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Fiscal Trifecta Very Much in Play

With the House Republicans agreeing to raise the U.S. debt limit, the immediate crisis of default has abated. However, the agreement only increases the limit through May 18, which could precipitate another crisis in the spring. In addition, the two-month postponement of the across-the-board (ATB) cuts or sequestration expires on March 1. Finally, the Continuing Resolution (CR), which is currently funding the government during these first months of fiscal year (FY) 2013, runs out on March 27.

Thus, as the euphoria of inauguration day fades and the President's State of the Union address looms on February 12, the above fiscal trifecta remains very much on the agenda. Another casualty of all of this is the FY 2014 budget, originally scheduled for release on February 4, in compliance with the Budget Control and Impoundment Act of 1974, which will get postponed possibly until mid-March.

Sen. Patty Murray (D-WA), the new Chair of the Senate Budget Committee, has announced that she will follow the other provision of the latest debt limit agreement and produce a Budget Resolution by April 15. In preparation for moving forward on this and other fronts, Murray has issued a Dear Colleague letter outlining where she believes deficit reduction has been and where it needs to go.

She asserts that over the past two years, the actions taken by the President and Congress have resulted in at least \$2.4 trillion of debt reduction. She declares that the next steps must include "equal amounts of responsible spending cuts and new revenue from the wealthiest Americans."

The analysis by the Senate Budget Committee staff notes that based on the deals made so far, discretionary spending has been reduced by \$1.5 trillion for fiscal years 2013 through 2022. An additional \$200 billion will come from interest savings. These reductions have resulted from "a series of Continuing Resolutions that cut spending by about \$550 billion over ten years" and from the implementation of the spending caps of the 2011 Budget Control Act (BCA). Murray proclaims that "the result of these cuts is that discretionary spending will fall to its lowest level as a share of the economy in over half a century."

In addition, most of those cuts have come from the non-defense side of the budget. The Committee analysis shows that defense spending under the FY 2013 CR is essentially frozen at the 2010 level. Nondefense discretionary funding has been cut by more than nine percent below 2010 spending.

The recently enacted American Taxpayer Relief Act (ATRA) of 2012, which raised rates on those making more than \$450,000 and made other changes to increase revenue from high-income taxpayers, should reduce deficits by more than \$600 billion over the next ten years and save another \$100 billion in interest costs.

Yet, sequestration still looms. Murray notes that: "If Congress doesn't replace the automatic, across-the-board cuts scheduled to occur under sequestration in a balanced way, the ratio of spending cuts to revenue increases would be 4:1." The sequester, as deemed by the BCA, directs \$1.2 trillion in spending reductions. These cuts are spread evenly over nine years, suggesting \$109.3 billion per year that are split evenly between defense and non-defense spending.

The ATRA affected how the sequester would work for FY 2013. It delayed its implementation by two months until March 1. Thus, the amount of necessary cuts was lowered to \$85 billion. The difference of \$24 billion is paid for with an equal mix of spending cuts and new revenue. The spending cuts are applied to the cap levels with a \$4 billion decrease for FY 2013 and \$8 billion in FY 2014.

The costs to the agencies of the ATB cuts have also been recalculated. The percentage reduction for nondefense discretionary spending decreases from 8.2 percent to 5.1 percent. Cuts to defense discretionary programs go down from 9.4 percent to 7.3 percent. However, for agencies this is not all a silver lining. Because the cuts will be applied later in the fiscal year, "the delay means that a smaller portion of the year's funding is available to absorb the cut." In addition, there are programs that are exempt from sequestration-- Veterans' Health Care, Pell Grants, and those affecting the poor. OMB has recently charged the agencies to provide more details on how they would absorb the sequester for FY 2013.

In dealing with the expiration of the CR, Murray indicates that the ATRA changed the nomenclature from defense and nondefense programs to security and non-security programs. This would necessitate some adjustments resulting from the reduction of the overall cap and this new division. At the moment, according to the Committee's analysis, the current CR's "security level" funding exceeds the limit for that category by \$7 billion. This would require another adjustment to avoid sequestration.

Therefore, Murray and her staff conclude that as we move forward "we cannot simply solve this problem [the deficit and debt] on the spending side alone." She further asserts, that "it would be tremendously unfair and unbalanced to ask sacrifice from the middle class and most vulnerable families, while the wealthiest Americans and biggest corporations continue to benefit disproportionately from the countless preferences embedded in the tax code."

She discusses the \$1.2 trillion in foregone revenue from these tax expenditures. At the same time, she points out that the ATRA projects a ten-year revenue average of 18.5 percent of GDP, not sufficient to produce a balanced budget, since the last five times that has occurred revenues ranged

between 19.5 and 20.6 percent of GDP.

Clearly, the House Budget Committee, as represented by the budget presented in previous years by its Chairman Rep. Paul Ryan (R-WI) has a different perspective. How this all gets worked out is still quite difficult to predict.

Collins Discusses Impact of FY 2013 Budget Process on NIH

At January 14th meeting of the National Institutes of Health's (NIH) Scientific Management Review Board (SMRB) meeting, director Francis Collins shared his frustration with the lack of a FY 2013 budget for the agency and the impact it is having for planning science and the morale of the agency staff.

In his director's report to the SMRB ([see related story](#)), Collins characterized the current budget situation as an "an odd time" for the NIH to "try to plan" because while the threatened fiscal cliff for January 2nd was averted, if sequestration happens he informed the SMRB, it will result in a "very serious loss of support for biomedical research." Collins noted that a potential sequester is "still very much out there," with March 1 as the next deadline. He remains hopeful "that there will be thoughtful ways to resolve the crisis."

Collins further explained that in this current fiscal year (FY 2013), he and the directors of the 27 institutes and centers "have no real certainty on what resources [they are] going to be able to invest." He lamented that it was "certainly not a stable way to manage something that has long term consequences for our nation." It is not an easy time to try to carry out the NIH's mission, he declared. At the same time, Collins stressed that "it is fair to say the science [the agency] support[s] is never more exciting so [NIH] will press on with that foremost in ... mind." His hope is that ultimately NIH will have the chance to see "something like a stable trajectory," which he underscored is "essential for the health of this particular scientific community which is very much under stress right now."

Collins also reviewed the SMRB's work and updated it on NIH's progress in implementing the various recommendations from the various [reports](#) that the Board has issued. Regarding the NIH Clinical Center, the recommendation that NIH establish a governing board to provide strategic oversight to deal with budget recommendations has been implemented. Collins also noted that the agency has applied the Board's recommendation that NIH make the resources of the clinical center, some of which are quite unique, available to extramural clinical investigators. Per that discussion, the agency issued a funding opportunity announcement on November 28, 2012, providing what he described as a "really remarkable and innovative way support for intramural and extramural collaboration." The deadline for applying is in March. The agency, however, Collins reported, continues to weigh the pros and cons of having the Clinical Center's budget funded via the line item in the appropriations bill, an issue of great discussion by the SMRB. He acknowledged that it is a "very complicated issue."

Collins also highlighted NIH's implementation of SMRB's recommendations regarding translational science including the creation of the new National Center for Advancing Translational Science (NCATS) and the appointment of a permanent director, Chris Austin. He acknowledged his excitement about the Center's creation and the science it is doing and emphasized that it is not substituting for the "translational science going on in all of the institutes, but providing a hub for activities and programs that otherwise didn't quite have a central home." He gave "much credit" to the SMRB for having gotten the agency "into a place where it can push forward this exciting agenda."

Concluding his report, Collins highlighted what he noted as being most relevant to the SMRB's agenda -examining the value of biomedical research -- the recently released National Academies' report, *U.S. Health in International Perspective: Shorter Lives, Poorer Health*, (see Update, [January 14, 2013](#)). The report compares health outcomes in the United States to other developed nations and the U.S. does not stack up particularly well across a wide range of health measures from birth to later life, Collins explained. He pointed out that there is no single problem or single solution suggested in

the report, "but it certainly provides a wake-up call to any who say our public health system is in perfect shape. We at NIH feel we have a lot to contribute to that in terms of providing the evidence about how to improve things." The report, Collins further noted, is also "worth looking at" because of the enormous economic costs of the health problem we have in the U.S. He declared that "research can improve individual health and those of families, communities but also save the economy from otherwise unnecessary expenses." "That's one more argument why [NIH] is a valuable investment of the U.S. government," he concluded.

NIH SMRB Begin Discussion of the Value of Biomedical Research

The National Institutes of Health (NIH) Scientific Management Review Board (SMRB) held its 14th meeting on January 14, 2013. The Board began a discussion of the SMRB's ensuing undertaking, examining the Value of Biomedical Research (VOBR). Led by Gail Cassell (Eli Lilly and Company), the VOBR Working Group will focus principally on the economic value of biomedical research, according to SMRB Chair Norman Augustine. Augustine pointed out that the economic value of biomedical research is "by no means the only value and [the SMRB] will address other issues such as quality of life...so on, subsequently."

In July, 2012, Collins [charged](#) the SMRB to "identify appropriate parameters and approaches for assessing and communicating the value of biomedical research (VOBR) supported by NIH." Specifically, the SMRB is asked to:

- Analyze current strategies for assessing the value of biomedical research, examining both national and international methodologies;
- Evaluate the strengths and weaknesses of both extant and potential approaches for evaluating the value of biomedical research; and
- Identify fundamental principles that should guide any comprehensive and rigorous approach for assessing the value of biomedical research.

Gilbert S. Omenn, Professor of Internal Medicine, Human Genetics, and Public Health at the University of Michigan, filling in for Cassell, stated that the working group envisions multiple chances to learn from a broad range of experts with different perspectives. He noted that a number of SMRB members are participating in the working group, reflecting an area of "high level interest."

Omenn noted that in the current scientific, political and economic environment it is important to identify "sound approaches to the value of NIH programs." He highlighted that the NIH receives significant amount of public funds by some metrics; in return, society expects tangible benefits.

The NIH mission, Omenn pointed out, should provide guidance to the study. That mission is: *To seek fundamental knowledge that enhances health, lengthens life, and reduces burden of illness and disability.* Metrics would need to include the status of health, life expectancy, and the burdens of illness and disability. The study would also require a subset of outcomes that represent the goals and activities of the agency, he suggested. Ascertaining biomedical research's value and identifying its broader effects on society, of which there are many, he proclaimed, are other areas for exploration. Acknowledging that there are many other actors, players and accomplices is another challenge, Omenn noted, in figuring out the contributions of research to health.

Another possible frustration, Omenn argued, is the complex process of incomplete application. If there is something that would have a great health benefit and reaches only half the intended population, the benefit is reduced by half. That is not necessarily attributable to the NIH. Furthermore, Omenn indicated that there is always a lag time from discovery to implementation, pointing to classic studies that show that the process for basic discovery and innovation to change in medical practice has a mean time of 17 years.

Attaching Value to R&D

SMRB heard presentations from William B. Rouse, chair of economics and engineering, Stevens

Institute of Technology; Andrew A. Toole, economist, Economic Research Service, U.S. Department of Agriculture; and Simon Tripp, senior director, Technology Partnership Practice, Battelle Memorial Institute.

Rouse, who is co-chairing the National Academies' (NAS) *Healthy America* initiative with Bill Stat (Vanderbilt), presented an effort he has been working on for many years: how to attach value to a research & development (R&D) portfolio. There the question is how to create the highest value healthcare system in the United States across all its components. The NAS committee with half its members from IOM and half from the National Academy of Engineering "wrestled quite a bit regarding what is actually its purpose," he explained. What it came up with was the notion that it had just one goal-- a healthy educated, productive population that is competitive in the global marketplace. So from that point of view the value issue is what's the importance of having a healthy educated, productive population that's competitive through the global marketplace? Hence, they are looking at economic issues quite broadly, Rouse explained.

The value focus therefore is on organizational outputs or outcomes, rather than inputs, and relates to the benefit of the outcomes rather than outcomes themselves. For example, said Rouse, it is nice to have journal articles and a knowledge base, but what's the benefit of doing that? A lot of the work within the National Library of Medicine is to make all this material useful, readable and understandable.

As far as characterizing value, Rouse indicated that he would view NIH as an R&D organization in the enterprise of the United States, maybe more broadly. He argued that what the NIH produces from a scientific technology point of view is options. These options are just like those in the stock market. Other organizations might choose to exercise them, for example, the pharmaceutical and biomedical companies. The agency's job is to produce viable options, but not to take them to the marketplace. Whether or not these are exercised is an enterprise challenge, it is not an NIH challenge. NIH provides the primary means for enterprises to manage uncertainty, he explained. The agency is in the business of managing the uncertainty associated with the health of the country and creates options that will enable the country to deal with uncertainties associated with health.

We try to assess, he indicated, the value streams and value networks and try to project how different technologies, different capabilities make it to the marketplace. The projections are laced with uncertainties, and probability distributions. Projections are based on baseline data on market penetration and product lifecycle. When the data is unavailable, projections are based on organizational simulations of health care delivery and user behaviors in interactive online games, he continued to explain.

Rouse concluded his remarks by sharing his observations as they relate to health care delivery:

- There is an inherent conflict between payers and providers, especially when one organization pays and another organization receive the benefits.
- Alternative payment mechanisms-- fee for service, capitation, and pay for outcomes-- have enormous implications for how best to organize delivery. The current model will not scale for pay for outcomes.
- Appropriate framing of "the system" is critical to understanding sources of problems and improving outcomes-- what seems to be exogenous variables may be sources of great leverage. In healthcare you could argue that education is an exogenous variable. Prevention and wellness and chronic disease management is primarily an education problem, not just a healthcare problem.

The Challenges of Classifying the Benefits of NIH Research

According to Toole, an economics perspective can help quantify returns to biomedical research investment. He highlighted the fact that the meeting was not the first time the NIH has organized a meeting to ask economists if the tools and concepts they use can reveal the value of NIH-supported

biomedical research. He noted that 17 years ago, then NIH director Harold Varmus convened the Economics Roundtable on Biomedical Research. Led by economist Richard Zekhouser, and populated with economists, sociologists, physicians and scientists, that group examined three broad questions: 1) How to think about the benefits of biomedical research; 2) How does the totality of biomedical research operate; and 3) How are the results of biomedical research applied in medical practice. Toole, who noted that he was a graduate student at the time and attended the meeting, said that among the many findings and perspectives that were provided at the meeting, one stood out-- the need for studies that demonstrate a connection between basic research and medical innovations.

Aside from the immediate impact of NIH research on the volume of research activity, on the employment and education opportunities of students, and on the economic activity of lab and educational input suppliers, most of the activities supported by the NIH are intended to produce new and refined knowledge, he pointed out. This knowledge once disseminated and adopted, can create value in at least three broad contexts:

1. When goods and services are exchanged through market transactions. The profits to sellers and surplus to buyers combined to make the total social value from these transactions. The social value can be at least partially attributable to the NIH when the supported biomedical research plays a role in creating that new product or that improved product or service. Drugs and medical devices are common examples of this type of value creation.
2. Through improved health outcomes. These improvements add value above and beyond market transactions. He cited vaccines as an example. Improvements in health outcomes can also take place when there are changes in behavior that happen outside the market complex completely, for example if somebody were to eat a healthier diet, stop smoking, or start an exercise regime, and some of those decisions were partially attributable to the NIH. Research, then, would be a form of value creation, Toole explained.
3. Finally, value is created through education, research and education outcomes. He emphasized that it is important to recognize that the cumulative nature of scientific research means that the current research builds on past research to make it reliable and applicable to current needs and opportunities. For instance, noted Toole, NIH research might complement and stimulate private industry R&D investment, students might benefit from better knowledge about diseases or through training opportunities.

Toole classified the challenge of estimating the benefits derived from NIH-supported research into two broad categories. The first category is the connection challenge of identifying the links between knowledge produced by the NIH and where value is created. The ability to see these links is limited, he said. Consequently, it leaves us in a situation of having to adjust expectations about overcoming the connection challenge. Accordingly, the first step is to gain understanding of how informational outputs are produced by various activities supported by NIH. It would help to know more about the relationship between NIH support and scholarly output or other ways which the research is communicated and recorded, said Toole. It is also beneficial to understand how the information based outputs are accessed and used to create products and services.

The second category is the benefit and attribution challenge. Once a framework is established that connects NIH-supported research to where value is created, the need is to know how much value is created in that context-- the market context or the health outcome or educational research outcome. Toole indicated that economists have a body of theoretical and empirical research to help them understand and measure these kinds of benefits. However, even if the total benefit is known, there is still the challenge of splitting the benefit among various players and performers who contributed along that circuitous path from research to outcome, he explained.

In order to overcome this connection challenge, Toole emphasized the need for a map that aligns research activities in groups. We need to recognize the cumulative nature of research, he argued. Essentially this means that some aggregation across projects will be needed. To address the attribution challenge we need high quality data and good models of outcomes, said Toole. He

emphasized that the collection and availability of good data is essential and can improve the empirical models that we have about outcomes. The NIH can continue and expand collaboration with other public and private organizations to facilitate access to data on markets, health, research, and education outcomes. But the proper attribution of benefits to NIH supported research requires models that hold other influences from performers and other funding sources constant, he explained.

Much work remains to be done to address the connection challenge. Case studies are vital and provide the rich detail that informs general modeling approach that is used in economics. Due to wide variability in different contexts that create value, distinct models and distinct data are needed. He underscored that there is not one overarching model that encapsulates all the tremendous diversity seen in the NIH investment and its various impacts. From his perspective, project-specific or project-level analysis of economic benefits is too narrow. It fails to account for the cumulative nature of science. As one who has done the research over a decade, Toole indicated that he is optimistic about going forward.

Underestimating the Impact of Government-Supported Research?

Tripp provided the Board background on impact studies and impact analysis, how they work, and the difference. He also suggested that the case study of the Human Genome Projects' (HGP), economic impact provides an example of one major NIH investment. Echoing Toole, he also discussed the challenges in evaluating NIH impacts overall, emphasizing that there are many.

Battelle, Tripp indicated, has experience in a broad range of impact areas. According to Tripp, there are two basic types of impact analysis, backward linkage impact studies and forward linkage impact studies. Tripp noted that an example of a backward linkage impact study is an expenditure impact study. This entails examining how an entity expends money in the economy. Funds go to payroll, goods and services. In turn those organizations and individuals that receive those funds re-spend them providing a multiplier effect, and generating more economic impact in a region nation or state.

Forward linkage impacts look at the specific mission-based activities of the organization. NIH does not exist to simply spend money, he explained further. NIH exists to carry out its specific missions in terms of scientific knowledge expansion, technological practice innovations an education and scientific workforce development that then have functional impact in the actual community. These occur at the national level, the individual level for the individual families, and the community level, which make it more complex. While the discussion is currently regarding the economic functional benefits, Tripp stressed that there are individual and societal benefits that go along with these benefits. He indicated that future discussions by the committee should go beyond simply economic benefits.

Referencing the 2008 *Families USA* report "In Your Own Backyard," an example of backward linkage, Tripp noted that the NIH had the benefit of having this research in hand. The report looked at the expenditures of NIH funds, how they went to each state in the United States and what affect they had on the state's economy. While it is a perfect legitimate way to look at economic impacts "it significantly under sells." In that study, for every \$1 of NIH-related expenditure, another \$2 were generated at the state level, a good return for the states, said Tripp.

But once you start looking at forward linkage impacts, the benefit of NIH research becomes far more complex. The economic impacts that occur through the generation of new products and technology are then commercialized. That's a broad suite of technologies emanating from NIH research, everything from drugs and biologics to diagnostics to vaccines. You have the impact on the economy of improvement in terms of health of the individual, as well as in terms of increased productivity, a major issue in the developing world. You also, perhaps, have the value of a life saved. Other factors might also include improved personal income, Tripp explained further.

Tripp indicated that with the Human Genome Project Battelle took both approaches. The study worked because it was a single very large scale readily definable project, said Tripp. What Battelle found in this case of NIH-based research, and the Department of Energy which co-funded the HGP,

that the benefits from the project are widespread and were in six main domains -- human health; agriculture and food; environment; forensics, justice and security; industrial biotechnology; and veterinary medicine. He underscored that "it gets complex quickly when you go down the pathway of functional impacts." One fundamental discovery at the basic science level doesn't necessarily have a one-to-one relationship with an individual project downstream, he clarified; it may have a relationship to hundreds of projects downstream, such as the case in the HGP. So when we look at \$796 billion in return on investment for the HGP, we "are considerably underestimating what the impact is of this one government research project," Tripp declared.

He reiterated that the volume and broad scope of NIH activity makes a forward-linkage impact analysis "extremely challenging." There is the issue of the time horizon of going from bench to bedside, which is not unique just to medicine, said Tripp, noting that agricultural biosciences are taking longer to bring a transgenic crop to market than a drug to market. Another challenge is the complex pathways from discovery to commercialization. He pointed out that many of those pathways and steps are not controlled by NIH and cautioned that when the agency looks at economic results it has to be careful because it could judge itself on things over which it has no control. The challenges also include the "sharing-out" of multiple technology contributions in an end product. Data availability on research outcomes in relation to publications, citations, intellectual property and commercialization are additional challenges. You also have great variation in innovation ecosystems. So the result to which an NIH discovery ends up in commercialization may be highly variable depending on where the research took place. There is also potential cost in time required to do the subject justice particularly in light of Congressional discussions taking place. Agreeing with Toole, he stressed again that the case studies are absolutely fundamental, pointing out that the HGP study obviously made a very compelling case.

Concluding his presentation, Tripp acknowledged that performing an appropriately in-depth assessment of NIH impact can be done. He cautioned again, however, that it will be complex and challenging. Functional impacts have to be evaluated. To look at pure expenditure-related impacts on NIH's 'sales' is a dangerous pathway to take. He indicated that it will require industry cooperation in case studies, but he expects industry would be highly cooperative. The study is of fundamental importance to U.S. funding of science moving forward, not just for the NIH, but for federal funding in all areas of science, Tripp proclaimed.

NICHD Holds 149th Advisory Committee Meeting

On January 19th, the National Advisory Child Health and Human Development Council (NACHDC) of the *Eunice Kennedy Shriver* National Institute for Child Health and Human Development (NICHD) held its 149th meeting. Reporting to the Council, NICHD director Alan Guttmacher declared that it had been a "really wonderful few months of celebrating the 50th anniversary" as well as the concurrent publication of the institute's scientific vision document (see Update, [December 10, 2012](#)). Guttmacher reported that the Institute has received a lot of feedback on the report, noting that it was a "useful stimulus for thought and conversation." He informed the Council that they would have significant involvement in helping the Institute figure out where it goes from here.

He noted that the *Visioning* document was never intended as a traditional NIH strategic plan to say exactly what the Institute should be doing. Instead, it was an exploration of the across-the-board mission of NICHD, and what promising scientific policy and other opportunities could inform NICHD. Thinking of the visioning areas as "opportunities and challenges," Guttmacher declared we must figure these out together.

Guttmacher discussed the FY 2013 budget for the Institute. He noted that the threatened 8.2 percent cut of the sequester has been averted. If the postponed sequester does occur on March 1, the threat to NIH is an approximate 6.4 percent cut, which would be applied across the entire NICHD from the FY 2012 budget funding level. He pointed out, however, that it did not mean that the Institute had to cut every item funded by 6.4 percent. Noting that the budget year started on October 1st, if the cut

goes into effect, it will essentially occur halfway through the year. Given that this scenario has been in the background since the beginning of the fiscal year, the Institute has been spending accordingly.

He explained that the intramural program, conversely, is different from the extramural program in a number of ways. The vast majority of the costs of the intramural program revolve around payroll where the bulk of the costs are fixed and there are fewer places to achieve savings. The need to furlough people, however, would have to come from the Office of Management and Budget. The Administration, according to Guttmacher, is confident that Congress will agree to replace the sequester with a balanced approach to long term spending and budget deficits. Meanwhile, he indicated that the Institute is not ramping down in anticipation of a sequester, but is continuing to operate cautiously.

Even if the sequester is averted, Guttmacher lamented that the NIH is in a "tough financial time." He highlighted the fact that this is not a one-year phenomenon and asserted that it would be "a terrible mistake to say in this environment we have to hunker down...It is a time we have to be particularly careful in some ways where we place investments but we have to continue to place investments in good science, whether new science, old science, in a meaningful way." It is ironic, he added, that it should happen at a time "we think we have really unparalleled opportunities."

Extramural Reorganization Official

The NICHD director also reported that the Institute's extramural reorganization is now completely official (see Update, [February 6, 2012](#)). The new Division of Extramural Research has been formally established and Cathy Spong, once head of the Institute's now Pregnancy and Perinatology Branch is formally the head of the new branch. Two new branches have also been established in the extramural program - Pediatric Trauma and Critical Illness, led by Acting Branch Chief Valerie Maholmes, and the Gynecologic Health and Disease, led by Acting Branch Chief Trent MacKay.

The Institute has gone through the complete portfolio grant by grant to determine which should be transferred to new branches or established branches, said Guttmacher. He noted also that some staff had been transferred as well. There are searches on for leadership of both of the new branches and for the Pregnancy and Perinatology branch. Caroline Signore, M.D., MPH, has been selected as Deputy Director of the NICHD's Division of Extramural Research, effective January 27. She comes from the Pregnancy and Perinatology Branch and previously, the Division of Epidemiology, Statistics, and Prevention Research.

IOM National Children's Study Workshop "Very Useful"

Guttmacher noted that the Institute, which is charged with leading the National Children's Study (NCS), had a "very interesting meeting" at the Institute of Medicine on January 18th, to discuss the design of the Main Study. The meeting focused on questions regarding sample composition, weighting, imputation, and estimation in the design and how best to capture those, which to prioritize. This topic was discussed in some detail, said Guttmacher, along with ways of weighting and imputing data. It was a very useful workshop, he acknowledged. He also pointed out that the NCS has a number of individuals who feel deeply tied to the study and feel that it has the potential to do something very important. He noted that they will take the Institute to task frequently if they feel that somehow the NCS is not living up to their particular hopes and dreams for it. Guttmacher admitted that this deep commitment is a "double edged sword." He thinks that the NCS is on track to have a "really wonderful study that will inform us a lot, not just about child health and human development, since we all around here know that child health really does contribute to the health of adults."

He reported on the National Institutes of Health (NIH) Blue Ribbon Panel focusing on the National Center for Medical Rehabilitation Research at NICHD. The Panel submitted a final revised report to Guttmacher in December. According to the Director, he has already met with a number of NIH institute directors that have large stakes in rehabilitation research to figure out which of the recommendations makes sense to implement and how to implement them. A primary focus of those

meetings has been to examine how to better communicate and to better coordinate rehabilitation research across the NIH. While this is not unique to rehabilitation research, he explained, it is good example of another double edge sword. The real advantages of having multiple institutes interested in an area are that they bring diverse talents, diverse communities, and diverse pots of money. Yet, when things are spread across many institutes you can have duplication as well as niches that are not occupied because everyone assumes it is being done by other institutes. He indicated that job coordinating is one of the issues high up on the agenda with this group of directors.

Guttmacher also noted that the Institute has asked a blue ribbon panel to look at NICHD's Division of Intramural Research, something that he cited as traditional around the NIH. That work is in progress, he explained, and a report is anticipated from them in the coming months.

He recounted that on December 19, 2012, the White House launched the U.S. Government Action [Plan](#) on Children in Adversity, which aims to protect vulnerable children around the world. Clearly, the work that NICHD currently supports as well as that it supported in the past has assisted this group. The Institute's investments in research, training, and capacity building complement our partner agencies' work in policy-setting, development, and aid, said the NICHD director.

He noted that he had been appointed along with John Ruffin, director of National Center of Minority Health and Health Disparities (NIMHD), to co-chair of NIH's newly reconstituted LGBTI Research Coordinating Committee. The [Committee](#) is tasked with promoting collaboration across NIH to support research on the health of lesbian, gay, bisexual, transgender, and intersex people. The effort builds on prior NIH efforts, including the commissioning of an Institute of Medicine (IOM) report on LGBT health (see Update, [April 11, 2011](#)) and, more recently, an IOM [workshop](#), *Collecting Sexual Orientation and Gender Identity Data in Electronic Health Records*, to gather sexual orientation and gender identity data in electronic health records. Guttmacher conveyed that he thinks it is wonderful to have a leadership role and it fits in with a lot of what NICHD has done for years in its research portfolio. (The IOM will be holding an event on Tuesday, January 29, 2013 to release the prepublication version of the summary from the workshop.)

Guttmacher noted that the NIH is currently recruiting for two newly created positions, an Associate Director for [Data Science](#) to lead coordination of data management, communication, and data interpretation for the NIH community, as well as initiatives involving the biomedical research community at large; and a Chief Officer for Scientific [Workforce Diversity](#) to coordinate and oversee NIH efforts to diversify the biomedical research workforce (see Update, [December 10, 2012](#)).

BBCSS Considers Revisions to the Common Rule for Social and Behavioral Science Research

The federal regulations regarding the protection of human subjects in research (45 CFR 46, or the "Common Rule") were last revised in 1991. In July 2011, the Department of Health and Human Services in an Advanced Notice of Proposed Rule Making announced its intention to update these rules. A response to these proposed changes from the social and behavioral science community can be found at: <http://www.cossa.org/advocacy/2011/SBS-White-Paper-ANPRM-10-26-11.pdf>. Taking into account this and many other responses, the government in the coming months expects to issue a Notice of Proposed Rule Making (NPRM).

On January 14 and 15, the Board on Behavioral, Cognitive, and Sensory Sciences (BBCSS), under the National Academies' Division of Behavioral and Social Sciences and Education (DBASSE), held two open sessions to solicit input for a workshop on these revisions as they apply to social and behavioral science research. The workshop is planned for March, with a summary report to be published shortly thereafter. Pending the availability of additional funding, a second phase would produce a consensus report offering conclusions and recommendations. A number of COSSA's member organizations are helping to fund the workshop.

Members of the social and behavioral science community addressed a twelve-member panel, which

will plan the upcoming workshop, on areas of concern in the proposed revisions to the Common Rule. Tora Bikson, RAND Corporation, gave a presentation that touched on several issues, including the tension between mandatory data standards and the values of institutional review board (IRB) flexibility, the emphasis on written consent versus the quality of the consent process, and the necessity of defining "minimum risk" in a social and behavioral science context. Concerns raised by other participants included the need to acknowledge and plan for poor-quality IRBs, how to handle multi-site studies, the challenges of working with marginalized populations, and the need for an evidence base for the proposed changes.

On the second day, Kellina Craig-Henderson, National Science Foundation and a 2012 COSSA Colloquium speaker, shared the results of an NSF working group that discussed the proposed changes. She noted that the working group expressed concern about the elimination requirements for continuing review for "exempt" and "expedited" studies and about the possibility that changes to how pre-existing data and specimens are treated could have a chilling effect on research.

The members of the panel are:

Susan Fiske (Chair), Princeton University,
Melissa E. Abraham, Massachusetts General Hospital,
Thomas J. Coates, University of California, Los Angeles,
Celia B. Fisher, Fordham University,
Margaret Foster Riley, University of Virginia,
Robert M. Groves, Georgetown University, former director of the U.S. Census Bureau
Robert J. Levine, Yale University,
Felice J. Levine, American Educational Research Association, member COSSA Executive Committee,
Richard E. Nisbett, University of Michigan,
Charles R. Plott, California Institute of Technology, former member COSSA Board of Directors
Yonette F. Thomas, Howard University, member COSSA Board of Directors, and
David R. Weir, University of Michigan, former COSSA Congressional Seminar speaker.

Information about the project is available at:

http://sites.nationalacademies.org/DBASSE/BBCSS/CurrentProjects/DBASSE_080452#.UQKpqB3nMrU.

EDM Forum & AHRQ Launch New Journal, eGEMs

The Electronic Data Methods (EDM) Forum, supported by the Agency for Healthcare Research and Quality (AHRQ), announced the creation of a new electronic open-access journal, *eGEMs* (Generating Evidence and Methods to improve patient outcomes). The journal is focused on "using electronic clinical data to advance research and quality improvement, with the overall goal of improving patient and community outcomes." The journal's content is organized into four themes: Methods, Informatics, Governance, and Learning Health System. For more information and to view content and submission information, visit: <http://repository.academyhealth.org/egems/>.

Brookings Foreign Policy Scholars Advise on "Big Bets and Black Swans"

On January 17, the Foreign Policy program at the Brookings Institution held an event to launch *Big Bets and Black Swans: A Presidential Briefing Book*, which is comprised of memos to President Obama written by Brookings fellows about different foreign policy challenges and opportunities for his second term.

The "big bets" are areas where the U.S. has the chance to have a transformational impact. The "black swans" are low-probability, high-impact events that could derail the President's foreign policy agenda; the book recommends ways to mitigate the risk of these events occurring. In his introductory remarks, Martin Indyk, Vice President and Director for Foreign Policy at Brookings, noted that in his second term President Obama has a "historic opportunity to shape the global order." David Gregory,

host of Meet the Press, moderated two panels, the first focusing on the "big bets," the second on the "black swans."

Robert Kagan argued that the world's current instability has created a "plastic moment," where the global order can be shaped by strong U.S. leadership to promote liberal democratic values. Suzanne Maloney noted that the international climate combined with Iran's domestic turmoil has made this a good time to take steps to resolve the nuclear crisis with Iran. Noting that Obama has already made a "big bet" by rebalancing his foreign policy toward East Asia, Kenneth Lieberthal argued that the U.S.-China relationship must itself be "rebalanced," so that the U.S. can benefit from economic growth in the region, not just pick up the tab for providing security. Charles Ebinger suggested that the U.S. rethink its energy policy and export coal, oil, and natural gas to meet growing demand in Asia. He argued for a tax on fossil fuel production to be put into research on carbon capture and sequestration and advanced battery technology. Mireya Solis argued in favor of pursuing free trade agreements with both Europe and countries in the Asia-Pacific region. The other "big bets" in the briefing book are: investing in the rise of India, ending the Syrian crisis, thawing the relationship with Cuba, ending maritime conflicts in East Asia, establishing new rules of warfare, reforming U.S. defense spending, and building on nuclear disarmament deals with Russia.

During the "black swan" panel, Bruce Riedel discussed the possibility of the fall of the House of Saud in Saudi Arabia, which would send oil prices skyrocketing and have a major geopolitical ripple effect throughout the region. Vanda Felbab-Brown noted that a major breakdown of security in Afghanistan would have far-reaching implications for U.S. interests in the region and could lead to conflict among U.S. partners as they vie for influence. Khaled Elgindy spoke about the demise of the Palestinian Authority, which would lead to mass Palestinian unemployment and cause a security crisis in the Palestinian territories, leading Israel to take on a governing role. Thomas Wright argued that the collapse of the Eurozone would be the single greatest threat to the U.S. economy and would send the global economy into a tailspin, creating security crises throughout the world. Elizabeth Ferris noted a rise in the sea levels caused by accelerating climate change would create more major weather events and humanitarian crises. The other "black swans" are: international war or domestic revolution in China, conflict with China over North Korea, and the renewal of conflict between Egypt and Israel.

More information about the briefing book, including a link to download it, is available at: <http://www.brookings.edu/research/interactives/2013/big-bets-black-swans>.

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