HOUSE APPROPRIATIONS SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES

"FY 2023 BUDGET REQUEST FOR THE NATIONAL INSTITUTES OF HEALTH"

MAY 11, 2022 – 10:00 AM

OVERVIEW

On Wednesday, May 11, the House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies (LHHS) held a hearing to examine the President's FY 2023 budget request for the National Institutes of Health (NIH)

Members asked about NIH's research priorities; ARPA-H; COVID-19 and pandemic preparedness; pan-coronavirus vaccine; ethical alternatives to fetal tissue for research; Undiagnosed Diseases Network; gain of function research; diversifying the biomedical research workforce; opioid overdose deaths; Cancer Moonshot; falls among older adults; health inequities; NIH Equity Action Plan; worsening mental and behavioral health in young people; firearm violence reduction; universal flu vaccine; organ transplants; pediatric research at APRA-H; and stillbirth, among other issues.

WITNESSES

- Dr. Diana Bianchi – Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development
- Dr. Anthony Fauci – Director, National Institute of Allergy and Infectious Diseases
- Dr. Gary Gibbons – Director, National Heart, Lung, and Blood Institute
- Dr. Douglas Lowy – Acting Director, National Cancer Institute
- Dr. Lawrence Tabak – Acting Director, National Institutes of Health
- Dr. Nora Volkow – Director, National Institute on Drug Abuse

QUESTION AND ANSWER SUMMARY

Rep. Rosa DeLauro (D-CT) – What are the determining factors in setting NIH research priorities? Is there an emphasis on large scale initiatives? What happens to research in important areas of health that are not included in large scale initiatives or ARPA-H? How do we determine progress in these initiatives?

Dr. Tabak – It's a balance that needs to be struck. In recent years, there has been an emphasis on large scale investment because the scientific opportunity presented itself due to new technologies or emerging areas of concern. In each instance, the institutes prioritize their efforts based on whether the science is ready to move forward, what the public health need is, and whether or not the portfolio that they currently sustain is sufficient to move the field forward. Each institute and center has a strategic plan and they work with their national advisory council to make sure that work that is supported aligns with those strategic plans.

Rep. DeLauro – What do we believe is being left behind and not being included in the large scale initiatives?

Dr. Tabak – Our success rate overall is roughly 20%. Historically, we have observed that meritorious applications come in at least through the top one-third so the difference between the 20% and the 33% represents what's being left behind. Those are studies that are certainly worthy of support but with finite resources, prioritization has to occur.

Rep. DeLauro – Why did NIH's success rate decline from 20.6% in 2020 to 19% in 2021 despite a funding increase of $1.3 billion? What is NIH doing in 2022 to avoid another year of decline in the success rate?

Dr. Tabak – The success rate is simply the number of applications that are funded divided by the number of applications that we receive. In FY 2021, we received an unprecedented number of applications. This increase is largely what drove the modest decrease in the success rate. We can't control the number of applications that we receive.

Rep. Tom Cole (R-OK) – What is the $4 billion that we allocated for ARPA-H going to do?

Dr. Tabak – Our first step is going to be to build out the administrative infrastructure of the organization. We will draw upon some of the equities that are used across HHS such as the electronic system for grants. The search is underway for the inaugural director, who is a presidential appointee . Our charge at the moment is to focus on the administrative issues. We will certainly bring in a small group of senior operational people focused on the operational side. However, no program managers driving the science will be recruited until the director is in place.

Rep. Cole – What is the funding rate at the National Cancer Institute for applications as compared to NIH district-wide? How promising is the science in cancer going forward?

Dr. Lowy – The funding rate at the NCI currently is 11% pay line for experienced investigators and 16% for early-stage investigators. Last year, thanks to the generosity of Congress, we were able to give more awards than we have ever given before. Funding has gone up by 25% for experienced investigators over the last four years and about 60% for early-stage investigators. There has been a substantial increase in applications to NCI. This is very good news and is a reflection of the optimism that people have of being able to make progress in cancer. However, a direct consequence is that there is a decrease in the pay line and the success rate.

Rep. Lucille Roybal-Allard (D-CA) – Do you believe a laboratory facility managed by Charles River Laboratories can meet the physical and psychological needs of chimpanzees previously used in biomedical experiments better than a sanctuary created and designed specifically to meet the needs of chimpanzees retired from research?

Dr. Tabak - It's a balance between the facility the chimp is currently housed in versus their medical condition. It is the opinion of a panel of veterinarians from NIH and from Chimphaven and the facility that a certain number of chimps are just too frail to be moved safely. There is also some consideration that several of the chimps who are part of a social network should remain for that purpose as well.

Rep. Andy Harris (R-MD) - Are your statisticians going to take an early look at data to see if intravenous Aviptadil works or works adequately enough to authorize it and scale it up so that when we have a surge in infections this fall, we will have a late stage therapeutic available for patients?

Dr. Fauci – Yes. As you know, the company who sponsors this has the opportunity to present the data to the FDA for an application for emergency use authorization (EUA). The NIH, in our clinical trials, provides all of the resources necessary to do that. It is not an NIH issue of whether this gets submitted to the FDA for an EUA. One of the things that's very clear is that we don't interfere with the way that the Data and Safety Monitoring Board (DSMB) looks at clinical trial data. That would be a conflict. We always welcome what they do. If DSMB takes a look at the data and feels it should be an early look then we welcome that.

Rep. Harris – The mean age of principal investigators at NIH increased from 2015 to 2020. The NIH is failing to address this properly. What are you going to do?

Dr. Tabak – You're correct in the data. We are doing several things. Unfortunately, institutions around the country increasingly want their new faculty hires to have bridge funding before they give them a permanent appointment on their faculty. That was never an intended purpose of some of these transitional awards but they become a surrogate for deciding who gets tenure track position or not. We have instituted the CATS award which is an R01 application that does not allow any preliminary data for the submission of that award. The purpose is that it frees the young person from the work they did as a post-graduate student and allows them to go straight away to apply. We have also done a series of mentoring networks around the country to convince young people that the first R01 is something they should be striving for sooner rather than later. We're going to keep working on this because it's important.

Rep. Mark Pocan (D-WI) – What do we need to be doing to prepare for the next coronavirus or any other future pandemic that we aren't currently doing?

Dr. Fauci – This is really part of the strategy that we have put into place not only to address the current outbreak of SARS-CoV-2 but also as part of our forward looking pandemic preparedness plan. What we're doing with regard to the current coronavirus is having already in place early clinical and pre-clinical studies of a pan-coronavirus vaccine. We've already have four or five variants in the world and the U.S. has experienced three of them. The strategy is to develop a vaccine that would have effectiveness against all of the current variants as well as any variant that might arrive out of the SARS-CoV-2 group and then extend that through the phylogenetic tree of coronavirus. The pandemic preparedness plan is built on a concept that was developed in our group by Barney Graham who developed the SARS-CoV-2 mRNA vaccine for Moderna. He suggested taking a representative microbe from each of the families that have potential pandemic capabilities and then do studies that would position us so that if we do get an outbreak from an Arenavirus, Alpha virus or Flavivirus, that we could get a vaccine into trial and ready to go within 100 days and in the second 100 days, be able to start distributing it.

Rep. Pocan – Do you consider pandemics like COVID-19 to be a threat to national security?

Dr. Fauci – There is no doubt about that. Whenever you have something that threatens the economy and political stability of nations, it is part of global security. That's the reason why we take outbreaks very seriously. SARS-CoV-2 is historic and unlike anything we have seen in 104 years.

Dr. Tabak – Absolutely. Anything that destabilizes the economy and a nation represents that threat.

Rep. Pocan – In regards to the pan-coronavirus vaccine, will the NIH require its awardees to meet global access conditions on pricing, supplying, and technology sharing for any future vaccine?

Dr. Fauci – We don't have that capability of guaranteeing global access. That's part of the broader government plan, which we're trying to do right now. As you know, $5 billion of the $15 billion was supposed to go to global. That global was not necessarily to get vaccine doses. We have enough vaccine doses for the developing world. What we don't have is developing the infrastructure to be able to turn vaccines into vaccinations. We are very committed to doing that and have always been but that's not in the realm of what NIH can do.

Rep. Chuck Fleischmann (R-TN) – What is the NIH's plan for moving towards more ethical alternatives to fetal tissue for research?

Dr. Tabak – We continue to support research for alternatives in this instance but as you know, in order to validate the alternative, you have to compare it to something and that in fact is fetal tissue in many instances. We have awarded a number of grants in this area and we continue to make progress in that direction. However, it's difficult work and we continue to fund that type of research.

Rep. Fleischmann – How does the NIH plan on supporting the Undiagnosed Diseases Network (UDN) sites once the Common Fund support expires? How can we help develop a plan to sustain the work of UDN going forward?

Dr. Tabak – Programs that are initially supported by the common fund graduate out of that program, which is meant to be an incubator space. UDN has done very important and outstanding work but you reach a point where the effort begins to blend into standard of care versus research so we need to define where that boundary is. We're working with the various groups around the country to see what options we may have going forward to sustain that portion of the UDN that remains in the research space but allow the portion that is in the standard of care to move into that arena.

Rep. Fleischmann – Considering the impact that COVID-19 has had across the world, do you advocate for a continued pause of gain of function research?

Dr. Fauci – It's very important that we abide by the set guidelines of the conduct of research. One of the problems with the word gain of function is that it means so many different things to different people. There have been multi-year processes that have set the guardrails for work on different pathogens. Those guardrails have worked quite well and everyone is very sensitive to make sure that research is conducted in a safe and effective manner and that it is peer reviewed by people who are qualified to make that determination.

Rep. Bonnie Watson Coleman (D-NJ) – What kind of success have you had in expanding the diversity of the NIH workforce and the diversity of the grants that are funded?

Dr. Tabak – I want to assure you that I'm committed to diversifying the biomedical research workforce. I've been using a variety of approaches to try and diversify our grantees. For example, we have developed the first award which is designed to build communities of scientists in an effort to ensure that you have a sustainable and inclusive environment for new hires. We have also increased support for the NIH MD loan repayment program, which currently supports over 100 talented scientists each year from racial and ethnic minority backgrounds or scientists interested in health disparities. Several of the institutes have specific programs that are designed to onramp individuals from diverse backgrounds into positions of tenure track at universities.

Rep. Watson Coleman – Which of these initiatives have been implemented in the last year and a half?

Dr. Tabak – The first program I mentioned is in its second year and we are currently looking at applications for year two. They are under review. The last program I mentioned is new within the last year. The loan repayment program has been used in prior years.

Rep. Jaime Herrera Beutler (R-WA) – How is the FY 2023 budget request going to help you reduce opioid overdose deaths?

Dr. Volkow – The budget is going to help us accelerate research in this area that is becoming very challenging because the complexity of overdose deaths has increased during the COVID pandemic. Initially we started with research investments to improve the treatment of patients who suffer from pain so they would not be given opioids when they didn't need it. Then it shifted to heroin and then after that it shifted to synthetic fentanyl. Now fentanyl is being mixed with cocaine and methamphetamine to illicitly manufacture pills. So, we need to diversify our scientific projects to go beyond interventions for prevention that just focus on pain and expand into addressing the needs and vulnerabilities of individuals that may be exposed by accident to these substances. This requires a range of interventions. At the same time, we need to do research to give us better medications to reverse overdoses because Naloxone is not so effective in this new era of very powerful drugs.

Rep. Lois Frankel (D-FL) – How will the Cancer Moonshot invest in patient navigator services to ensure access to any new treatments?

Dr. Lowy - Patient navigation is one of several aspects in trying to provide optimal treatment for patients with cancer, which has become much more complicated in recent years, in part because of its success. In terms of approval of patient navigation, this is beyond the NIH. However, we conduct research to try to optimize patient navigation along with many other aspects of trying to help people have appropriate and full access to cancer care. This includes doing patient care at home, changing radio therapy, and figuring out how to provide optimal care to all patients.

Rep. Frankel – Is there a timeline for new products to monitor falls in older adults?

Dr. Tabak – The National Institute of Aging's Small Business Program has made several awards and supported a small company that has developed a medical alert pendent that does automatic fall detection. This has been licensed and integrated into medical devices broadly and is available through a variety of mass market retailers. They're also supporting additional research to develop sensors that detect floor vibrations, which could be very valuable for people who are hospitalized or otherwise infirmed.

Rep. John Moolenaar (R-MI) – Can you comment on policy that allows scientists at NIH to receive royalties? Will you take a fresh look at that policy?

Dr. Tabak – The award of royalties is based on the Bayh-Dole Act, which makes no distinction as to whether or not the inventor is paid by the government, the private sector, academia, etc. So, we're following that Act when it comes to that. In terms of the potential for conflict, no individual who is in a decision making role on a particular product would have benefitted from being the inventor of that product because we separate out those functions.

Rep. Cheri Bustos (D-IL) - What broader impact would the FY 2023 budget request have on addressing inequities that lead to disparities in access to care and patient outcomes?

Dr. Tabak – It will do so in several ways. Our work in health disparities is increasingly being done at the community level. We have learned that you can't just parachute into a community, study it, and then disappear. You have to establish meaningful trust, which takes time.

Dr. Gibbons – Addressing health inequities often involves addressing the social determinants of health. As a result, you need a multi-pronged strategy that often belongs in the community that can co-develop strategies with us to address inequities. This has been borne out to be very successful in addressing the pandemic and indeed has a broad array of capabilities to address cardiovascular disease, HIV/AIDS, maternal mortality and morbidity, etc.

Rep. Bustos – Can you comment on the President's budget request for NIH supporting the recently announced Equity Action Plan?

Dr. Tabak – Each institute and center is developing their own plan for their own individual organization. In it, they will point out what gaps exist in terms of what they do internally and externally. These plans will be shared among all the institute and center directors so we can learn best practices. This will be an annual event so they will be updated going forward.

Rep. Ben Cline (R-VA) – Would you agree that during the times of the COVID lockdown, we have seen increases in depression among young people?

Dr. Fauci – There's no doubt that when you put restraints on society that it causes emotional and mental stress but you have to have a balance of saving people's lives from getting infected and in hospitalizations.

Rep. Cline – Would you agree that suicide rates have increased among young people?

Dr. Fauci – Indeed, they have.

Rep. Cline – Would you agree that domestic violence rates has increased?

Dr. Fauci- Yes.

Rep. Cline – Would you agree that drug and alcohol use increased during the lockdowns?

Dr. Fauci – I'm not sure if the lockdowns themselves caused that and I'm wondering why you're asking me about lockdowns because there were not complete lockdowns in this country. There were restrictions but there were not lockdowns. China is now going into a real lockdown. So, I would disagree with characterizing whatever went on in this country as a full lockdown.

Rep. Josh Harder (D-CA) - What can the NIH commit to doing with this year's budget to ensure that federal dollars are directed to programming and research to tackle the issues of air quality and asthma?

Dr. Tabak - The budget does request resources to study the effect of climate on health.

Dr. Gibbons - We've known for many years that air pollution has an impact on the lung development of children, such that it stunts the development of lungs and predisposes to conditions like asthma. We've actually seen trends over time, that when the air quality improves, there is an improvement in that childhood lung function. So, we know that if we can mitigate that exposure, it can have benefits. Similarly, we recognize that there are many communities, often lower income communities, communities of color, that are particularly besieged by the challenges. We are making progress and getting a greater understanding of the inflammation induced by those particles on the lung. Our treatment strategies have improved substantially as a result of basic research, in which we're understanding now the pathways, and now new therapeutic targets to reduce that inflammation and enhance lung health. There's greater precision medicine now in how we treat asthma. But certainly, we still need to do a lot more of the root causes that relate to climate, climate change, and the effects of wildfires and everything that's exacerbating that whole spectrum of etiology of asthma.

Rep. Harder – How influential do you think the wildfires in California are in some of the asthma and air quality concerns that we're seeing?

Dr. Gibbons - It clearly is contributory. We're seeing that pattern as measured in changes in those particulate matter. Air quality is deteriorating. Moreover, with the prevailing winds, those declines in air quality sweep across the country as well. We recognize that this is going to be a national problem. With the trends of climate change, wildfires, and declining air quality, an ongoing problem that we hope we can potentially address the health effects through this NIH program of climate change and health.

Rep. Katherine Clark (D-MA) - How is the NIH ensuring mental and behavioral health is appropriately addressed, including coordination among multiple relevant institutes and centers? Do you have the resources necessary to meet this moment?

Dr. Tabak – We do have opportunities across NIH for the different institutes and centers in the space to collaborate with one another. For example, the BRAIN Initiative is now seeking to understand how the circuits in the brain work. But there is also an emphasis on the community based level of making sure that the appropriate mental health services are provided to those in need, as well as efforts to avoid the stigmatization that accompanies mental health conditions.

Dr. Volkow - As we're addressing all of the challenges with the COVID pandemic, we realized that even after the pandemic, the problems that have arisen from mental health issues are going to be remaining. Children and adolescents are particularly vulnerable. We're already seeing that with 30% increases in depression, anxiety, and loneliness. We've also seen an increase in suicides among teenagers as well as increases in unintentional overdoses among adolescents. And for the first time, we're seeing overdose deaths in adolescents from fentanyl. The situation is clearly urgent. We're joining our efforts across the different institutes to try to understand how this ultimately affects the behavior of a child, what the trajectories are, and what interventions we can do to support them. It's clear that it's going to have to be personalized and that the social determinants of health are crucial. We've learned to recognize that those that are in adverse economic situations or social stressors are the most vulnerable. So, understanding those factors so that we can develop interventions that can be targeted and importantly, putting the resources that are necessary to provide those evidence based interventions to protect our children and adolescents.

Rep. Clark - Is there a plan on how to solicit and evaluate proposals for where ARPA-H will physically be located, and when do you expect a director to be appointed?

Dr. Tabak - The search process is underway for the inaugural director of ARPA-H. This is a presidential appointment so this is being driven by the White House. There has been no commitment made to the physical location of where ARPA-H will be located. We obviously are continuing to frame this out for the consideration of the Secretary and for whoever the inaugural director may be. But until that appointment is made no decision will be made on the physical location.

Rep. Clark – So, there is no timeline for a selection process?

Dr. Tabak - I can tell you that the search is definitely ongoing. And I know that the intention is to move that as rapidly as possible.

Rep. Brenda Lawrence (D-MI) – Can you speak to the importance of resuming federal research into firearm violence reduction?

Dr. Tabak - 10 awards were recently made. The future research directions will likely include work to better understand the interplay of the neurological, biological, psychological, and social and structural processes that may enter into this. Also, emphasis on violence and trauma screenings and interventions need to be developed, and then made available both in healthcare settings, as well as school settings. We have come to understand that the violence prevention efforts have to be multi-level and focused on mechanisms of action. So just to give you an example, one of the awards was made to evaluate the effectiveness of child and family traumatic stress intervention, to reduce PTSS in youth after they were assaulted. It's things like this that will hopefully help us reduce and eventually eliminate these tragic events.

Rep. Lawrence - Can you highlight the impact of last year's investment in mental health research? How does this year's funding increase build on the NIH's work from last year?

Dr. Tabak - The work that has been recently supported is really to strengthen mental health response during the time of the pandemic. It seeks to really increase uptake of those practices that we know that are effective. So, for example, it turns out that digital health care platforms are really good approaches, and we have to be able to figure out how to adapt those formats and platforms to where it is most needed.

Dr. Bianchi - One of the things that we are very excited about is the de-stigmatization of youth mental health issues. We are co-funding a high school essay challenge to bring high school students in to write about their experiences. There's no question that children and adolescents have been significantly affected by all kinds of issues related to the pandemic.

Rep. DeLauro - Can you provide us with an update on the development of the universal flu vaccine?

Dr. Fauci – The money that was given to us in the last appropriation has been very helpful and the additional plus up in the current 2023 budget will be very helpful. So, what we have been doing over the last couple of years now is bringing a number of new concepts into the universal flu vaccine. One of the approaches is to use new platforms, one of which is referred to as nanoparticle, which is a component of a vaccine that allows you to tack on to these micro particles, any of a number of immunogens. One of them is one that is very common to virtually all of the flu within a particular group of influenzas. In preliminary studies they look really very good both in the animal model and in phase one studies in which you induce a response that goes well beyond just the particular flu that you're vaccinating against. In addition, a number of studies both intramurally at the NIH campus in Bethesda as well as in our grantees have now put into both preclinical and phase one study a number of candidates using these various platforms. The results look actually really very good in the sense of a vaccination that goes well beyond the particular isolate that you're dealing with and covers. Flu is divided into two main groups, group one and group two. We now look like we can get good responses that have both depth and breadth against multiple ones within either group one or group two. So as months and years go by, we're getting closer and closer to what I think will be a much more effective and universal vaccine.

Rep. Cole - On the Alzheimer's front, we've made considerable investments and we've had a lot of concern about the sheer expense this disease imposes on us. How do you see the state of play? Also, what are your thoughts on marijuana use given the prevalence that we have now?

Dr. Tabak – We're funding more than 350 trials in this space now. 70 are pharmacologic treatment and prevention trials. 120 are non-pharmacological and prevention trials. Then the remainder are related to dementia care and caregiving intervention tools. Our public private partnership has identified over 550 new drug targets. The National Institute on Aging's IMPACT Collaboratory is developing pragmatic trial infrastructure to really look at how we improve care for Alzheimer's patients.

Dr. Volkow - Indeed, the use of marijuana has gone up, particularly among those that are 18 years of age or older. During the COVID pandemic, we have seen this has increased and among the areas that were most concerning is pregnant women. We've seen during the COVID pandemic a significant rise in the utilization of marijuana, whether it is for so called medical purposes or recreational use. All along, we've also been very concerned about the consequences of marijuana use particularly on the developing brain and that actually goes starting in fetal development or childhood and adolescence. The data already shows that the outcomes are much worse for women that smoked marijuana during pregnancy. The data also shows that use of marijuana in teenage years actually significantly impairs the performance of these teenagers at school. What is also worrisome is we have seen significant increases in acute psychosis associated with the use of marijuana across all ages. This is in part driven by the fact that the currently available marijuana has higher content THC so it's much more powerful. This is also associated with higher risk for accidents. There are other areas that are not clear, but the numbers seem to suggest that there is an increased risk, for example, on suicidal behavior among people that are using marijuana regularly. The extent to which they are using marijuana to escape suicidal thinking, as opposed to having causality association is unclear. But we are prioritizing these areas because the American public deserves to what the potential consequences are of taking marijuana.

Rep. DeLauro - Can you tell us a little bit about your research to reduce rates of maternal mortality and morbidity? Are you seeing progress? How are the Centers for Excellence going to help achieve the long term success?

Dr. Bianchi - The goals of the IMPROVE initiative are to prevent maternal mortality, decrease severe maternal morbidity, and promote health equity. Because of the timing of the budget this year, what we've decided to do is have three very strong pillars that will roll into the Centers of Excellence. The Centers of Excellence funding opportunity announcement will come out this summer. In the meantime, we have a major goal of increasing community partnerships. In particular, we want to bring in communities that have knowledge of the local culture and have a trusted relationship. We need people who have a trusted relationship in the community to begin to implement changes that will result in improved maternal care. The other thing that we're doing is we're developing technologies that will particularly improve care for women who are in underserved areas, the so called maternity deserts, as well as women in rural environments who don't have access to obstetric care. We're looking at wearables and we are looking at cell phone apps as ways that we can monitor women who are in trouble and who need to get appropriate care.

Rep. Roybal-Allard - Is there a difference in the drug overdose deaths across states that have criminalized fentanyl test strips versus those that have not?

Dr. Volkow - That is an important scientific question and one that we will look into. Currently, we do not have that data but we can clearly tell you from the epidemiological studies that have actually reported that a significant number of overdose deaths from individuals that are taking drugs like cocaine and methamphetamine that are contaminated with fentanyl was unbeknownst to the user. So, providing them with a tool that enables them to actually test the drugs that they are buying to see if they have fentanyl, would significantly decrease the risk of overdosing.

Rep. Harris – I know that the National Institute on Aging did not directly fund the Aduhelm research but do you think FDA decision's to take the particular track they have for payment for it, will have a relatively chilling effect on privately funded Alzheimer's research going into the future?

Dr. Tabak – This is something that NIH has no authority over. Partnerships with industry are very important to moving our agenda forward.

Rep. Fleischmann - Given the recent efforts in xenotransplantation, does the NIH have any plans to develop protocols and research into this area, given the shortage of cadaveric organs readily available for patients in need?

Dr. Gibbons – From the standpoint of the National Heart, Lung and Blood Institute, this is an area that has been investigated for decades. And certainly, there has been some progress made, particularly related to newer technologies, even genetic engineering, gene editing technologies. However, I think we do need to be sure that the zeal of with which this is being implemented is done in keeping with that science. And so, it's quite clear that there still needs to be a lot more work done before this is really translating into clinical practice. Also, some major issues that may need to be addressed with regard to still acute rejection. This is an area that has been on the horizon for many years. There are some opportunities for progress but it's still in the early days.

Dr. Fauci - There are a lot of problems with xenotransplantation. I think we just recently had the experience of the transplant of a pig heart in an individual and what happened was that there was a pig virus in the organ that was transplanted. It was very likely that with the immunosuppression following the transplantation that you reactivated a cytomegalovirus from the pig, which might have actually caused the death of the individual. It's a very important goal because of the shortage that we have but there's a lot of work that needs to be done.

Rep. Herrera Beutler – Will ARPA-H be providing funding for pediatric research?

Dr. Tabak – We don't know what ARPA-H will be funding yet. That will be driven by the inaugural director and the program managers that he or she hires. Certainly, I can't imagine that we would leave children behind.

Rep. Herrera Beutler – Do we know more about stillbirth? Are we able to treat this better?

Dr. Bianchi - Stillbirth refers to a spontaneous death of the fetus after 20 weeks in the womb. It's a tragedy and it's something that we still don't know a lot about. What we do know is about 20% of the stillbirths are caused by an extra chromosome. Presumably there are some additional genetic causes that involve only one gene or a cluster of genes. One of the things that we have funded in the past year, in conjunction with the Human Genome Institute, is an expert curation panel on gene mutations as a cause of stillbirth. In the past year, there's been tremendous progress in the sequencing of the human genome, but what you need to know is how to interpret that information. So, we are funding an expert panel of computer scientists, maternal fetal medicine specialists, geneticists, etc. to look at these mutations, and then determine which ones of them may be associated with stillbirth. Adverse outcomes of pregnancy are a very high priority for our institute and preventing those adverse outcomes.

Rep. Moolenaar – What are your insights on when we will no longer call the current COVID-19 public health emergency a pandemic? Are there criteria or benchmarks? What kind of a process will we go through to make that determination?

Dr. Fauci - No, there really is no firm, widely acceptable definition. When one talks about pandemic, you talk about a highly transmissible infection that is essentially widely distributed throughout the globe. When you're in the acute fulminant stage of pandemic the way we were in the U.S. just a few months ago, we had 900,000 cases a day, tens of thousands of hospitalizations, and we were averaging 3,000 deaths a day. That's a highly fulminant stage of a pandemic. We then came down to a low level and now we're unfortunately ticking up a bit. When you get down to a level where it isn't disrupting society, it isn't causing deaths that stress your hospital system, and you have a level of infection that, might be comparable to what you see with respiratory syncytial virus or para-influenza, it wouldn't be considered a pandemic in the classic sense. But there's a lot of gray zone about the definition. I don't think you're going to see all of a sudden one day that there's going to be a declaration that the pandemic is over. It will likely be that it is no longer in the pandemic phase and it's more of an endemic kind of infection that you could live with. Right now, we're not there.

Rep. Moolenaar – Where do we stand with the public health emergency and legal definitions within the states and throughout the country?

Dr. Fauci - I'm not sure I can answer that with any authority because that's not what we do here at the NIH. There will be a time when an examination of the level of infection and the level of impact in the country will then dictate whether or not it's pulled back as an emergency. I don't think I can give you a really good answer on that.

Rep. Moolenaar - What is your sense and recommendation going forward with respect to vaccinations? What would a definition of fully vaccinated be?

Dr. Fauci – It's very clear right now if you look at the hospitalizations and the deaths of those who are unvaccinated, compared to those who are vaccinated and boosted, the data are stunning. In the era of Omicron, it's very clear that a booster is needed. If you look at both the durability of protection, there's no doubt not only to natural infection for which you recover, but also from vaccination over a period of time, there's a waning of immunity. Other countries like Israel have really good data that when you get x number of months out, even from the third shot, you then get an increased risk, particularly among the elderly and among those with underlying conditions, of hospitalizations and death. So right now, the FDA and the CDC have said that people 50 years of age or older are eligible for a fourth shot of an mRNA vaccine. The advisory committee to the FDA met and is looking at what the recommendations are going to be as we get to the fall, specifically, what's going to happen when we get to September and October. It is very likely that all of us who have been vaccinated will have a diminution of the level of protection after a certain number of months and it is likely that they will be recommended for everyone to get a boost then. It will be determined whether we have to be boosted every year the way we do with flu and we don't know that right now because of the fact that we're having different variants. But right now, we're in the Omicron era, and the vaccines that we all got worked pretty well, so long as you do get a booster shot. I think sometime in the middle of the summer, we're going to know what the cadence is going to be about how often we're going to have to vaccinate people.

Please click here for the archived hearing.