-conception stage and intergenerational perspective as the adolescents grow up. Biostatisticians within DIPHR are actively working on the methodology to combine these cohorts in sequential order and synthesize all of these findings across developmental stages.

The Division has been in a period of transition since the retirement of Dr. Germaine Buck Louis, the former director, in September 2017. During this time of transition, the division has been moving forward with the implementation of its strategic goals with new research initiatives planned. DIPHR is also actively searching for a new chief of the Biostatistics and Bioinformatics Branch. We would like to have a worldwide leader that will come to NICHD as a scientific director for population health research, who plays a leadership role at not only the division-level but also the institute- and trans-NIH levels.

Questions followed. A propos of DIPHR's relationship with the population group in the National Institute on Minority Health and Health Disparities (NIMHD), Dr. Schisterman indicated that NIMHD's group is much smaller but that the investigators in each institute have collaborated on one another's studies and that he served on their strategic plan working group. In response to another question, DIPHR investigators are not currently taking advantage of some of the research patient-based databases at the state-level but are hoping to explore that avenue in the future. It was also clarified that the Contraceptive Development Program has its own fixed budget.

Scientific Presentations

Dr. Stratakis then introduced the next speaker, **Dr. Steven Coon**. The BSC had asked Dr. Coon to present on how the Molecular Genomics Core operates and the types of services and technologies it brings to the DIR.

Steven Coon, PhD, Molecular Genomics Core, NICHD

The Molecular Genomics Core (MGC) continues to grow and provide excellent sequencing services to the NICHD research community. As the core grows there are issues that need to be resolved to maintain the quality of service as demands increase. The BSC identified several of those issues as a result of last year's site visit. MGC is working to address those critiques/comments, as well as others; Dr. Coon presented solutions to these. For near-future large equipment replacement, MGC is communicating potential needs with the Office of the Scientific Director (OSD). Though not imminent, the OSD will cover the cost of the next generation of DNA Sequencer when the need arises. Regarding the sustainability of the current billing model and its long-term sustainability, the MGC is currently operating within the budgeted allocation. If the situation changes, the operating shortfall will be made up by an increased allocation from the OSD and a decrease in the subsidy provided to investigators for sequencing at the MGC. A more-detailed explanation of MGC finances was presented for clarification. To ensure that MGC is providing relevant quality and type of services, questionnaires for both immediate feedback and long-term strategic feedback are being implemented. The MGC is working with the recently hired Scientific Information Officer, Dr. Ryan Dale, and his team to maximize bioinformatic support for NICHD. The groups interact freely and meet formally every other week. Dr. Coon is also working with the SIO to streamline data storage and archiving pipelines and is considering instituting a LIMS system. Through careful consideration and implementation of these solutions, MGC will continue to provide valuable services to NICHD.

Questions followed. A propos of the MGC's request for a NovaSeq, Dr. Stratakis clarified that the request had not yet been approved or prioritized. It was also clarified that investigators do not necessarily have access to some of the facilities available to extramural investigators or those residing in other ICs. Rather than try to do everything, the MGC focuses on offering specialized "boutique" services to the DIR, with larger sequencing projects generally being outsourced. Regarding the funding model, MGC charges senior investigators 75% of the cost of the reagents and tenure-track investigators 50%, with the OSD subsidizing the remaining costs. The annual operating cost is approximately \$240K plus personnel salaries.

Following a short break, Dr. Stratakis introduced the next speaker, **Dr. Veronica Gomez-Lobo**.

Dr. Gomez-Lobo will be starting at NIH on July 1, 2019 to develop and head the Pediatric and Adolescent Gynecology Program. She is currently at Children's National Medical Center where she has been heading their pediatric gynecology program. In addition, Dr. Gomez-Lobo will work with Dr. Alan DeCherney to provide gynecological consult service at the CRC.

Veronica Gomez-Lobo, MD, Pediatric and Adolescent Gynecology Program

Dr. Gomez-Lobo reminded the BSC that she and Dr. Alan DeCherney had originally presented their vision to the BSC a year ago to create a comprehensive and innovative Pediatric and Adolescent Gynecology (PAG) program within the NICHD which leverages community clinical and research resources. This program will integrate regional clinical care with a post-graduate training program to populate primarily human clinical studies of

gynecologic disorders that begin before, during or shortly after puberty, to understand both childhood and adult gynecologic disease and fertility. Since a lot of pediatric gynecology is emergency based and surgically based, NICHD is planning to partner with Children's National Health Systems and MedStar. NICHD will recruit four clinical fellows, one in PAG and three in reproductive endocrinology. Children's National Health Systems is a large clinical site with expertise in complex pediatric care and clinical care will be covered by NICHD and MedStar PAG faculty. MedStar will be the clinical care site for adults with complex reproductive anomalies and will be supported by Dr. Lauren Damle of MedStar as well as one NICHD PAG faculty member.

MedStar Washington Hospital Center agreed to continue to support the PAG program during a one-year transition period, ending June 30, 2019. During this time, NICHD has hired a program coordinator, approval was obtained to transfer the fellowship to NIH, and sponsorship for the NRMP Match participation was changed for 2020. Two fellows will be starting in July 2019: Dr. Shashwati Pradhan and Dr. Allison Mayhew. One PAG faculty member, Dr. Tazim Dowlut-McElroy, has been recruited, with plans to recruit a second faculty member in 2020. In addition, Dr. Jacqueline Maher, an REI faculty member with an interest in PAG, was hired as a staff clinician to work with Dr. DeCherney to provide additional support to the program.

Dr. Gomez-Lobo then summarized some of her recent research relating to genital immunity and microbiome, oncofertility, and disorders of sex development as well as the work of Dr. Dowlut-McElroy and Dr. Maher. Going forward, Dr. Dowlut-McElroy would like to focus on Turner-Syndrome and Dr. Maher will be focusing her research efforts on looking at ovarian function in pediatric patients. Dr. Gomez-Lobo will be focusing her efforts on studying Androgen Insensitivity Syndrome and Mayer-Rokatahnski-Kuster Hauser Syndrome. Dr. Gomez-Lobo also sees the opportunity to add a gynecology component to some ongoing research at NICHD where it has been lacking and will be meeting with various teams to discuss these opportunities once she officially starts in July.

Questions followed. The BSC congratulated Dr. Gomez-Lobo on her vision and pointed to the need for more research in a number of pediatric and adolescent gynecologic areas. The BSC specifically pointed to the need for research supporting transgender medicine.

With that, the open session concluded.