Seeking Comments on
Implementation of the NIH Public Access Policy
Thursday, March 20, 2008, 10:00:00 AM

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Transcript based on videocast available at:
http://publicaccess.nih.gov/open_meeting_march_2008.htm

John Burklow:

Good morning everyone. I'm John Burklow, Communications Director for NIH, and welcome to the open meeting on public access. I'll be your MC today.

So before we get started with our series of speakers, I'd like to go through an introduction and the goals and the process for the meeting. So just to go over the charge of today's meeting that's listed in the NIH Guide: "To seek public comment regarding the implementation of the NIH revised policy on enhancing public access to archived publications resulting from NIH-funded research".

Okay, and that's it. Okay, just kidding, sorry. Okay. Public access, the RFI, will be out from March 31st-May 31st and we'll be seeking information from the public, including all stakeholders, about the NIH public access policy and as revised by the NIH guide for grants and contracts, to incorporate the requirements in Public Law 110-161. And here is the website…you can find it on the NIH home page as well…to submit and view comments.

So the results of the meeting today and the RFI, all pre-meeting comments, a video cast of today and a transcript of today's meeting, will be made publicly available on that same website. And NIH's report on the meeting and the pre-meeting comments, as well as the RFI comments, will be issued by September 30th of this year.

So the goals of the meeting: to obtain broad participation and comment on the implementation of the public access policy from all stakeholders, NIH-funded researchers, representatives of universities, other NIH grantee organizations, publishers, patients, public health advocates and members of the public; and for us to continue a transparent and open dialogue with all stakeholders. So, the focus today, is to comment on the NIH public access policy and its implementation. The role of NIH staff today is to receive input from the community without providing feedback until a later date. So it's a listening session today. When all comments have been compiled and analyzed. As many public comments as possible will be heard in the time allotted today. And I understand many of you have signed up. And if you have not signed up for a spot to speak today, I will manage that process and introduce you, etc. Speakers, sign-up opportunities are provided on a first come first served basis. So the process, the speakers for each comment session will be seated in designated rows at the front of the auditorium. Those with odd numbers preceding their name to the right when facing the stage and those with even numbers to the left. The order of speakers will be listed on the screen to facilitate the flow of each comment. Session: The session moderator will call for each speaker by name, that's me. If the speaker is not present when called, his or her name will be called again at the end of the session. Speakers are requested to use one of two floor microphones that you see up in front here, which will face the audience. Each speaker is asked to provide their name and affiliation before their comment. Oral comments are limited to a maximum duration of 5 minutes. A timing light will indicate whether a speaker's time is running green, and you're okay; running out, yellow; or red. And you see there is the stop sign… stoplight kind of device that we have. And if you look on the floor, that's the X, the trap door, don't make me use it. But, the good news is it goes right to the metro. So, anyway…. Speakers are asked not to cede time to each other or increase the duration of any particular comment. So, let me introduce our first speaker, Dr. Elias Zerhouni, NIH Director. And he'll give opening remarks. Dr. Zerhouni.

Elias Zerhouni:

Good morning. I want to welcome everyone to this meeting. Again, I will try to get a little bit of a context for the meeting and also give you the perspective about how we see the public access policy, its genesis, where we are, where we need to be, and set, if you will, sort of a set of parameters here that I think are important.

As you know, this topic is not a new topic. It's a topic that has been discussed for over 10 years. And however, from our standpoint, the standpoint of the agency, we think it's an important way for the public access policy to evolve for NIH to increase the value of its scientific investment, given the advances of informational technology. And I've made that point many times. If the world hadn't changed our policies wouldn't have changed. I think if the world was no longer was a … still, a paper world, where typical concept at the Library existed, as it existed, in the past, was still the same, I don't think that NIH would be trying to advance these 3 aims, one it's obviously archiving. It's important for the main output of the taxpayer's investment at NIH, which is NIH-funded research publication and preserve that research for years to come.

The second is important goal is to advance science in the context of a world of information technology that is moving faster than we can imagine or we did imagine a few years ago. And the fact that today, you can, through synergy, increase the value of the … return of the entire research investment made so that this can be a dynamic resource. To not only research and display publications but link them to all sources of knowledge that NIH has invested in and to better manage the entire research investment and obviously access easy through internet, is something that the public has expressed as a need. And this will make it available to the public. And when I say the public, the public at large. I mean, for me scientists at large are part of the public, patient advocacy groups are part of the public. There is a notion that this "public", has to be someone who is completely ignorant of science. And I disagree with that. I think there is more to the public than one subcategory of it. I think it's important to understand what we consider the implications of a successful public access policy. I think we believe that easy access through our research, research funded by NIH, will help advance science and improve human health. And this is where I think--I have said it many times, I'd like to develop win-win scenarios with the stakeholders present today. I think we need to work together to try to make sure that the goal, the fundamental goals of the policy, better advance science and improve human health are our common goals so all of us here and understand that we want to protect also very important values. Peer review is something we do not want to damage. And we believe in the importance of the viability of the publishing enterprise across the world. So we do not want to damage that as well and we are completely open to interacting and to adjusting and to correcting things within the context of a statute that as you know, is the one we are trying to implement. So we want to meet the public's expectation that articles based on NIH-funded research are publicly available after an appropriate embargo period. We never intend this to violate copyright laws. We want to be respectful of copyright laws, as we've stated many times. NIH wants to monitor, mine and develop its portfolio and NIH-funded research more effectively. And when we say portfolio of NIH-funded research, we are not just talking about publications. We are talking about the genome data banks, we're talking about protein data banks, we are talking about the genome-wide association study data bank, various instruments that science requires today to advance at the pace it needs to advance

given its complexity. NIH-funded research also becomes more prominent, integrated—and the word integrate is key here—and accessible so that we can build on this sort of world of knowledge, tools, hopefully built by industry itself that will make it easier for all scientists to pursue NIH's research priorities areas not only competitively but synergistically.

I think as you know, the law requires that manuscripts be made publicly available on PubMed Central. And PubMed Central is called central because it's central to a whole family of databases as you know as I just described, protein structure, data banks, SNP databases, the books that we have, the OMIM database and many other instruments, if you will, that are absolutely required now for science to evolve. And today, as you know, we have 380 member journals of PubMed Central which was established in 2000. And there are about 1.4 million full text articles. And I'd like to stress the fact that we see the value, not just in the primary form of a paper, but we see the value in an integration of many things.

First, search results. Search engines are becoming key to the activities of science and the scientists and public as well. And so PubMed has intrinsically the ability to search the entire world literature and to connect as much as possible all of the fundamental elements of scientific information, whether it be chemical structures, referred to in an article, or a compound, or a 3D view visualization of the protein or a chemical attached to a protein. And I think these tools are really important, we believe, and have been, I think, in many ways, the sort of value added proposition that all of us are searching for that goes beyond the author's names, the journal titles and really tries to go into a world of smart searching and interconnected knowledge data points that need to be connected and PubMed Central is one model of doing it, obviously. And it's been in the mission of the National Library of Medicine, digital archive of life sciences and clearly in the context of PMC, the full text of articles is available and searchable as well with other NIH and worldwide resources by the way, it's not just NIH databases.

So if you look at all of the PubMed Central tools, I don't want to belabor the point but we do link to compound substance and reference articles and the taxonomy and the taxonomy tree, basically everything we believe will accelerate the research we refer to methods, for example, and those can be searched as to where they can be validated so that scientists don't have to go through the very costly process of revalidating a method that was already developed. I think I'm just going to …I don't know why these slides are not the ones that …just very quickly go through all of this sort of the tool set that we envision as being very important to researchers. Again, I think that policy does not impose any requirements on publishers themselves directly, although I recognize that we want to work with all publishers to make sure that we preserve the important values that all of us feel are critical here. But they also relate primarily to NIH articles or NIH-funded research. I think it's important to see that when you look at a journal, for example, we do recognize the need for the journals to be linked directly. Their articles are linked directly and we provide all of the instruments, if you will, freely to the entire community to be able to do so with the tools that we have developed. So what is at stake? About 64,000 journal articles we estimate arise from NIH funds each year and basically have not been captured under voluntary public access policy. I think we want to apply 21st century technology to the investment to promote science, health and commerce in the context of the globally wired and networked world of scientific information. These changes are not

those that we have created. They have been imposed on us. All of us, as a community, we want to make NIH more transparent and accountable and better able to make strategic decisions about its portfolio and ensure that NIH and HHS can better promote science and health information derived from NIH-funded research.

So, you might wonder why did we see Congress move to mandatory submission. Frankly, this is the one slide that sort of carried the day. And that is that only 7.9% of manuscripts were deposited under voluntary policy. I think that it is important to again recognize that this is a long evolving process with many, many steps, both in terms of congressional action. You can see here all of the different —and I'll go in detail over those resolutions of Congress and how these have connected to NIH action. As you know, there is the E-Biomed, in '99, the start of PubMed Central in 2000. And then we have H.R. 5006, which really started the whole conversation here. I'd like to go over some of these details. And most of you know already all of these events that lead to the current situation. But, H.R. 5006 really started in our view the need for us to be proactive in addressing this issue, because it rose to the attention of many members of Congress. And the H.R. 5006 stated very clearly that the committee is very concerned that there is insufficient public access to reports and data resulting from NIH-funded research. The situation is contrary to the best interest of the U.S. taxpayers who paid for this research. And then the committee went on to a very direct recommendation saying, the committee recommends that NIH develop a policy to apply from FY 2005 forward, requiring ...so the first iteration of congressional intent was in fact a mandatory policy…that a complete electronic copy of any manuscript, it wasn't really looking at authors or publishers. It really said those should be available within 6 months, that was the embargo period, or immediately in cases in which some or all of the publication costs are paid with NIH grant funds. That meant that any page charges or publications costs paid by our grantee will trigger an immediate posting of that manuscript in a database.

In June 2005, H.R. 3010 said, in support of the policy, the committee is hopeful that the policy will be a first step towards providing free and timely access to the published results. As know, at that time, we went into a process of interaction and we, through the interactive process, thought that a voluntary policy was a step that we needed to implement for cooperation from all parties, publishers and others will lead to a successful implementation-- we believed. And that at the time, we thought that a 12 month embargo period , up to 12-month embargo period, was more appropriate. We responded to the input we had from the community and decided that indeed, because of the totality of issues that were brought in front of us, that it was probably wise to implement a voluntary 12 month policy. In June 2006, House passes again an appropriation bill with a mandatory 12 month maximum delay period public access. This was June 2006. However, because of the continuing resolution process that was the way to budget the government for that year, no bill language was attached to appropriation. So we knew as an agency, what the intent of Congress was in June 2006. In July 2007, both the House and the Senate appropriations passed again a law with the only change being the mandatory nature of the policy but they kept the embargo period for 12 months. In December 2007, the requirement becomes law after the President signs the bill.

So, I just want to make sure that we understand that from our standpoint, this is a continuous process of iterative interactions that have lead to decision-making that in many ways have been responsive to the many public inputs we have received. For

example, if you look at our Federal Register notice in September 17, 2004, we received 6,249 comments. And that was at the time the proposed 6 month policy, even though 66% of the respondents agreed it should be 6 months, 22% disagreed. We, as an agency, really took into consideration the issue of financial viability of journals that may have less than a weekly or monthly publication schedule. We believe those arguments were real and therefore advocated for a 12 month, and implemented a 12 month embargo period. Now, as you know, this policy then met with various degrees of success in terms of being able to engage all of the stakeholders into helping this policy succeed. Congress then noticed the data that showed that in fact it wasn't succeeding, for many reasons. And I think the policy intent is still the same as I described initially. We wish to be successful on behalf of science and public health here.

So, if you look at the proposed policy, in September of 2004, the draft policy requested but did not require that NIH supported investigators submit electronically the peer-reviewed author's copy—that was a major clarification of their manuscript—on acceptance. The manuscripts have to be archived in PubMed Central and the author's copy will be made available 6 months after the study's publication. And the final policy says fine for voluntary, fine for author's copy, fine for preserving peer review, PubMed Central that was unchanged and then at the time of submission, the author will specify for up to 12 months. And then basically in January of '08, because of the passing of the resolution and of the law, the new statute, the only change really is the voluntary to mandatory nature. I wanted to really also do a comparative analysis of what the NIH policy is, relative to those of many other institutions. As can see, most of them are mandatory 6 months. We do believe that mandatory 12 months, up to 12 months is really the right place to be while we go forward. So, from my standpoint, I think I want to reassure everyone here that the NIH wants to move forward.

There is no doubt that there is a tremendous amount of both frustration, as to the fact that this policy is not advancing fast enough from the public stakeholder standpoint and from others who feel that it is advancing too fast. And clearly from my standpoint, I think that what we need to do is listen to exactly what is it specifically the implementation of this policy that can be adjusted, changed, so that we implement the policy while being sensitive to its policy goals, which is not to slow down science, not to slow down public health. But in fact accelerate that, in a way that has a win-win scenario at the end for all involved. So we are all ears. We want to adjust the policy. We are not saying that this is the end all, be all of the policy details. But we are saying that we need to move forward and we are completely open to an interactive process here that will take into account all inputs to adjust the policy in its implementation.

However, the statute, from our standpoint, is so clear and so unambiguous, that we have no choice, given the history of this that the agency would be seen as very unresponsive by not going forward. And the policy, by the way, which obviously is not going to be completely implemented on day one. Remember, the policy is a prospective policy and it does not look back. And hopefully, I see this as a continuous improvement process, because at the end we achieve the goals of the statute, which is public access, while respecting copyright laws and not damaging peer review and making sure that science and public health are advancing. Thank you very much.

John Burklow:

Thank you Dr. Zerhouni. We will now hear from Dr. David Lipman, the National Center for Biotechnology Information at the National Library of Medicine at NIH. And he will review the manuscript submission process.

David Lipman:

I'm just going to go over some operational aspects of how documents get into PubMed Central. And first, one main distinction to make is that between documents or manuscripts that get into PubMed Central because there are publisher agreements directly with PubMed Central. So this approach has existed since February of 2000. And when Dr. Zerhouni refers to 380 journals who are participating, this is the way they do it.

It doesn't really show there, but sort of the a start-up of all this and the publisher comes to the Library of Medicine interested in joining up with PubMed Central and we go over this publisher agreement with them and once that is signed, we move forward. We get the full text XML and PDF articles from them. In some cases, they are in an archival format we can automatically use. The one that was developed by NLM or it is one we have to work to convert it and we do a process of QA and when the data flow is working well enough and the quality assurance is good enough we move forward to a production mode and we continue doing QA. And this also doesn't indicate that the supplementary data and so forth also is included. That goes into PubMed Central. And in those cases, we work with the publishers to get what we call, the PubMed Central journal branding. There's some bit of a menu of things that the publisher can choose from the... and the banner the publisher puts on the top links back to the publisher of a variety of sorts.

The other approach is the manuscript submission system we put together for the voluntary policy. In that case, the publisher or some other third party or the NIH researcher themselves, uploads the manuscript files in any format. So these are primarily coming in as word processing files. And also include supplementary data and so forth. And we, at the NIH, create the XML, digital archiving format from that. We get it back to the NIH researcher, the author, to look at it and make sure that it looks okay typically because the process, the tagging process, is a manual process; sometimes there are issues in terms of the interpretation of the alignment of a table and so forth and so we want to make sure that the author has looked at that and agrees that it's correct or if there is some errors to send it back. And then it goes into PubMed Central and the author would have set an embargo period up to 12 months. And then it goes out. And there the "branding", is a generic one for these manuscripts that are submitted by authors directly.

For the PubMed Central publisher agreement, there are several kinds, and I think it's worth just going over it quite briefly. Most of the journals that are in PubMed Central now opt for the full PubMed Central participation. They essentially send all the articles into PubMed Central. And the implication that this has, vis-à-vis, an NIH author who is publishing in one of those journals, is they don't have to do anything. There is already in place an agreement between the publisher and NIH in terms of the use of the article within PubMed Central. And the archiving aspects of that and so forth. And furthermore the author doesn't need to do anything to prove anything because we are basically working off of the QA that happened between the author and the journal.

The second way which we developed on the basis of input from publishers since the voluntary policy started, is called the NIH portfolio approach. And in that case, the publisher only uploads those articles that were NIH-funded articles. And again in that case, both the copyright aspect of the publisher is explicitly saying it's fine for this content to be available in PubMed Central and the technical aspects, the operational aspects, the author doesn't need to do anything. So for those journals, the relationship is between PubMed central and the journal and the author really doesn't need to be involved at all.

The final approach, which we call selected deposit, there is a number of publishers now who provide author pays open access options. And this is a case generally speaking, it's a case where the author has paid a set amount or has made some agreement with the journal and in most cases, those articles are immediately available. These are also, however, articles for which we've worked out the technical details with the publisher. And it may cut across all their journals, like Oxford University Press, Springer, there is a number of other publishers for which any of their journals and articles, if the author opts for this, will come in and associated with it are licensing aspects that may be full open access, or along those lines, it comes to us, it's available in most cases immediately. But that means that for that journal, only a subset of the articles, the articles for which an author opted to get it to or into PubMed Central this way, only a subset of those articles are available that way. And that means that for the journal as a whole, there is a possibility that some of the articles may come in through the NIH Manuscript Submission system because the authors did not opt to in some cases, pay an additional fee for it to be immediately available and in PubMed Central. And some of the articles come in through this route. So those are a mixed bag.

Okay, for the submission process itself, there is sort of 3 steps. The article is uploaded, in most cases so far by the PI, although it may have been initially uploaded through a bulk approach that the publisher made arrangements for, but then we have to contact the PI by e-mail. They enter a minimum amount of article metadata. They designate the NIH-funding, so this is where they connect the paper up to the funding source they have from NIH. The files are uploaded including supplementary data. And they see a PDF version of what they submitted and that takes on the order of about 10 minutes. We have done various sorts of timing studies. If you look at the second time they have done one of these, it takes less than 7 minutes. But it's not particularly onerous. Once it comes to us this way, we go ahead and we send all these files to an XML tagging vendor. They put it into our archival format. They do the conversion. They send the files back and we have an additional quality assurance step that we do to see that it looks okay to us. And the turn around time there is on the order of about 10 days.

The PI and NLM, in the next stage, the principal investigator gets an e-mail from us. They click on a link and they look at the web version rendering of the document. And generally speaking, it's taking less than 10 minutes for most folks. We give simple instructions in terms of for example, paying attention to tables and so forth as I mentioned before. And then it's approved at that stage and it waits not accessible to the public until the embargo period is over. At that point, it's uploaded publicly into PubMed Central and of course that varies…the timeline for that, because the embargo periods vary. And that's really all I wanted to present. Thank you.

John Burklow:

Thanks, Dr. Lipman. Now we'll hear from Dr. Norka Ruiz Bravo, Deputy Director for Extramural Research at NIH. She'll discuss policy issues and public input.

Norka Ruiz Bravo:

Thank you, John. Good morning everyone. I'm all that is standing between you and the public comments so I'll try to be brief. But I thought it was important that we all start from similar understanding so I will go over with you some of the policy details. Okay. So I will be giving you a policy overview. I'll be telling you about who is pre-registered. A little bit of demographics. I'll be taking or giving you a little bit of a view of some of the comments that we got at first look. It's a very preliminary simple tally. And I'll tell you a little bit about the request for information.

So, I thought it would be important for us to start out with a similar understanding or the same understanding of exactly what it is that the statute says. So this is the statute, Sections 218. "The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine PubMed Central an electronic version of their final peer-reviewed manuscript upon acceptance of publication to be made publicly available no later than 12 months after the official date of publication provided, that the NIH shall implement the public access policy in a manner consistent with copyright law".

And you heard Dr. Zerhouni's statements to that effect and that in fact we are very conscious of being consistent with copyright law. There was an NIH guide notice that basically stated what this policy was, and with some implementation dates.

Definitions, just so that we are all on same page with respect to what we call what:

PubMed Central is the NIH digital archive of full text, peer-reviewed journal articles; its context is publicly accessible and integrated with other databases and you heard that this was actually started in 2000. It's been with us for a long time and in fact, the earlier version of the policy, the voluntarily version, used PubMed Central just like the current mandatory policy does. PubMed provides access to citations for biomedical literature and includes over 17 million citations from MEDLINE, another life science journal for biomedical articles back to the 1950s, along with links to full text articles and other scientific resources.

The final peer-reviewed manuscript is the author's final manuscript of a peer-reviewed article accepted for journal publication including all modifications from the peer review process, and the final published article is different. That's the journal's authoritative copy of the article including all modifications from the publishing peer review process, copyediting and stylistic edits and formatting changes. The policy applies to the final peer-reviewed manuscript. The policy basically applies to any final manuscript that is peer-reviewed, is accepted for publication in a journal or on or after April 7, 2008 and arises from any direct funding from NIH grant or corporative agreement active in FY 2008 or beyond, or any direct funding from a contract signed on or after April 7, 2008 or any direct funding from the NIH intramural program or an NIH employee.

So that's basically what the policy covers. All of this is detailed in the NIH guide notice that is on the URL which is given below. To comply, the author first must address

copyright. Institutions and investigators are responsible for ensuring full compliance with the public access policy including any copyright or other agreements that are consistent with submitting to PubMed Central. The author must submit manuscripts upon acceptance for publication and you heard from David Lipman that there are a couple of ways to do that. Some journals will fulfill the submission requirements for authors; that's the URL to find those. And for other journals the author must inform the journal of the policy upon submission for publication. The author must ensure copyright and other agreements comply with the policy, and reserve the right to put things into PubMed Central. And the author must submit the final peer-reviewed manuscript to NIH upon acceptance for publication.

The third piece of the policy is that the author must cite the article. Include the PMC number for applicable articles in application proposals and reports. Basically if an author wants the peer-reviewed article to count, if you will, towards as evidence of productivity for example, in a peer review, or in any reports for NIH, then that article if it was supported through NIH funds, must have a PMC number. This is where you can go for additional information about the policy, including frequently asked questions. We'll have training resources; we will continue to develop training resources as we hear from you and we find out what it is that you actually need. One of the hardest things we do is communicate, so we want to make sure we are meeting your needs in order to comply with the policy.

And the last link is for the NIH submission system. This is just a simple profile. It's a very preliminary look at who is pre-registered. We have over 100 people pre-registered. We have stakeholders from various communities. We have stakeholders here from awardee institutions; we have NIH-funded investigators registered; we have patients and representatives from a public health organization; we have publishers, including commercial organizations, professional societies and journal editors and we have other interested members of the public. So it's a broad range of stakeholders that we have and that have an interest in this policy. This is a very preliminary first look at the kinds of comments that we have been receiving. There are comments that have expressed policy concerns, some of them fundamental concerns with the policy. Some of them are concerned about the financial impact. Some would like clarification or revision, and some are concerned about the embargo period. As you recall, the embargo period is up to 12 months. Some have expressed absolutely no concern. General support for the policy, actually the majority of them, and they are expressing support for the policy and they would like to share implementation approaches. And we have some that really didn't fall neatly into those categories. And we have some duplicate submissions. So a total of about 451 comments to date. Remember, of course, that we have the RFI, the request for information coming up. That should be available for you; I think the beginning date that we slated is March 31. That will be available for you to submit additional comments for an additional 60 days. And we would certainly welcome your comments and encourage you to comment. Thanks very much. And I think I'll turn it over now to John to get the public comment period started.

John Burklow:

I will see the names and I believe you'll see the names as well. Those who will be coming up to give public comment. And if I don't see the names, perhaps…there they are. So first is Jack Ochs from the American Chemical Society. Okay.

Mr. Ochs:

Good morning, I'm Jack Ochs and I'm here to speak on behalf of the American Chemical Society. We're grateful for the opportunity to comment on the implementation of the public access policy. Although we hold the view that this meeting and the RFI that's been announced by the NIH are a step in the right direction, they are no substitute for the formal notice and comment rulemaking that's required by the Administrative Procedures Act. And we believe that the NIH should not only postpone the implementation but also the formulation of its revised policy until this process can be undertaken.

It's also clear to us that no single meeting, however long, will be able to resolve the many issues and questions that surround the NIH's implementation of its revised policy; there are too many to go in this 5-minute period but they are detailed in the written comments submitted by ACS and other publishers. Because we don't have time to go into it, we do think that it's essential that the NIH establish a formal and ongoing consultation with publishers to safeguard the integrity of the scientific record to implement the policy, the NIH's policy, in a manner consistent with copyright law and to fulfill the intended purpose of Congress when it directed NIH to work with publishers in implementing the new policy.

We think that NIH missed an opportunity to make its voluntary policy a success by not proactively including publishers as it developed that policy, and we feel that consultations with publishers are even more critical today to resolve a number of copyright and implementation issues that the agency faces. We can speak from our own organizational experience about some of these issues. We publish approximately 4,000 articles a year that acknowledge the NIH as a funding source. And we've been trying since 2005 to resolve copyright and intellectual property issues with the agency in connection with our efforts to deposit those articles on behalf of our authors who asked us to do so. Despite our efforts, we've been told by NIH to suspend our article deposits, and that prohibition has prevented us from depositing more than 3,000 articles on behalf of our authors. During this same period, PubMed Central has accepted unauthorized postings of our copyrighted material, and repurposed and openly displayed those materials, and not following either its own guidelines or the legitimate terms and conditions that we as the copyright holders have set to protect the integrity of the scientific record. Our issues and concerns remain unresolved to this day. And we can only feel that the mandatory policy will do nothing to help this situation and may in fact exacerbate it.

We'd like to point out that the vast majority, if not all of our copyright concerns, could be resolved by the NIH if they would abide by the original intent of the public access policy and post unaltered final author versions of peer-reviewed manuscripts on PubMed Central without reformatting, repurposing, modifying or mirroring on third party web sites, and accept the offer made by many publishers, including the ACS, to link to the final authoritative version of record on publisher web sites. We are aware that there are some people that have the opinion that publishers have been slow to take advantage of the opportunities created by the web to enhance the scientific literature but nothing could be further from the truth. Publishers are experimenting with data mining and visualization tools, semantic web applications, on-line navigation aids, flexible display, free access to the recent archive of published articles and web 2.0 applications as well as

supporting the development of international standards to enhance the scientific literature, web sites, and maximize the discoverability of science in general. Thanks to publisher efforts, global access to scientific information for investigators at institutions like the NIH are easy and widespread. And researchers are now one of the very few online communities that spends more time analyzing and reviewing content than actually finding it. More than any other industry that we are aware of, publishers have embraced the internet and our investments and licensing options have made more content available in more ways to more people than at any time in history. And that includes the NIH. Copyright is one of the main tools that has made this possible.

Regardless of the nature of the issues that have been raised here and will be raised here this morning and have been raised in the written comments, we choose not to believe that the NIH is willfully disregarding copyright and the intent of Congress. We stand ready to work with the agency to establish the kind of ongoing productive dialogue that we feel is in the public interest. Thank you.

John Burklow:

Next we'll hear from Christopher Fox from the International Association of Dental Research.

Mr. Fox:

Good afternoon, colleagues. Thank you, Dr. Zerhouni, for this opportunity to provide public comments on the implementation of NIH public access policy. I'm Dr. Christopher Fox, Executive Director of the International Association for Dental Research and the American Association for Dental Research. We are two 501(c)(3) not-for-profit associations based in Alexandria, Virginia. We publish the Journal of Dental Research, the number 1 dental publication in terms of scientific impact factor. While an international publication, most years we have about 30% of published articles with some NIH-funding, although it has been as high as 57%. So the implementation of this NIH public access policy will certainly have an impact on our Journal.

Here is the antiquated print version of this month's Journal of Dental Research for those of you who remember print, but we are also online through the High Wire Press platform from Stanford University and have also digitized our entire journal content back to Volume 1, Issue 1, published in March of 1919. By publishing online with High Wire Press, we are part of the largest repository of high impact peer review articles in the world with over 1 thousand journals and over 4.5 million articles. By partnering with High Wire, although we are a small association, we are also able to offer to our readers, all the linking services to references, similar articles and our journal as well as the ISI web of science, links to Google scholar and links to PubMed and downloads to Citation managers and a variety of formats. Real 21st century technology. The Journal of Dental Research fully supports open access as a signatory of the Washington, D.C. Principles of Open Access. All of our content is free of access controls no matter the funding source 12 months after publication. Scientists, dental practitioners, students and the public can access all of our content from March 1919 to March of 2007, 87 years of oral, dental and craniofacial science. And by being part of High Wire, the Journal of Dental Research is part of the largest archive of free full tech science in the world, with over 1.8 million free full-tech articles.

While we support open access, we strongly object to NIH's interpretation and planned implementation of the mandatory language contained in the Consolidated Appropriations Act of 2008. Specifically and most importantly we do not believe that NIH has adequately addressed Congress' proviso that "NIH shall implement the open access policy in a manner consistent with copyright law". For a small professional association, we have invested significant resources to establish an effective peer review system, to develop in-house copyediting and production systems to launch our journal online in 2002, and to digitize all our volumes back to 1919. The only way for the association to recoup this investment, not make a profit, just recoup this investment, is retain the copyrighted materials and to offer individual and institutional subscriptions. Once a significant proportion of our copyrighted journal content in the form of accepted manuscripts is available free on PubMed Central and possibly onto PubMed Central international, we forecast the decline in our subscriptions which will undermine and threaten the sustained viability of the number 1 journal in the dental sciences.

Furthermore, the IDR and ADR as publishers of the Journal of Dental Research, we are more than willing to provide PubMed Central with a link to our site with a final authoritative version of the published article within the same embargo period. Yet the proposed implementation of the public access policy would retain the earlier non-authoritative version of the accepted manuscript on the PubMed Central site. If this is about public access, surely the interest of the public is better served by having access to the final authoritative publications rather than to an unedited manuscript. To address these concerns, we believe that the NIH should undertake a formal administrative procedure and rulemaking, and a rulemaking would provide the public and all interested stakeholders with a formal mechanism for comment with adequate lead times and a formal procedure for NIH to address the concerns. All publishers from the corporate publishing houses to small societies like ours have questions not addressed in the frequently asked questions section of the public access website. Significant copyright concerns remain.

While we appreciate this opportunity we don't believe that seeking public input with an open meeting just 18 days prior to the implementation date with one week to prepare is sufficient to address all of our concerns. I certainly have additional concerns that I don't have time to discuss in this allotted 5 minutes. Should the NIH undertake a rulemaking and carefully consider the comments from all stakeholders, the final NIH public access policy would be greatly improved for the betterment of science, clinicians, and the public. Thank you for your time.

John Burklow:

Now we'll hear from Donna Dean from the Association of Independent Research Institutions.

Ms. Dean:

Good morning. I'm Donna J. Dean speaking today for the Association of the Independent Research Institutions. Dr. Zerhouni, Dr. Kington, and Dr. Ruiz Bravo, we appreciate the opportunity to provide our comments on the NIH revised policy on enhancing public access to archived publications resulting from NIH-funded research. The Association of Independent Research Institutes (AIRI) is a nationwide association of nearly 90 nonprofit independent research institutes that conduct peer-reviewed, basic

translational and applied research in the biomedical and behavioral sciences. AIRI institutes are recipient of approximately 11% of NIH extramural research grant funding, and we are pleased we have the opportunity to articulate our position today.

Nonprofit research institutes, independent research institutes are stand alone, academic style centers that offer scientists a focused research environment to conduct innovative science. Therefore, despite the fact that ARIE member researchers may not have an institutional repository to assist authors with depositing their manuscripts into PubMed Central, we stand ready, willing and able to comply with the requirement. Our board has not expressed any concerns with the policy and actually believes that this requirement may enhance overall support for science once the public is able to view firsthand the benefits that result from federally funded research in a more timely and open way. AIRI applauds the National Institutes of Health for undertaking the effort to implement the intent of Congress and we believe the requirements are clear, easy to follow, and do not constitute an excessive burden on our researchers or our research institutes. We also enthusiastically support making our research available to all who can benefit from it since it is federal tax dollars from the public. We thank you for the opportunity to express our views today. And we hope that you will continue to look upon the Association of Independent Research Institutes as a resource on this and other issues as NIH moves forward with the next implementation step. Thank you for the opportunity to respond.

John Burklow:

Thank you, Dr. Dean. We'll next hear from Crispin Taylor from the American Society of Plant Biologists.

Mr. Taylor:

Good morning, everyone. Thank you very much for your time; it's a pleasure to be here. My name is Crispin Taylor from the American Society of Plant Biologists. I want to make 3 points, if I can. I'm going to tell you that the mandatory policy is unnecessary and flawed. I think that it inhibits small publisher innovation and it's a fundamental departure from the voluntary policy. I also will make a plea for NIH cooperation and constructive engagement with publishers and for a full public comment rulemaking.

So ASPB is a small professional society. We have 5,000 members. Even so, we manage to publish two of the top 3 journals in plant biology. By impact factor they are very well represented and regarded worldwide. The content of both of those journals is posted on PubMed Central in its entirety in one of the mechanisms that Dr. Lipman described earlier. It is also hosted on the journal sites that we own at High Wire Press. Entire annual budget for the Society is less than many NIH grants. We are a nonprofit and our annual operating income pays for the entire activities of the Society including the innovations that we do make in publishing. Nonprofit or not, publishers have made hundreds of millions of dollars in investments in putting their peer review process online and their journals online. Through High Wire, as you've heard, ASPB journals are part of an archive of 4.7 million articles from hundreds of publishers. 1.9 million of those are already freely available right now. They are fully interlinked. They are indexed by Google and they're connected already to many other databases of biological information. So, the mandatory deposit policy is duplicating efforts by publishers already and is

unnecessary in that regard. These efforts by publishers are self motivated. Nobody told us to do this. We want to do this because it's part of our mission.

I also dispute the need for a central monolithic repository regarding articles to link to all sorts of other things. On today's internet, it's all about discoverability and as I said, the journal content on our own site is already easily discoverable. It's richly interlinked and it's connected to all sorts of other information resources. One of my biggest bug-bearers with this mandatory policy has to do with publisher innovation. And ASPB, like many other small publishers, has indeed welcomed and embraced this new world of online publishing and we worked hard to find ways to innovate that don't greatly impact our bottom line. This implement now, figure out the details later approach that the NIH is prescribing right here, I think it violates the letter and the spirit of the law passed by Congress. I think it will divert money from the primary mission of funding research into human health. We don't know how much. And for ASPB, this sort of Damocles' that's hanging over us, this threat that the literature will be made open access by fear, is stifling out our facility to implement our own innovations and to do research on our own.

As I mentioned, ASPB deposits the full text of our articles in PubMed Central. We have been doing this for years. We felt it was important for reasons to preserve the literature to have a second archive in addition to the one that we pay for at High Wire Press. We felt it would be an opportunity to reach new audiences, either public audiences or audiences in different fields of science that may not be familiar with our work in the journals, which is very important, of course, in this era of interdisciplinary science. The NIH also very generously and graciously funded conversion of content pre-internet from both of our journals and created an entire archive for us and it was a very constructive engagement at that the time. Since then, however, NIH has not, in my opinion, worked cooperatively or constructively with ASPB which I think is a missed opportunity. We don't have access to usage data that would allow us to determine whether or not we are indeed reaching the new audiences through this partnership. And therefore we have no capacity to determine whether or not our goals are being met.

The NIH has also sought to take the content that we deposited with them under license and distribute it around the world, although they didn't actually do that. And my sitting in on public access working groups and PMC advisory committee meetings, I have to say that the NIH has been dismissive of publisher motivations, our expertise, our perspective and willingness and desire to cooperate and help. So, I would argue that robust and respectful engagement with publishers whose content NIH seeks to take in this mandatory policy is essential. And like others, I would argue that a full comment and rulemaking is necessary before implementation. And that the voluntary switch to mandatory policy is a fundamental change. Thank you for your time.

John Burklow:

Thank you. Next we'll hear from Kathy Case.

Ms. Case:

I'd like to say I'm not here under false pretenses. I figured you would have heard enough from publishers so I'm here as a cancer survivor to speak about the issue of insufficient public access to the information. I'm one of 10 million cancer survivors in this country. I'm also a heart attack survivor. My life was saved by well informed doctors who knew what they were doing. During both of my illnesses, I had access to

anything I wanted in the literature through the NCI, through heart associations; I was not ill-informed in spite of the fact that people have to pay for subscriptions. I don't believe the cure for cancer is hidden in the literature and just being kept from us by greedy publishers. Many of you know I have been a publisher for 40 years. I'm about to retire. I don't accept the judgment that we have failed. I don't accept the judgment that the librarians have failed. Our doctors are the best in the world. They save our lives every day. They saved my life.

The Congress made a ruling based on a notion that there is insufficient public access to the literature because a handful of people convinced them of that. The rest of us were silent. There weren't 10 million cancer survivors there saying that. There weren't people like me. I wish I had gone there and spoken to them instead of taking the role of a publisher, who has worked her whole life to get information out to the public there. So … there is a lot of heat, a lot of emotion around this but there is not a lot of truth around it. Our role as publishers and scientists and whatever we are, has been to improve healthcare and it has worked. So why are we allowing the negative PR that somehow all you librarians, all you publishers and the government have failed? I'd like to see the energy. I'm not even following my notes anymore, amazingly enough…I'd like to see the energy put into this, put into the fact that research is what saves lives. Why aren't we out there advocating for not having a research budget slashed, which is what's happening. Why aren't we out there? Doctors save lives. 47 million people in this country don't have access to doctors, don't have access to healthcare, that's where we need to be putting our energy. We have all this brouhaha based on a myth that lives are being lost, and this is what the Congress bought. I'm not talking about the National Library of Medicine or the National Institutes of Health. I'm talking about the Congress believes. That a few people went to them and said, we are dying because we can't get a hold of an article from the "New England Journal of Medicine ". That's pretty much hooey. You can find whatever you want on the internet. And you can also ask your doctor.

In that sense maybe we've succeeded because as we have a well educated medical cadre. Why don't we put our information, I mean our energy to work, dealing with where the real problems are with getting advances in research, not spending more on bombers than we spend on medical research. And it's very disturbing…I'm a taxpayer. I'm a citizen. I'm about to retire. So I'll be a retiree. I won't be a publisher. So I guess I won't be the bad guy anymore. Maybe I can be a survivor and speak from that point of view. But this is very disturbing, disheartening to those of us who spent all of our lives trying to improve the access to medical information; in fact trying to improve healthcare in general.

Most of us, whether you're in the for-profit or not-for-profit, really believe we have a mission. Some of those missions make money, some of them don't. I published 3 journals that didn't make any money but they had a mission behind them. So my concern is the judgment is now that we have failed in our ability to get out medical information. That's what the Congress said with this ruling. And that is now the role of the U.S. government to get that information out. I would argue that we shouldn't accept that. We should put some of our energies into where the real problems are, which is what saves lives is not the medical literature. What saves lives is the research behind the medical literature. And that is where we should be putting the combined energy and resources of everyone in this room. Thank you.

John Burklow:

Next we'll hear from Marty Franks using an alias today.

Mr. Franks:

My name is Martin Frank. I'm a taxpayer. I'm a patient and an Executive Director of the American Physiological Society, founded in 1887 and publishing The Science of Physiology since 1888. I'm the coordinator of the DC Principal Coalition, a coalition of 70 not-for-profit publishers who make their content freely available after a interval determined by their business and publishing models.

The APS, along with many of the coalition members, utilize the services of Stanford University's press, High Wire Press, to publish a content of our journals on-line. High Wire Press hosts the largest repository of high impact peer-reviewed context with over 1100 journals, 4.7 million full text articles from over 140 scholarly publishers. High Wire hosted publishers have collectively made over 1.8 million articles available for free. We are here today to talk about the efforts of NIH to duplicate the efforts of High Wire Press to create a repository of a small fraction of the content resident on their site. The content specifically derived from research funded by NIH or approximately 80,000 articles annually.

Not-for-profit publishers question the need to utilize scarce research dollars in order for the NIH to become a publisher of that research. As Dr. Zerhouni indicated to me yesterday, we are having today's public access discussion solely because the scientific literature is available on-line and is more readily accessible to the public. While true, the scientific literature is available only because of the millions of dollars invested by publishers to publish their content on-line. Public access advocates tell us that the taxpayer paid for it. Therefore the public should have it for free. That is untrue. The taxpayer may have supported in whole or in part the research that appears in the articles, but the publication process is paid for by consumers just as consumers pay for the loaf of bread produced from the taxpayer subsidized wheat. The 4,000 articles published annually by the APS costs the society approximately 12 million dollars annually. The appropriation of the content by NIH is being done in a way that might limit the publisher's ability to recover these costs.

We are here also because according to NIH, the voluntary submission policy has been a failure. Only 4% of the 80,000 eligible articles were submitted by the NIH-funded author investigators. What NIH and others failed to indicate is that publishers have deposited another 20% of the eligible articles. Publishers have repeatedly offered to work with NIH to facilitate the deposit of the NIH-funded articles but NIH is unwilling to negotiate with publishers in good faith. During the summer of 2006, I met with NIH as part of a delegation representing 56 society publishers responsible for the publication of over 15,000 NIH-funded articles. We were offering to deposit the final published articles on behalf of our authors under the NIH portfolio agreement. Those negotiations broke down because NIH told us that their international agreements to create international PMC repositories were more important than the taxpayer access to NIH-funded content.

Publishers also offered to work with the National Library of Medicine to fulfill its mission, preservation of the biomedical literature. By offering to provide them with the full text of our on-line journals just as it had been done previously with print journals. Not only would the NLM be able to host the NIH-funded research, but they also received

the research articles arising from support provided by all funding agencies. Instead of trying to work with publishers to fulfill its mandate, NLM rejected the offers as unworkable. In reality, working together, we could have made it succeed. Instead, we now have a plan that will only provide the public with access to 10% of the literature funded by NIH. Can we truly advance science and find cures for disease by only accessing 1 in10 articles? As a patient, I want access to every research article and it appears that right now the best way to gain access to both NIH and non-NIH-funded research is to access that content through High Wire Press.

For the NIH public access to succeed, NIH must agree to work constructively with publishers. Even with mandatory deposit, author investigators will not deposit their peer review manuscripts. They do not want to be burdened with bureaucratic requirements. We believe NIH must not regulate first and ask questions later. It must undergo Administrative Procedures Act discovery before implementing the plan. We urge NIH to create a better plan by listening to the community, working with publishers before implementing the mandatory deposit aspect of the public access plan. Thank you.

John Burklow:

Thank you. Next we'll hear from James Phimister from Elsevier

Mr. Phimister:

Good morning. Elsevier appreciates the opportunity to contribute to the NIH meeting on public access. Elsevier has an unqualified commitment to the growth, quality and efficiency of peer review publications and to widening access to scientific and medical research. Each year we spend hundreds of millions of dollars to collate, review, edit, correct, produce and disseminate nearly 300,000 articles in over 2000 trusted specialized peer review journals. We have also invested over half billion dollars in electronic digitization, hosting and distribution of over 8 million articles, dramatically increasing effectiveness and efficiency of researchers and practitioners. For the past 3 years, we have sought to work collaboratively with the NIH on implementation of the voluntary public access policy. We proactively identified authors who report NIH-funded research, deposit their manuscripts to PubMed Central and actively monitor policy compliance. We calculate Elsevier's contributions and increased current deposit rates to PubMed Central to over 30% of articles reporting NIH research. However, we consider the move to mandatory policy to be a very significant change. It should not be done hastily.

There is a fundamental difference between the government working with researchers and the publishing community to achieve common goals and the government asserting rights to copyrighted content and competing directly with scholarly publishers. Due to the far-reaching implications of the NIH's new public access policy on grantees, authors, institutions and publishers, we urge the NIH to expand the consultative process and conduct a notice and comment rule making as defined by law.

Indeed, in 2005, when the NIH introduced the voluntary public access policy, the NIH stated: We believe that the voluntary nature of the final policy is preferable to one-size-fits-all requirement as it permits sufficient flexibility to accommodate the needs of different stakeholders. Significant departure from this position warrants a formal consultation with stakeholders. The Department of Health and Human Services should follow the Administrative Procedure Act and stay the effective date of the mandate until a

full notice and comment rulemaking is completed. We urge the NIH to ensure the implementation of the policy and respect the basic principals embodied and copyrighted and not undermine those rates that provide incentives for publishers to invest in peer review, publishing and the communication of scientific and medical research. Without sufficient consideration, the mandatory public access policy left unintended and undesirable consequence.

It is therefore important that we address critical questions. How will the NIH ensure that PubMed Central does not compete with publisher websites? That traffic is not diverted to PubMed Central and that content on PubMed Central will not displace the definitive published version? What actions are the NIH taking to ensure that PubMed Central does not undermine the viability of journals whose economic stability varies widely? How will the NIH ensure policy will not negatively impact commercial, nonprofit and the society publishers and will the NIH compensate publishers for the added value of services that publishers provide? Third parties could commercially exploit the content that appears on PubMed Central without the consent of the publisher. How will the NIH prevent copyrighted material available on PubMed Central from being altered, pirated, made into derivative works, redisplayed, republished and resold? Many manuscripts that currently appear on PubMed Central are in contravention to publisher policies. How will the NIH ensure individuals post the correct manuscript version to PubMed Central to be publicly available at the correct time as consistent with publisher policy? In the NIH's processing of manuscripts, manuscripts that appear on PubMed Central may differ from the definitive version hosted by the publisher. How will the NIH ensure that researchers are not mislead as to the accuracy and validity of the manuscripts on PubMed Central?

In conclusion, we see scientific and medical publishing as a system that has developed over many years and is core to the continuing success of the research community. As the publishing system evolves, we must sustain quality and balance. We wish to work collaboratively with all key players, particularly the NIH, to demonstrate leadership in this evolution, to address the issues we raise, and to develop viable solutions that will benefit everyone. A rulemaking is a critical and necessary step. Thank you for the opportunity to contribute to this meeting.

John Burklow:

Thank you very much. Now we'll hear from Fred Dylla from the American Institute of Physics.

Mr. Dylla:

Thank you, Dr. Zerhouni and others to from NIH to give us the opportunity to make some comments this morning. My name is Fred Dylla. I'm the Executive Director of the American Institute of Physics. This is an umbrella organization of 10 member societies and 23 affiliated societies that represent 135,000 physical scientists. And you might think that we don't have much of an oar in the water when dealing with medicine and biomedicine, but your distinguished director is a very credible radiologist and prior to Dr. Zerhouni's directorship, we had Harold Varmus who noted to Congress and the public and the medical community that physicists are valuable to medicine. We developed MRI. We invented the x-ray. A high-energy physicist invented the web to share large amounts of data. And physicists we are perfectly happy and willing to share all of this

for the worldwide good. Our society members are all for increased access and open access, public access, all these words get confused. They have various definitions. We support the goal. But…and it was very good for us to hear this morning from Dr. Zerhouni in his remarks that this policy is moving towards presenting information to the public, to scientists, for wider public access. And with respect to copyright law, and he does not want to harm the peer review process of the publishers which aggravate and provide this information, that's very good to hear.

But it's the implementation that concerns us at the American Institute of Physics and our member societies and our publishers, as you have already heard from this morning. When you ask the public or Congress about the fact that NIH is paying for a certain amount of research, it should be made available, of course they'll say yes. The survey we heard about this morning, 66% said yes, they want public access. If you ask anybody, if they want something for free, they are going to say yes. Unfortunately the public, members of Congress, most of them, and many of our authors do not understand the economics of journal publishing. Journal publishing has been around for 3 centuries and it's gone through a tremendous transformation in the last decade, thanks to the physicists providing the worldwide web as a very interactive way of presenting information. The American Institute of Physics hosts 300,000 pages from over 100 journals on our own platform. And since we introduced that, our access has gone up by an order of magnitude. But we risk damaging the entire journal process. We risk damaging the value of scientific societies and we risk damaging science if we don't very carefully migrate our economic models to open access models.

I'm a big fan of NIH. It's the largest funder of science in the country. And I'm very distressed as a citizen and as a scientist that the budget for NIH has been flat over the last 5 years. I'm also distressed in my new job. I have only had this job for a year. I was an active scientist for 3 decades before that. I'm distressed that I see NIH spending its good money duplicating what scientific publishers do both profit and nonprofit. This gets very technical. You heard this morning talk from David Lipman this morning, the entire bottom half of a slide is duplicating what publishers do to have interactive database…documents have to be referenced with a digital number. NIH has duplicated what publishers have done en mass with that. They have to have an interactive database; you have to have a very complicated cross-referencing scheme. All the publishers that work together in an organization called Cross-Ref that allows that to happen. And NIH should not be spending its precious funds to duplicate those things.

My final remark has to do with the fact that the public confuses public access to research with the public translation of science. I have a degree from MIT in biophysics and I can't read a state-of-the-art journal in cancer research. What we do in our society is take some of the money that we have for publications and provide translations of that science that the public can understand. I don't want to see that damaged. Thank you very much.

John Burklow:

Thank you. Next we'll hear from Michelle Hogan from the American Association of Immunologists.

Ms. Hogan:

Thank you for this opportunity to speak. I'm Michelle Hogan, I'm the Executive Director of the American Association of Immunologists, which is a professional association representing 6,500 research scientists and physicians dedicated to understanding the immune system. We publish the Journal of Immunology, the world's most cited immunology journal and one of the top ranked journals in the ISI. It publishes over…we publish over 15,000 text pages a year and we are part of the High Wire Press at Stanford. We respectfully submit the following comments and these are in brief some of the comments.

AAI continues to believe the NIH public access policy will duplicate at great cost to the NIH and to taxpayers publication services which are already provided cost effectively and well by the private sector. The private sector including not-for-profit scientific societies already publishes and makes publicly available thousands of scientific journals that report cutting-edge research funded by both NIH and other public and private entities rather than creating a new government bureaucracy, a particular burden in this era of severe budget constraints. NIH should partner to develop a plan that enhances public access but addresses the publishers' key concerns, of which we've heard of many today, and also ensuring journals' ability to provide high quality independent peer review of NIH supported research assuring to the public and the to NIH that in which they are investing.

AAI has strong concerns about the implementation of this policy. In our submitted comments we have noted a number of the issues which include legal and procedural concerns that the NIH must address prior to issuing the RFI. But even if NIH addresses these concerns, we need additional information in order to submit thoughtful comments in response to the RFI. Therefore, AAI respectfully request that NIH publicly respond to the following questions before the RFI is published.

One, what are the total funds that were expended on implementing the voluntary public access policy starting May 2, 2005 to January 11, 2008? We've never seen that number. What is the cost anticipated for implementation of the mandatory NIH public access policy in FY 2009, including one time costs as well as annual reoccurring costs? In responding to the above questions, we ask NIH to report specific costs included in the NLM as well as various NIH institutes, centers and offices which will undoubtedly be involved. We have provided these specific costs in our written comments but they include items such as the number of FTEs and contracted services used to accommodate this initiative. What steps is NIH taking to ensure that it posts only articles that comply with a particular publisher's embargo policy? We have certainly had this violated for us and have a full-time FTE just looking this over to have them taken down. Who will ensure the NIH complies with the publisher's copyright rights once a manuscript is submitted? That is, who will make sure the NIH does not transfer a manuscript to any other entity or repository without permission from the publisher? Who within NIH and the various institutes will be responsible for determining whether a grantee is in compliance? Is it institute directors, is it program officers? How will this process be carried out and who is responsible? And in fairness to our members, what will the penalties be for noncompliance specifically? What is the evaluation plan for the public access effort and when will it be assessed? How can NIH move forward with this

implementation plan when NIH will not be responding to the RFI until September 30, 2008?

And finally and specifically we would like to know why the NIH will not accept the linking proposal offered in 2005, described by Marty Frank, by 56 not-for-profit scientific publishers. It would enable the journal's website to be available seamlessly on PubMed Central and enable readers full text … the access to full text articles funded by NIH and most instances all articles irrespective of the funding. This proposal has the following advantages and provides public with free access, provides the final published articles. It's cost effective since the NIH would not have to recreate and continue supporting a new repository, educate grantees' compliance and copyright and monitor for copyright and compliance. It addresses publishers' copyright concerns and upholds embargo periods. It satisfies new laws. And finally in discussions with the NIH and the linking proposal we offered to satisfy NIH's need for a repository of NIH-funded works with a dark archive for internal purposes only. Thank you for your time and attention.

John Burklow:

Thank you very much. Next we'll hear from Ellen Garrison from the American Psychological Association.

Ms. Garrison:

Thank you for the opportunity to comment on behalf of the American Psychological Association, APA, regarding the new mandatory NIH public access policy. I am Dr. Ellen Garrison, Senior Policy Advisor to our CEO, Dr. Norman Anderson, and I'm accompanied today by Susan Harris, APA's Senior Director for Journals. APA is the largest scientific and professional organization representing psychology in the United States, and the world's largest association of psychologists with 148,000 researchers, educators, clinicians, consultants and students. APA is also the largest publisher of behavioral science research with 37 of the premier scholarly journals in the field of psychology. Given that the 6 leading causes of death in the U.S. are behaviorally determined, it is clear that psychological science has a critical role to play in improving the health of our nation. Accordingly, APA strongly supports efforts to enhance public access to scientific publications but has serious problems about the new public access policy as related to copyright, compensation, scope of coverage, and date of implementation.

Underlying this new policy is the faulty presumption that publishers will not experience significant financial hardship due to the 12 month lag between data publication and posting of the peer-reviewed manuscript on PubMed Central. While this may be true for a handful of publishers, it hardly applies to the industry as a whole and certainly not to our association. This is due to the fact that the cutting edge research that we publish is rarely obsolete within a year, and may have a shelf life of 5 to10 years. Moreover, only 15% of the eventual lifetime usage of our journal articles in the form of downloads occurs within the first year after publication. About one-third of the articles in 9 of our journals resulted in whole or in part from NIH grant support. Our authors reflect the wide diversity and the behavioral and social sciences field including new investigators. Our overriding concern is that when peer-reviewed manuscripts are made widely and freely available online, the commercial value of the finished public work is likely to be seriously diminished while resulting declines in subscriptions and licensing

agreements. This loss of income is likely to lead to less scientific publishing, and thereby less public access to research.

According to the statute, it is the responsibility of NIH, not the institutions or investigators as NIH contends, to "implement the public access policy in a manner consistent with copyright law". In clear violation of copyright principles, publishers for the first time ever are essentially being made to forego their copyright interests without just compensation for their investment. It is critical to realize that publishers add immense value through such functions as editorial selection, peer review, copy editing and design production. The public access policy must not have a negative impact on publishers both in this country and internationally nor on U.S. business or industry that would undermine our high quality of research. The policy by its very nature compromises a quality of scientific publishing by ultimately making available two versions of scientific papers. How does NIH propose to ensure that the postings in PubMed Central will not adversely affect the copyright interests of publishers, the value that they add to research and the interests of the public in maintaining the quality of scientific publish? In certain aspects, NIH would be well-advised to scale back the reach of its policy, specifically the policy should only apply to scholarly work fully funded by NIH. So as not interfere with the interests of other funding sources and to empirical research, not literature review.

And lastly, NIH should not hold investigators and their institutions responsible for the submission of manuscripts that arise directly from the research that they did not author or coauthor. NIH is to be commended for holding this open meeting and for issuing a request for information (RFI) later this month. Yet even taken together, these actions do not substitute for a formal notice and comment rulemaking which NIH is still urged to pursue. Rather than take precipitous action, NIH should delay implementation of its policy to allow time for the consideration of today's comments and those arising from the RFI and should not apply the policy to any grants issued before its effective date. In keeping with the Senate report language, it is also critical that NIH meaningfully engage publishers in the implementation and evaluation of its new public access policy. Thank you once again for this opportunity to comment.

John Burklow:

Thank you. Now we'll hear from Carol Blum from the Council on Government Relations.

Ms. Blum:

Good afternoon. I'm Dr. Carol Blum, Director of Research Compliance and Administration at the Council on Governmental Relations, or COGR, an association of more than 175 research universities, their affiliated academic medical centers and research institutes. As an association, COGR concerns itself with the influence of federal regulations, policies and practices on the performance of research conducted at its member institutions. COGRs' members are aware of the statute and the implementing National Institutes of Health policy on enhancing public access and are working to assist their investigators in meeting the statute and policy requirements. Because the mandatory requirement is applicable only to articles funded by grants, contracts or cooperative agreements with current active support, grants funded since October 1, 2007, and contracts awarded after April 7, 2008, we have time to inform and insist our

investigators in meeting this shared obligation. We can focus first on those researchers with continuing funding whose research may be sufficiently advanced to have results to report. As new awards are made, we will provide notification and support as needed to assist our investigators.

Public reports of the policy have given rise to some confusion and we appreciate the resources NIH has made available, notably the frequently asked questions to clarify the applicability of the policy and how grantees and their investigators meet their obligations. We would note that the policy needs further clarification to reflect the relationship between NIH-funding described in the FAQ, and the acceptance for publication, the criteria described in the policy. Normally, institutions do not join the relationship between authors and journals. As educational institutions, universities seek to balance scholars' rights as authors with our fundamental mission to promote the free exchange of ideas and research results and we urge our faculty to publish their scientific and technical research.

In accordance with this academic tradition, most institutions do not claim ownership to pedagogical, scholarly or artistic works regardless of their form of expression. However, as the grantee, a research institution is obligated to meet the terms and conditions of all its agreements. As such, institutions must act to ensure compliance with the statute and NIH requirement. Where publishers' practices would restrict required access to research results, we will remind our investigators to retain their rights individually to provide a copy of the final peer-reviewed manuscript that has been accepted for publication to PubMed Central under current copyright law provisions. We appreciate that NIH is providing an example of language that can be used in copyright agreements to meet this obligation.

Some of the burden of meeting this statutory requirement would be eased if more journals would collaborate with NIH and the research community in meeting these statutory obligations. Recognizing the requirement, we hope the publishers will modify standard copyright agreements to include a provision that acknowledges the author retains the right to provide a copy of the final peer-reviewed manuscript to NIH and to make the article available in PubMed Central. Alternatively, journals could agree to deposit the final published manuscript in PubMed Central. In this case, a significant portion of the burden on the grantee institution and its investigators is relieved. There are currently over 250 journals and 60 open access publications submitting directly to PubMed Central. This assistance from NIH and these journals to secure agreements is particularly important since many manuscript submission and copyright authorization procedures are electronic and do not offer the authors an opportunity to adapt the publisher's submission procedures to meet the NIH policy. The consequence to investigators who inadvertently fail to reserve their rights to submit are not clear and should be addressed by NIH. We are equally concerned for investigators, particularly junior investigators, whose career advancement may be jeopardized if some journals refuse to accept the reservation of rights or the investigator lacks access to sufficient resources to pay the price for public access. As NIH creates programs to encourage and support new investigators, it needs to address the challenges of publishing results of that research that may fall particularly hard on these new scientists. The research institutions intend to meet their obligations and responsibilities under the statutory requirements as

implemented by the policy. And we appreciate the opportunity to make these observations and comments today.

John Burklow:

Thank you. Now we'll hear from Ellen from the Association of American Public Schools.

Mr. Adler:

Actually you're going do hear from Alan Adler who is the Vice President for Legal and Government Affairs for the Association of American Publishers. But that was good because it demonstrates that even the NIH is not infallible. Which I think is very important point for why we are all here today. We submitted formal comments to the NIH in which we discussed the problems that we've had in obtaining meaningful consultation with NIH for the journal publishing community. We outlined some of the specific concerns we have about protection of publishing rights including copyright, and we also talk about a number of issues raised about good faith implementation. So I want to summarize for you in a sort of a broad fashion why it is that publishing is so concerned about what the NIH is doing.

The concerns of scholarly publishers stem mainly from the manner in which NIH and its staff responsible for PubMed Central have implemented this public access policy, both when it was a voluntary policy and now when it has become mandatory. Briefly, they have taken liberties with copyright content in a fashion that simply competes with the activities of independent publishers and that undermines the rights of those publishers including copyright. Specifically, by reprocessing and enriching manuscript submissions and expropriating publisher's value added investments in peer-reviewed content, NIH is creating enhanced derivative publications that go beyond the explicit congressional mandate of posting researchers' documents that report on the results of federally funded research. Let me say that again. They are going beyond the explicit congressional mandate of posting researchers' documents that report on the results of federally funded research.

What you have seen demonstrated in the presentations by NIH officials are the processing and reformatting and repurposing of the materials that are submitted to them by the researchers is not at all required by the mandate that Congress enacted in the Consolidated Appropriations Act. It is simply the way that NIH has chosen to implement that policy. And in doing so, they have doggedly disregarded proposed alternative ways in which this could be done coming from the publishing community which knows a thing or two about publishing. Rather than just posting, what it receives, whether it's an author's version after peer review or a publisher's submission in a PDF or other fixed format, NIH has embarked upon XML based, reformatting and tagging procedures to create alternative versions of published works that when made freely available will substitute for the definitive articles in which publishers have already made substantial investments. And therefore, in effect, there is no question in the minds of the publishing community that NIH is itself entering the publishing business, and more to the point, enabling other international entities to enter the publishing business with the same material through mirror locations of its database. And they will do so by creating enhanced derivative versions of the materials that they receive.

So, the question we come with today primarily is what does NIH have to fear in conducting a notice and comment rulemaking consistent with the Administrative Procedures Act? You heard from NIH, their willingness to receive input from the public, that's why they are conducting this meeting, that's why they are going to announce their request for information. But that's not an indication NIH is willing to respond to the input that it receives. And that is where the Administrative Procedures Act becomes very important. Over 60 years ago it was an acted by Congress to ensure generally that the agencies of the federal government in imposing regulatory policy do so in a manner that is rational rather than arbitrary and consistent rather than abusive of their authority under the law. It requires that the agencies not simply request and solicit public input, but also that the agencies respond to that input and particularly in responding to that input, do so in a way that justifies and explains the nature of their regulatory policies and demonstrates that those policies are in fact necessary and reasonable.

So why is the NIH afraid to conduct an APA rulemaking in this area? Could it be because they don't want to engage in that justification? They have to engage in that justification because the law requires it. We hope that the APA rulemaking will in fact take place because there are a number of important issues that need to be aired and need to be discussed in broader terms in greater detail that can be discussed in a forum such as this one. For example, this government imposed rule and mandatory license may well be equivalent to exceptions to copyright that would contravene fundamental obligations of the United States under treaties such as the Bern Convention and Trips Trade Agreement, and therefore may be directly counterproductive to this country's intellectual property law advocacy abroad in the global marketplace. We hope that ultimately there will be an APA rulemaking and that the NIH will not only solicit comments but will also itself comment in a meaningful way on what it is doing. Thank you.

John Burklow:

Thank you, Mr. Adler. To be honest, I was wondering why the public schools had a stake. But now I understand. Next we'll hear from Patrick Kelly from the John Wiley and Sons, Incorporated.

Mr. Kelly:

Hello. I'm Pat Kelly. I'm a publishing director within Wiley Blackwell, which is a Division of John Wiley and Sons. Wiley Blackwell is one of the world's foremost academic and professional publishers with a combined list of more than 1400 journal titles. We are also the world's largest society publisher. More than half of those titles we don't own. We publish on behalf of scholarly, medical and professional societies. The 700 or so societies have more than a million members worldwide. As stakeholders in the research community that have invested billions of dollars to advance science to peer review and editorial production distribution and archival processes, publishers will be significantly affected by the implementation of this new public access mandate. What Wiley and many other publishers want is for NIH public access policy to be implemented in a way that maximizes its effectiveness to the public and scientific research community, ensures protection of copyright, and protects our and our employees and our society partners' interests. What we don't want is a regulate first and ask questions later approach that harms more than it helps.

The key to ensuring for us, that the public access policy meets its stated objectives and is effectively implemented, is for NIH to work closely with publishers and other stakeholders in the scientific research community to seek their detailed input through a full notice and comment rulemaking under the Administrative Procedures Act before the implementation of the policy. The public had a similar opportunity in 2005 when the voluntary public access policy was first announced and it should have that opportunity again, as directed by Congress. Wiley supports enhancing public access to government funded research, and we look forward to partnering with NIH to get this policy right. We have a number of concerns in various areas but I thought I would just highlight a couple in the area of protection of copyright that bother us particularly.

In our view, implementing the public access policy in a manner consistent with copyright law and the intent of its congressional mandate would mean that NIH would respect the integrity of the copyrighted content it receives and ensure that any revisions to copyrighted material, such as reformatting, enhancing, linking or otherwise changing the articles are undertaken only when consistent with copyright. We also have significant concerns related to how NIH will safeguard against domestic and international piracy of deposited manuscripts. NIH seems to assume that only U.S. copyright law is pertinent to the worldwide posting of articles by PubMed Central, yet the application of foreign copyright laws to the worldwide mirroring or downloading by PMC would have to be analyzed in far greater detail and in respect to the law of each country where such activity may occur. On a practical level, that makes publisher's final peer review manuscripts vulnerable, both to the interpretation of foreign government's and to international piracy of U.S. government funded research.

Peer review represents a significant investment by publishers like us and many others and neither originates with license or authors nor is the product of NIH-funding. Yet under this new policy, NIH insists on appropriating the final peer-reviewed manuscript. Publishers recoup the expense of peer review production and distribution by several means including commercial sales both domestically and overseas. As a result, when copyrighted articles are freely available online their commercial value in our view is significantly diminished. When peer-reviewed manuscripts are made widely and freely available online, the commercial value of the finished, published work is eroded significantly with resulting declines in subscriptions and licensing agreements.

This global effect will seriously harm publishers of all sorts but especially many of the smaller society publishers that we represent here today and whose journal titles we publish. Scientific, technical, and medical publishers employ some 30,000 people in North America alone with perhaps an equal number indirectly supported. How will those publishers be compensated for the economic loss that results from the NIH taking of the publisher paid peer-reviewed articles? NIH could undertake direct licensing arrangements with publishers to deposit copyrighted work on behalf of authors. It would be the simplest and cleanest way to do business, to ensure compliance with the public access policy agreements with publishers regarding payments for their journal articles, removes the administrative and financial burden of compliance with the policy from authors. The new NIH mandatory public access policy places heavy undue burden on institutions and investigators to uphold the copyright provision of the statute while the private sector is equipped now to help implement this policy effectively.

So, in conclusion, and on behalf of Wiley Blackwell, I want to thank NIH for the public meeting and the upcoming RIF proceedings. But considering the far-reaching implications of the substantial change in the NIH public access policy, we urge NIH to do a full APA notice and comment rulemaking. Publishers look forward to working with NIH to enhance public accessibility of scientific research results. We hope to find ways to do so while continuing to protect the publishing enterprise that has nurtured and served the scientific community. Thank you.

John Burklow:

Thank you. Next we'll hear from Prudence Adler from the Association of Research Libraries.

Mr. Adler:

Good morning. I'm Pru Adler with the Association of Research Libraries. ARL's very pleased to present comments on the revised NIH public access policy. ARL strongly supports the policy and commends NIH for soliciting comments while moving ahead in a timely manner with this critically important congressionally approved policy. Most ARL libraries support researchers who receive NIH-funding, thus are collaborating with others to ensure effective compliance with a policy. As is abundantly clear by the numerous comments filed by ARL members, there is strong support for the revised policy because it is integrally tied to the mission of higher education. As Dr. Zerhouni noted earlier, since the policy was first introduced in 2004, there has been extensive public comment, legislative consideration, review by an NIH appointed working group that included publishers, and many meetings with effective parties and NIH as we saw this morning. Now is the time to work collaboratively to ensure that implementation is successful as public access to federally funded research, furthers scientific discovery, enhances U.S. competition and importantly improves the health of Americans.

ARL and its members are actively engaging in a number of activities to assist institutions and their researchers in complying with the NIH policy. Steps taken today demonstrate that institutions believe that the compliance is achievable. This is due in part because research libraries focused on copyright management and access issues well before the NIH policy surfaced. This involves helping authors make informed decisions to exercise their interests and their institutions' interest in the ownership and use of copyrighted works and to do so in a manner that promotes the greatest possible scholarship and public use of their work. This includes promoting tools that allows authors to deposit their works in disciplinary repositories such as PubMed Central and in their own institutional repositories. The resources and communications strategies that we have designed and developed are designed to accelerate the readiness of institutions and the researchers to comply with the NIH policy.

Now with regard to possible changes that we were asked to consider, we encouraged NIH to reconsider the embargo period of 12 months, and once again solicit comments on a 6 month embargo as was originally proposed. As is widely understood, even with a 6 month embargo period, research libraries will not cancel journal subscriptions. Publishers, therefore, are not at risk from this revised policy or from a shortened embargo period. Thank you.

John Burklow:

Thank you. Next we'll hear from Emma Hill, from the JCB Rockefeller University Press.

Ms. Hill:

Hi. First of all, thanks very much for the opportunity to present our comments here today. It's very much appreciated. I'm Emma Hill, I'm the Executive Editor of the Journal of Cell Biology, which is published by the Rockefeller University Press. The Press is a nonprofit organization, which you may guess is linked to Rockefeller University. We publish 3 well respected scientific journals—the Journal of Cell Biology, the Journal of Experimental Medicine, and the Journal of General Physiology. I speak for all three journals and the Press as a whole today.

As a university publisher, we represent the middle of the road in the ongoing dialogue about public access to published data. Somewhere in between, the advocates to complete open access, and publishers who hold most or all of their content behind access controls. We applaud the NIH for their efforts to move forward with this policy which we wholeheartedly endorse.

The content of all 3 Rockefeller University Press journals is released on our own websites 6 months after the date of publication. More recently we worked with the National Library of Medicine to post the full final, copyedited and formatted text of all of our content on PubMed Central which is made available to the public 6 months after publication. With us we are ready to comply with the NIH public access policy. We estimate that this only costs us approximately 6 dollars per paper, which is not a significant cost. We do not charge the author. We see multiple copies and important digital archiving of our content in a public database as a completely positive aspect and in no way is this in competition to our own journals' websites. Greater availability of our content equates with enhanced visibility of our journals. Two of the Rockefeller University Press' 3 journals have been freely available to the public 6 months after the publication date since January 2001. Even though our content is only under access control for this short period of 6 months, our subscription revenues have continued to rise over the last 7 years.

The Rockefeller University Press is in a unique situation of demonstrating that it is financially feasible for publishers to permit the release of all their content in accordance with the NIH public access policy. At the Press, we strongly believe that scientific publishers have an obligation to release their content to the public to provide much of the funding to generate that content and to buy subscriptions. In an ideal world, all publishers would fulfill and facilitate this obligation on their own. Although many publishers are already doing so, there are still many who are not. Some may see this as duplication of effort by the NIH. I think this is wrong and that this is the NIH protecting their own interests and making sure they have ongoing access to the research that they funded with taxpayers' monies and also as a counter against the possibility of any publishers, especially those small and society publishers who may sadly eventually disappear. Their content will then be maintained within the PubMed Central archives. Publishers who oppose this policy may present various arguments but the bottom line is possibly they lose …they fear losing subscription revenue. In a sense, their stakeholders are a conflict of interest with respect to this debate which should be declared upfront just

as we also review as to …excuse me…just as publishers do with authors and reviewers in regards to their submitted manuscripts. If some people wish to demand financial accountability from the NIH, then we should also demand the same from many concerned stakeholder publishers. With taxpayers' monies, the NIH funds the research. NIH-funded research performs and reviews any research and thus the data from any resulting publications can and should be made available to the public. To this I don't think there should be any argument.

We believe that publishers can and should facilitate the implementation of this policy and see no need for any further comment period. We thus strongly support the NIH public access policy and urge you to implement this mandate as soon as possible. Thank you once again for the opportunity to talk and present our comments.

John Burklow:

Thank you very much. We are now going to take a break. It's 12:30. We'll go to lunch on our own up in the cafeteria upstairs. And you want to resume at 1:30 or do you want to move it sooner? Okay, so we'll be back here at 1:30.

BREAK

John Burklow:

Okay, we'll resume, so if you would like to be seated. And just a reminder, if you do want to make public comments you did just sign up in the back, I think Sharon Terry was just about to speak an hour ago. So let Sharon begin. Thanks.

Ms. Terry:

Thank you. I'm the President and CEO of Genetic Alliance. Genetic Alliance transforms health through genetics. We accomplish this by integrating improving individual family and community perspectives to improve health systems and by bringing together diverse stakeholders to create novel partnerships and promote individualized decision making through increased access to information. Our network includes over 650 disease specific advocacy organizations and hundreds of partnerships with universities, companies, government agencies and policy organizations. The network is an open space for thousands of shared resources, hundreds of creative tools and dozens of dynamic programs.

We applaud the Congress for enacting this policy and NIH for implementing it. We are pleased by this action but we are also acutely aware of the profound urgency inherent in a society that requires accelerated translation of basic science to meaningful clinical interventions. All information, the raw materials of making sense of disease and mitigating its effects should be immediately available.

We also ask the NIH go a step farther and make submissions of articles mandatory at 6 months as a compromise to immediate access. We live in an age of an over abundance of information. Information is not a scarce commodity anymore. Material that is 12 years old is old. It is unconscionable that scientific information is not immediately available to everyone. While publishers argue that they create value around raw information, we would argue that scientists funded with federal dollars and also stewards of the public trust infuse these articles with value. There is no doubt that publishers add value and the value proposition around this body of knowledge should be

paid for. But not the research results themselves. It is the duty of NIH as the primary funder of biomedical research to facilitate sunshine on the data and to bring these articles into the public commons as quickly as possible. Information critical to health and biomedical research should no longer be held hostage by arcane publishing practices. It is time for publishers, both private and academic, to redesign their business models in response to a new age of information, sharing a stronger sense of the scientific commons.

The myriad of solutions proposed and in use simply formulate the walls of silos, only a central repository will allow robust, annotated meta analysis. We have seen business paradigms for all sorts of publishing industries evolve as information aggregation changes. It is time for this industry to evolve as well. Public access to scientific information is critical. It is the bedrock of our current system of discovery and the catalyst to build on science. Scholars and educators will find riches of new data and studies to use in classrooms. Researchers across disciplines will have new opportunities for collaboration as they engage this treasure of publicly funded knowledge and the work of all authors will be cited more frequently. Public access to the biomedical literature funded by NIH will yield untold benefits for medical research and discovery of treatments.

I also stand here today as the mother of Elizabeth and Ian Terry, two kids with a genetic disease. It's rare. It's not well understood and there is no treatment. We are facing an uphill battle, a future of blindness for the two of them and thousands more with this disease. Another 6,000 or so genetic diseases burden more than 25 million Americans. When I began speaking about public access, I tried to carefully counter all of the arguments which we have heard today. My thinking has evolved. While I once thought we should move forward carefully and try to ease into these paradigm shifts, I think now, years later, we have evidence that the public banking of the genome, journals that have 3 month embargoes and less and then open access and the commons of information are thriving. I have also during this period watched thousands of people in our community die in these years and the time for waiting is over. Let's do it. Let's not spend any more of our precious time debating on this, commenting on this. We live on the promise and inestimable value of publicly funded science. Obstacles to translating basic science into practice abound. But gated access is an artificial obstacle. Remove barriers to information immediately, open access to publicly funded research without delay. We've got a great deal of work to do and we need the tools now.

John Burklow:

Thank you, Sharon. Next we'll hear from Peter Jerram from the Public Library of Science.

Mr. Jerram:

Hi, I'm Peter Jerram, I'm Chief Executive of the Public Library of Science, or PLoS for short. We are a leading open access publisher of scientific literature. And I'd like to thank the NIH for the opportunity to speak today and to share our views. Over the past several years, we and other open access publishers have conclusively demonstrated the high impact of open access scientific publishing. PLoS Biology, for example, is now the number 1 general interest biology journal in the world. PLoS has been in de facto compliance with the NIH policy since day 1 since all of our articles are already sent to the PubMed Central archive. And since we already grant copyright to our authors, we

have no concerns over this aspect of the policy. The policy itself in fact will greatly expand the availability of the more than 60,000 articles that result each year from NIH-funding.

At the most fundamental level of the course, the taxpayers have the right to see the results of the research that they have funded without paying an additional fee. But beyond basic rights, the policy's impact will be far reaching and deeply felt. Two profound implications stand out.

First, the impact on public health. Currently the public generally does not have access, unrestricted access to, rigorous peer-reviewed high quality research. There are numerous examples of citizens seeking health information on-line only to be denied the access for which they have essentially already paid. Similarly due to high cost of medical journals, many physicians can't afford to keep up with the latest research in their own fields. And health policymakers who formulate influential public policy are likewise barred from reading the full text to avoid this research. In all of these cases, most people are forced to rely on abstracts alone which are sorely inadequate as the basis for critical, clinical and health policy decisions. In fact, there are several recent studies that suggest that abstracts often inaccurately represent the content of the research they purport to summarize. A recent editorial and no less authority than the Lancet concluded that, "abstracts are known to be fickle representations of an article."

Secondly, the internet has enormous power not only to disseminate information but also to bring to bear computational tools to find, share and combine that information into virtual interlinked libraries that will spark new ideas and spur scientific discovery. The Wellcome trust, Great Britain's largest private funder of medical research, has noted that, as the tools for mining become more sophisticated, we will see new knowledge being created by the linking of research papers that previously not been seen as relevant to each other. For this to happen, however, papers must be held in an open access repository and not remain hidden behind publishers' authentication systems. We, as scientific publishers, support the NIH's open access policy. Over the past 4 years, we've taken the time to comment on the policy and have had ample opportunity to make our thoughts known. The policy will not only encourage others to follow suit with their own open access mandates, it will itself help unlock the power of scientific data and enable scientists to pioneer new kinds of computational research that can only occur in the open environment. Thank you.

John Burklow:

Next we'll hear from Rebecca Kennison from Columbia University.

Ms. Kennison:

Columbia University welcomes the opportunity to implement the NIH public access policy. We believe that the policy is consistent with educational and research objectives of the university, and of the right of the public to access government supported research. The NIH policy has also provided an important occasion for offices within the university to continue to collaborate and coordinate policy and procedures on the importance of managing our research output and ultimately making it more readily available to the public that has supported both the research and our researchers. In conjunction with the institutions around the country, Columbia University is taking steps to implement the NIH policy in full by the stated dates of April 7 and May 25, 2008. To

that end, Columbia has done the following: coordinated efforts between the office of research and the libraries; developed local implementation policies and procedures; drafted guidance documents and forms for submission of articles to journals and for agreements between authors and publishers; begun development of educational programs and tutorials for faculty members and other researchers and authors; created an original website of materials and information related to the policy.

We do have concerns about some of the challenges to implementation raised by the submission and compliance processes currently in place. Many of those concerns have been raised by other institutions grappling with the same issues. Our authors, as is true, throughout the Academy, submit directly to journals without going through any university office making tracking full and complete compliance difficult.

There are also several logistical concerns, that the person submitting is required to enter into the NIHMS as part of the submission process the date the paper is to be published but since submission is upon acceptance, that date is almost assuredly not known at that time; that the designated PI is required to approve the XML tagged version of the submitted manuscript before the PI can obtain a PMC ID number and the compliance in this step may be difficult to ensure; that the mechanism in place for correcting errors that might be discovered within the submitted paper once it has been approved is unclear; that authors may face long delays in obtaining PMC ID numbers for those publishing in a journal that submits the final published paper to PMC as the time from acceptance to publication can sometimes be quite lengthy.

That said, we are committed to working with NIH to develop and refine an increasingly smooth process for implementation of this policy. Implementing a new policy is never simple but we believe that Columbia University will be on schedule for implementation and we are motivated in large part by our support for the objectives of this important new policy. Thank you very much for this opportunity to comment.

John Burklow:

Thank you. Next we'll hear from Kate Oliver from Johns Hopkins.

Ms. Oliver:

Good afternoon. I am Kate Oliver. And I serve as Chair of the Scholarly Communications Group at Johns Hopkins University. Our group is a part of the University Libraries Council. I also serve as Associate Director of the Welsh Medical Library and as a member, as a staff member of that library, our library is part of the Association of Academic Health Science Libraries.

The Johns Hopkins University Library Councils strongly support the NIH public access policy. The requirement provides an important opportunity to make published research funded by NIH and written by Hopkins authors accessible to all…the public, healthcare providers, educators, and scientists, among others. This improved access will help advance science and ultimately improve human health. Deposit in PubMed Central ensures that research results will be preserved in a state-of-the-art digital repository. Free access within a 12 month period will maximize the visibility of Hopkins research and ensure that researchers and students around the world will be able to read and build on Hopkins work, regardless of their ability to subscribe to the journal in which the journal is published … the article is published or research is published. Preliminary research suggests that articles freely available are cited more often and have greater impact than

those articles that are locked away behind subscription walls. NIH public access will foster development of new research tools, open doors to new research initiatives, and advance scientific discovery.

At Johns Hopkins, we have taken the following steps to respond to the NIH public access policy. We have scheduled a meeting between the Dean of Libraries, the Director of the Welsh Medical Library and the Vice Provost for Research. The purpose of the meeting is to explore how the university and its libraries can assist its authors in meeting the NIH mandate and support open access to scholarly output from the university. We will present recommendations to the Provost on a university-wide publication agreement, the role of the university's repository, J Scholarship, and the Harvard initiative. We have created an FAQ on the NIH policy including an authors' addendum. Library liaisons will assist Hopkins authors by directing them to the information on the policy and assisting them in the submission process. We have advised our vice deans for research in School of Medicine, School of Public Health and School of Nursing on the FAQ that we've developed. And we remain in close contact with the Office of the General Counsel sharing the Carol White Paper and other relevant analysis of implications of the policy for the university and its authors. The School of Medicine Vice Dean for Research sent two broadcast e-mails alerting them to their responsibilities under the new mandate. And the second e-mail directed authors to the FAQ that we had developed. Both the School of Public Health and the School of Medicine will be placing a link to the FAQ assisting authors on the Office of Research Administration site. And this FAQ resides in a scholarly communications website that was developed by the university: openaccess.jhu.edu. Finally, we are currently exploring how we might develop an interface between our repository and PubMed Central in collaboration with other institutions and software developers. These institutions include members of the Association of Research Libraries, and the Association of Academic Health Science Libraries. Thank you for the opportunity to comment.

John Burklow:

Thank you. Now we'll hear from Jane Diamond from the American College of Rheumatology.

Ms. Diamond:

Thank you for the opportunity to comment. I represent the American College of Rheumatology. We publish two monthly peer review journals that are the leading journals in our field. We have a number of concerns about the NIH policy, many of which are similar to the ones I'm going to say are the ones that you've heard before. We are fully in favor of the concept of open access to articles 12 months after publication backed as was mentioned by other publishers here. All of our articles, not just NIH-funded articles, are currently made open access on our own journals website 12 months after publication. We do have some concerns about the process, though, as it is proposed, one of the greatest of which has to do with the deposition of articles at the moment of acceptance before they've been fully vetted.

Peer reviewers vet the scientific merit of journal articles but they do not identify subtle errors in the data. This is done at the copyediting stage after articles have been accepted. In virtually every article in our journals, such errors are identified. Frequently errors appear in the results section and if not corrected could lead to misinterpretation of

some of the study findings which, if left, would be detrimental to patients and future researchers. Copyeditors identify errors by spotting inconsistencies in data presented in one section of an article versus another section and rectify them with the author prior to final publication of the article. These types of errors occur in articles accepted by all journals, even articles authored by the most seasoned and respected investigators. NIH policy requires that articles be deposited at PubMed Central immediately upon acceptance prior to correction of these errors.

Open access is proposed one year after publication and is open access to the final version at which time those articles would have been corrected, but our question is, who will have access to the articles in the form in which they are initially deposited? And if no one will have such access, we wonder why they need to be deposited in this form. We also had questions similar to something that was raised by a speaker just a few minutes ago about how the author is to know when his or her article is to be published so he can indicate that upon deposition of the article because that is not something that the authors definitely know at the time an article is accepted.

Also, I'd like to reiterate that journals do add considerable value to published papers by performing peer review. Over 98% of papers eventually published undergo revisions to improve the validity of the published product benefiting future researchers as well as patients. The expense and effort of this process is supported entirely by the journals. We like to know if it will be possible that at the time the final published version is made open access, if that could be done only by a link to the journal site. This would lessen the negative effect on the journal's ability to continue with this vital contribution.

Finally, I'd like to point out that many investigators do not seem to be aware of the new policy despite the fact that NIH plans to put it into effect very soon, April 7. The ACR urges NIH to delay this deadline so that authors and publications can adequately prepare for it, and the procedural questions can be adequately addressed. Thank you for the opportunity to comment.

John Burklow:

Okay, thank you. Next up we'll hear from Heather Joseph from SPARC.

Ms. Joseph:

Thank you. I'm Heather Joseph, I'm representing SPARC, the Scholarly Publishing and Academic Resources Coalition. We are very pleased that the revised NIH public access policy is moving towards a timely implementation. We strongly believe that effective immediate implementation of this policy will enhance researchers' ability to access, share and use the results of the critical biomedical research funded by this agency. As an organization of more than 220 academic and research libraries, serving both public and private universities and colleges across the United States, SPARC is committed to the promotion of policies that expand the dissemination of research results, reduce barriers to the use of those results, and leverage the network digital environment in an efficient and cost effective manner. We believe that the NIH public access policy provides an important opportunity to further these aims.

SPARC has been strongly supportive of this policy since it was first proposed back in 2004. The breadth of support for this policy was clear to us from the reaction of the American public in the first request for comments published in the Federal Register in September of 2004 when the vast majority of the more than 6,000 individuals and

organizations who responded did so in support of the policy. We have been actively involved in the numerous public discussions and debates that have taken place here at NIH, in the U.S. Congress, over the past 3 years as the policy has worked its way visibly and transparently through the legislative process. We participated in dozens of meetings devoted to discussion of this policy convened by interested policymakers, universities, libraries, publishers and other stakeholder organizations. We have been very pleased to see this issue receive prominent coverage year in and year out in national and international media outlets ranging from the "Washington Post" to the Wall Street Journal to the NBC Nightly News. This long and thorough and very public vetting process culminating in the passage of the policy by both houses of Congress and ultimately with the signature of the President, strengthened our commitment to see this policy through to its successful implementation.

Now that the policy has been signed into law, our focus has been on creating programs to ensure the effective enactment of the policy so that its benefits can begin to accrue to the public. We are pleased to see that most other stakeholder groups are also putting their resources into these efforts rather than into costly and unnecessary campaigns designed to delay this crucial policy. Our efforts at SPARC have centered around raising awareness of the policy on our campuses, facilitating the deposited manuscripts into PubMed Central, and ensuring that authors understand the rights that they, as the original holders of their copyrighted manuscript, need to retain in order to comply with the policy legally. This third element remains particularly important as a small but vocal number of publishers continue to make the misleading and incorrect assertion that this policy will somehow put authors into conflict with copyright law. We are very pleased to see by contrast the growing number of publishers who see that this simply is not the case and whose publication policies encourage and facilitate compliance with the policy. The several hundred journals listed on the PubMed Central website who fall into this category, underscored that many in this stakeholder group understand that no conflict with copyright exists and that deposit of an author's manuscript in PubMed Central complements rather than conflicts with publication of a final article in a journal.

To help provide clarity on this issue, SPARC and its partners recently published a widely distributed white paper outlining 6 options for copyright management strategies that can be adopted to guarantee that researchers and their institutions effectively meet the policy's requirement for compliance with current copyright law. While our member libraries are certainly playing a central role in facilitating compliance with this policy, they are no means acting alone. On many campuses, these efforts involve close collaborations among librarians, researchers, research administrators, and university legal counsel. SPARC's members view the NIH policy as a welcomed opportunity to work in concert with their campus colleagues and to contribute directly to the mission of higher education, the promotion and advancement of knowledge. SPARC commends the NIH for issuing clear implementation guidelines in a very timely manner and for being consistently responsive to queries about the implementation process from our member organizations.

We applaud the NIH, Dr. Zerhouni, the U.S. Congress and the President for advancing this important policy which will provide a rich and innovative sweep of new resources as well as access to critical biomedical research findings to researchers on campuses and beyond. Prompt implementation of this policy will accelerate the pace of

research and discovery, fuel innovation, and serve the public good. Thank you for the chance to comment today.

John Burklow:

Thank you, Heather. David Carlson from Southern Illinois University, Carbondale Campus.

Mr. Carlson:

I'd appreciate more NIH-funding into the froggy-throat syndrome first, so I apologize for the voice. Thank you for the opportunity to speak with you today. My name is David Carlson and I'm Dean of the Library at Southern Illinois University, Carbondale. I made a special trip to Washington today to attend this meeting and express my enthusiastic support for the deposit of NIH-funded articles into the PubMed Central database.

In 5 minutes I cannot give a full accounting of the reasons for the wide support that this policy has by the library and research community generally. The changes occurring as a result of the transition from print to digital are complex and strategic. These changes strike deep at the heart of traditional library processes and procedures. However, libraries are not idle. We are focusing our energies not on the elements of what we may be losing but on the opportunities of what can be gained with these changes. Libraries are exploring and experimenting with new models and modes of preservation, distribution, service, that preserve the important and successful elements of a print bound system but integrate and combine them with the exciting opportunities of a digital network environment.

I cannot stand here today and say this that particular requirement for article deposit will be a linchpin of a new information distribution environment. But we are confident that it represents the right direction and we applaud NIH in this change to change research distribution as we adapt and change to the new opportunities of digital networking. It's important that I take one minute of my precious 5 to speak to the critical importance of peer review. Libraries value peer review. We recognize that the peer review process is a critical element of the research infrastructure that must be preserved. Peer review insures that the information we provide is reliable and vetted to the best of our ability and present state of research and knowledge. We see no threat to peer review from this change by NIH. This article deposit requirement is not about a change to the quality of information but about a broadening of access to information and that distinction is vital. Library concerns about the article deposit requirement are much different than some of the other comments you've heard today. We want to see this change be successful and we stand ready to work with NIH and our researchers on campus to make it successful. However, I hope that you would consider two changes that we believe would improve the value and impact of the deposit requirement.

First, we believe that the lag time of one year for deposit of articles is excessive and longer than necessary. The information in medical research has long-lasting value but its market value in the information marketplace is immediate and rampant. Libraries favor a shorter embargo period than one year. We would urge an embargo period closer to 3 months after publication and certainly no more than 6 months. We believe that this would still preserve the market value of research information which is critical to the publishing community. But even if this were not the case, NIH has already paid for the

information gained from the research and as an agency of government expending public funds, we believe the primary obligation is not to the publisher's bottom line but the welfare and support of the public good.

Secondly, we would encourage NIH to strengthen its enforcement mechanisms for the deposit requirement. While the deposit of articles is a requirement, we believe that the current procedures do not have adequate enforcement. Minimally, we believe that noncompliance with the article deposit requirement should be in an element in the evaluation of future grant applications by researchers. Thank you for the opportunity to speak with you today and thank you for this change which in my judgment represents an important and progressive step in our pursuit of research system in a digital network environment that balances quality and excellence of content with access that is fair, equitable, and an appropriate use of public funds. Thank you.

John Burklow:

Thank you. Next we'll hear from Patrick White from the Association of American Universities.

Mr. White:

Good afternoon. I think today marks the official beginning of spring. So, let's sit in a windowless room and talk about public access. If I don't get more laughter, I'm going to run through 45 PowerPoint slides. I'm Pat White. I'm with the Association of American Universities. We are an association that includes 60 leading public and private U.S. research institutions. Our association focuses on issues important to research intensive universities, such as funding for research and scholarship, science policy issues, and graduate education. The goals of university research are the discovery, creation and dissemination of new knowledge for the benefit of society.

AAU, on behalf of its member university presidents and chancellors, has repeatedly endorsed NIH's efforts to implement public access. Most recently as the FY08 House Labor Appropriation Act was about to be debated on the House floor last summer, AAU president Robert M. Birdall wrote to Subcommittee Chairman David Obey endorsing what became the policy we are discussing today. Today, I speak on behalf of AAU and urging prompt adoption of the resulting NIH policy on enhancing public access to archived publications resulting from NIH-funded research. Our member institutions, several of whom have testified here today, have responded to the issuance of this policy by developing their own policies and procedures to alert, educate and assist faculty in complying with the new requirements. They have circulated specific instructions to faculty and administrators to ease adoption to the new requirements.

Generally speaking, our administrators appreciate the effort and thought that NIH has put into setting up this somewhat complex exercise of complying with the new requirements. Our principal concern with the change from voluntary to mandatory submission to PubMed Central is the requirement that authors of works subject to the new policy must obtain permission from the publication before submitting it to PubMed Central. Should a journal refuse permission to place an author's accepted manuscript in PubMed Central, the author would face the untenable and highly frustrating course of having to withdrawal the manuscript from publication in that journal and submit it elsewhere. We seek NIH's help in negotiating a blanket agreement with publishers that will greatly ease the transaction cost currently that is currently borne by the individual

author and by extension his or her institution, and indeed, by the publisher. What is needed is a modified standard copyright agreement acknowledging that the author retains the right to provide a copy of the final manuscript to NIH and post the article on PubMed Central within 12 months of publication by a given journal. We request that NIH encourage publishers declare on a blanket basis that they will permit authors to place into PubMed Central any manuscript they accept for publication on or after April 7, 2008 if the manuscript arose from any direct funding from an NIH grant or cooperative agreement. Active in FY 08 or beyond.

We understand the concerns that some publishers have had about the implications of PubMed Central for their publishing operations. We also understand and appreciate the efforts of the publishing community has already made in adapting to the new scholarly publishing environment, and the significant opportunities and challenges that NIH's new policy, and indeed the new world of electronic publishing, are bringing to all participants in the scholarly communications system. But we all must recognize, however, that public access to the published results of all NIH-funded research is now the law and urge publishers to negotiate in good faith so as to make the transition as straightforward and easy as possible. We believe a blanket license will best serve the interest of authors, publishers and NIH. In closing, let me reaffirm AAU's strong support for the new NIH policy by quoting from our 2005 endorsement of NIH's then voluntary public access proposal.

AAU strongly supports efforts to achieve the widest possible dissemination of the results of federally funded research and the association commends the NIH for its proposal to increase public access to published results of NIH-funded research. Making research results freely available to the public after those results are published should not only benefit the public through expanded access to information, but should benefit scientists and advance science through wider dissemination of new knowledge. NIH's policy on enhancing public access to archived publications resulting from NIH-funded research will promote the goal of sharing as broadly as possible the new knowledge made possible by the American people's investment in university research. Thanks for the opportunity.

John Burklow:

Thank you, Pat. Now we'll hear from Howard Gobstein from NASULGC, Public University Association.

Mr. Gobstein:

Good afternoon. My voice also is doing some funny things, David. I'm Howard Gobstein, Vice President of NASULGC, that's how that's pronounced, a public university association. The National Association of State Universities and Land Grant Colleges is the nation's oldest higher education association. Dedicated to supporting excellence in teaching, research and public service, NASULGC has been at the forefront of education, leadership nationally, for more than 120 years. NASULGC encompass more than 218 members consisting of public research universities and land grant colleges in all 50 states, the U.S. territories, and the District of Columbia, as well as 18 historically public black institutions and 29 public higher education systems. Faculty at NASULGC institutions undertake a very significant share of NIH supported research and award the dominant share of PhDs across the sciences and engineering. NASULGC serves as the

convener for many executive officers of our institutions, including the Presidents and Chancellors and Provosts, and one of my responsibilities is to work with our Counselor of Research Policy in graduate education consisting of research Vice-Presidents and graduate Deans. Thank you for this opportunity to offer comments on the implementation of the revised NIH public access policy.

I'm here to voice support for these policies in which to make several points. One, the NIH proposed deposit procedure clearly implements the intent of Congress expressed in last year's appropriation bill and the procedures NIH specifies for meeting the requirements are clear, easy to follow and do not constitute an excessive burden on researchers or universities. NASULGC has shared the NIH proposed implementation steps with our 218 institutions by sending it both to our Provosts and Vice-Presidents of research.

We also have cosponsored a webinar with the Association of Research Libraries during with they have full opportunity to be briefed on implementation. And our institutions have not brought us any serious concerns about the implementation or request to have it delayed.

Three, it seems to us scholarship may suffer if the PubMed Central deposit requirement is delayed. Not every scholar has access to every scientific journal. The deposit requirement is intended to ensure that this is not the case for NIH-funded work. While we cannot measure the loss to research productivity from this lack of access, it is potentially large. Faculty researchers at small universities and especially at poorly funded minority serving institutions potentially may make very large impacts on science if they have full access to the literature. Delaying deposit delays their opportunity to do so and society's opportunity to benefit from their work.

Four, support for science is enhanced when the public sees benefit from that science. Many members of the public, as we've heard already today, are interested in the findings that arise from NIH research. Their access to this work will be considerably enhanced when it is all available through PubMed Central, and delay keeps this material from them for a longer period of time as well. Five, our institutions feel an obligation to make the research available to all who can benefit from it, particularly to those in developing nations of the world who need access to our research findings but who cannot begin to afford to buy that access. Deposited through PubMed Central solves this research problem and brings the world this knowledge. Finally, we look forward to working with NIH, ARL, other university and science associations to ensure that implementation of these policies proceeds smoothly with minimal difficulties. I thank you very much.

John Burklow:

Thank you very much. Now we'll hear from Kari McCarron from MIT. Okay, it looks like it was submitted for the record. Is there anyone else? Okay, then I'll turn it over to Norka. Take a break? Okay. We'll take a 5 minute break and then…10 minute break, as I said, and then Norka will come back and have closing remarks. There are refreshments.

BREAK

John Burklow:

Now we'll hear from Dr. Ruiz Bravo, the Deputy Director for Extramural Research at NIH for closing remarks.

Norka Ruiz Bravo:

Once again I'm in one of those critical positions between you and something you want to do that does not involve this room. So, I will be very brief. But I thought it would be worthwhile to go over what some of the things that we heard today, and recognize that it's a very preliminary analysis and that there will be more coming down the road a bit later. So, okay, not that…ah, here we go. So some of the predominant themes in today's meeting, I'm going to go through a little laundry list of things we have heard about copyright. That is loud and clear. There is concern about adequate protection of publisher's rights. Those were concerns quite clearly expressed by many of the publishers in the room. And that there is also a call for publication agreements to support the policy. So there is a clear call for NIH to work with publishers to try to get some of this done. There was also…another theme was the implementation timetable. Some thought we were doing this too fast, that there is a need for rulemaking. And some thought that we should move forward now and this has been ongoing for a while, so why delay, let's just do it. Financial impact on publishers. Some thought it would be adverse effect. Others thought there would be no effect. What we haven't seen is any data so far. Article submission, different versions of articles are in circulation. That was a concern and also that submission methods were quite variable. Communication and collaboration. Many thought that NIH instructions are largely effective and others thought that NIH left open questions on the policy and that we should have stakeholder efforts to educate authors. Certainly we are open to any of those things. Others thought in terms of public impact that public access costs divert funds from research and some call for actually a very close accounting of exactly how much NIH has spent on implementing the public access policy. And some found that the benefits to science and health were also of significant public impact. The delay period was thought by some to be too short; by others to be too long. And then the role of publishers, the value added by publishers and some thought there was a duplication of…NIH was duplicating efforts already with the publishers.

Before I get to the further analysis, I think it's also worthwhile to think about and talk about some of the things where we actually do have, I think, real agreement. First of all, I didn't hear anybody say they were not for public access. So I think we can all agree that public access is a public good. I think that's something that we all want. The other thing I think that is also very clear is that the information … the access to the information, the way we access information, that publishing has gone primarily from a primarily print media to now an increasingly digital media so that's the environment, the context in which we are implementing this public access policy, and NIH's public access policy really is part of a much greater change that is occurring in this country with respect to how information is accessed. The third thing that I think we can all agree on is that NIH has multiple stakeholders with very multiple points of view. There are various publishers in the room. Some had one opinion about the policy and others had other opinions. So, and we heard from a broad variety of people and points of view. And the

fourth thing I want to say before I get to the next part of the summary is that, please understand that NIH is very committed to making this policy a success. And that we want to work with all of you to get that done.

So, further analysis of some of the comments. We're going to analyze the transcript of today's comments with other pre-meeting comments received and with the RFI results. The transcript and the video cast will be posted to our public access website, the URL is there. You're welcome to go and see. And we'll have a report on the meeting, the pre-meeting and comments and the RFI. Those will be out by September 30, 2008. Some asked why so long? Part of the reason is we want to give you all as much time as possible for input. The RFI will be out … will be available for input for at least two months. So, we will be …the projected date , the target date for this request for information, the RFI, is March 31st-May 31st. We will continue to seek information from the public including all stakeholders. And we will submit a few comments and that is the website. The RFI will be published in the Federal Register as a Federal Register notice as well as NIH guides and contracts. So we will make sure we publicize that as much as possible. You, of course, in your respective communities are free to send the information for the RFI to as many people as you would like. So, any other stakeholder comments can be reviewed at the public access website.

And I just in closing want to say we very much appreciate your energy, your commitment, your points of view. We welcome your feedback and please continue to provide those feedback via write us directly or via the RFI. Thank you very much.

END OF MEETING.