Public Comments

DR. TUCKSON: Well, thank you all very much for returning for the afternoon session. We are very pleased that everybody made it back on time and those that didn't, they know who they are.

We take the public comment session very seriously and we're very glad that we have our public comment people. I need Sarah Carr.

DR. TELFAIR: Shouldn't that be turned off during public comment?

DR. TUCKSON: What's that?

DR. TELFAIR: The screen?

DR. TUCKSON: Oh! Yes, I guess it should be since it's not relevant for that. That's good.

Where's Sarah? I need my list of the public comment people. Here she is. Okay. So I always love it when I can get somebody. I got Sarah the first time. Public comment people? What's the name of the people? Oh, here they are. Great! She has ripped out the page. She's upset with me.

(Laughter.)

You want the list, here! Take the list!

(Laughter.)

Okay. John Corcoran?

By the way, we do—though, I'm joking because I wanted you to wake up after your postprandial paralysis but we do take public comment very seriously and we are very attentive and appreciative of that.

John Corcoran is from Export Management Systems, Incorporated.

Are you available? Hey! Could you go that way so that our next will be appropriate craned?

(Laughter.)

MR. CORCORAN: Should I use the mike?

DR. TUCKSON: You're cool. You need a mike. Thanks. Otherwise they won't get you onto the web cast.

MR. CORCORAN: Okay. Thank you very much for having me here today. Just for clarification, my name is John Corcoran. I'm from an organization called Examination Management Services, Incorporated. That's EMSI for short.

The purpose of my brief comments today is really to address two policy issues that we've identified particular to the large population study that is being considered.

The first is the need, of course, to gather data on a national basis with equal diversity across the spectrum of all the data points being collected.

The second is also to focus on the comfort and convenience of the participants of the study.

Very briefly, EMSI is a national organization who collects biospecimens as well as medical records across the country. We've been doing this for about 32 years or so, mainly supporting the insurance industry. In the past five, six years or so, we've supported a number of federally funded projects as well as commercialization projects for pharmaceutical companies.

We have a platform which is basically a hub and spoke program. We are based in Dallas, Texas. We radiated out through about 250 offices into the community to collect data from the study participants through the use of our 6,500 plus certified phlebotomists.

The value that we bring to studies is that we offer the study participants again the convenience and comfort of having specimen and other data points collected in their homes or places of employment. Also, if they are mobile, as we are a mobile nation, we can track them on a longitudinal bases from place to place as they move forward.

We are also the largest collector of medical records in the United States. We collect medical records for our insurance clients as well as for our epidemiology and commercialization project clients. We do this again through a centralized coordinated secure hub in Dallas, Texas, where we reach out to over hundreds of thousands of institutions and providers across the country.

Our purpose today is to make the committee aware of our services and also to make the committee aware of what we feel are very important issues, specifically again to the point of the comfort and convenience of the study participants.

I know my time is limited and I want to thank again the committee for the opportunity to talk today.

DR. TUCKSON: Thank you very much for taking the time to share with us today.

Any particular questions from the committee? Okay.

Thank you very much, sir.

MR. CORCORAN: Thank you.

DR. TUCKSON: Next with us is David—David, I'm going to say this but there's a tendency that people seem to have to disagree with my pronunciation of their names.

MR. MONGILLO: A politically correct person would say, "Oh, that's pretty close."

DR. TUCKSON: But I think it's—

MR. MONGILLO: It's a soft "g". I can say that.

DR. TUCKSON: All right. So let me—now you really put the pressure on me.

(Laughter.)

DR. TUCKSON: What does that mean? David Mongillo.

MR. MONGILLO: Mongillo. That's right.

DR. TUCKSON: I knew it all along.

MR. MONGILLO: Very good.

DR. TUCKSON: I think, by the way, unless I've got this wrong but you may well be with the American Clinical Laboratory Association.

MR. MONGILLO: That's correct, vice president for Policy and Medical Affairs with the American Clinical Laboratory Association. Let me also add the welcome to the new members and the ex officios to this very distinguished group. We're very pleased. ACLA is pleased to provide comments upon the need for genetic testing oversight.

ACLA is an association representing local, regional, national, both independent and hospital-based laboratories throughout the United States.

ACLA agrees that the oversight of genetic test services is an important topic for discussion as advances in genetics and genomics lead the development of new laboratory tests and services. These tests are often driven and increasingly driven by physician and patient desire for technologies that hold promise of improving health care outcomes. Genetic tests make significant contributions to individualized personal health care in that they can detect disease or disease risk before the onset of symptoms when intervention might be most effective and they can target specific therapy for these diseases that might make it more effective for the individual patients.

We want to make several inter-related points with regard to regulatory oversight of genetic testing. First, the clinical laboratory industry is one of the most highly regulated health care delivery sectors. You heard this morning from Judy Yost and she pointed out that all clinical laboratory services are regulated under the Clinical Laboratory Improvement Amendments of 1988, CLIA.

CLIA regulations include multiple requirements, both general and specific, for laboratory quality such as requirements for appropriate training of laboratory personnel, quality control programs and proficiency testing. All of these requirements apply to laboratories that perform genetic tests. Further, CLIA utilizes a commercially—I'm sorry. Further, CLIA regulations require that before introducing a new method or test that does not utilize a commercially available test kit, the laboratory must establish and document performance specifications of accuracy, precision, analytical sensitivity, analytical specificity, and they have the responsibility for the quality of those results for patient care, clinical patient care.

We believe all of these are essential parameters of quality and performance. Adherence to CLIA is ensured by on site inspections every two years, either by a state agency or by a CMS representative. Penalties for noncompliance are severe and include the possibility of revocation of the laboratory's CLIA certificate, without which the laboratory cannot operate.

Secondly, ACLA wishes to emphasize the importance of making any regulatory changes related to genetic testing only after determining that such changes are focused on legitimate risks specifically related to genetic tests and that changes are realistic, targeted and effective to address such risks.

Third, it's critically important to keep in mind that genetic tests provide benefits today and promise great advances in the future in diagnosis, screening and patient monitoring. Any new regulation should not create undue burdens that will stifle innovation or restrict patient access to these valuable services.

In that regard, ACLA wishes to bring to the committee's attention a key issue that, if not carefully considered, will have significant negative consequences for laboratory operations and patient care. That's the question of how genetic tests will be defined for regulatory purposes and how that definition will affect any specific new regulatory requirements.

ACLA is concerned that an overly broad definition on genetic tests could sweep in many tests for which current regulatory oversight is substantial and adequate. Developing new regulations based on such a broad sweep would be a step in the wrong direction.

For instance, because virtually all diseases have some genetic component but not necessarily an inherited component, if the definition is overly broad, routine tests such as cholesterol, glucose measurements, basic blood counts, DNA-based tests for non-heritable abnormalities would be included. These are well understood and accepted tests. They have markedly different implications and concerns from those that would apply in a discussion of heritable predictive tests. Sweeping them into any new regulations for genetic tests will unnecessarily complicate the delivery of these well-understood laboratory services.

The record indicates that laboratory tests are accurate, reliable and provide information relevant to the patients and their health care provider. ACLA reiterates that it's important to ensure that any proposed regulatory changes focus on legitimate risk specifically related to genetic testing. We pledge to work with this committee, the regulatory agencies and the health care community to identify those concerns and the regulatory approaches that will address those concerns without stifling innovation or negatively affecting patient access and care.

Thank you very much. Appreciate it.

DR. TUCKSON: That was good. That was great. It was responsive and specific and I think you get to making sense here as a good collaborator and an organization we need to hear from.

I think the question, I guess, ultimately will be is I hear your call and I would think that just assuming the sense of the committee is that we would not want to do things that are unnecessarily burdensome, regulatory for their own sake, bureaucratic or a pain in the neck just to have regulation so I think we would probably be in agreement there.

I think you heard the earlier discussion today about some of the things that the committee is legitimately concerned about for this and so I think what I'm just sort of hopeful is that off line in the days to come we would have your informed participation in helping us to solve our problem. I would assume that you're not as an association taking the position that nothing needs to be done further, just don't do dumb things.

MR. MONGILLO: I hope it came across loud and clear that the latter is what we're taking a position on. We also—I think we've heard the word "gap" a lot this morning and I've seen it in print and other places.

DR. TUCKSON: Right.

MR. MONGILLO: We're sort of leaning towards—it may not be a gap. It may be a small crevice that needs some little patching but I think there's room for negotiation and discussion.

DR. TUCKSON: First of all, I just wanted to get clear that you all were coming at this from a positive good—

MR. MONGILLO: Yes, absolutely.

DR. TUCKSON: --collegial way and not folding your arms and saying, "Heck no, over our dead body."

MR. MONGILLO: We certainly want to work with you.

DR. TUCKSON: Is there any specific question on this? I think this is very good. Does anybody have any questions?

Well, listen, for the record then you are available and I think we will be in consultation with you about what we do and getting your input because I think you have a lot to offer. Thank you very much.

MR. MONGILLO: Thank you very much.

DR. TUCKSON: Very well done.

Next we have Carol—

DR. RAUCH: Rauch.

DR. TUCKSON: That's what I said.

(Laughter.)

Wow! It's like a ventriloquist thing.

(Laughter.)

Hey, Carol Rauch. I believe you may be with the College of American Pathologists.

DR. RAUCH: I am. More importantly, I'm with Fay so I get instant popularity.

(Laughter.)

Everyone has been saying "hi" this afternoon.

Good afternoon. My name is Dr. Carol Ann Rauch and I'm Medical Director of Microbiology and Chief of Clinical Pathology at Bay State Medical Center. That's in Springfield, Massachusetts.

I'm here today on behalf of the College of American Pathologists and I want to follow up on written testimony that had been previously provided to this committee surrounding your discussion on gene patents in March of this year.

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The college appreciates the opportunity to appear before you today to provide our perspectives on DNA based patents and licensing practice and their effect on access to quality laboratory tests.

The College of American Pathologists is a national medical specialty society representing more than 16,000 pathologists who practice anatomic pathology and laboratory medicine in laboratories worldwide. The College's Commission on Laboratory Accreditation is responsible for accrediting more than 6,000 laboratories here and abroad. College members have extensive expertise in providing and directing laboratory services and serve as inspectors in laboratory accreditation programs.

The college has been a leader in developing quality improvement programs for laboratories, including programs related to molecular pathology and cytogenetics.

We are in the midst of a scientific revolution in genetics that promises extraordinary advances in clinical medicine. As medical specialists in the diagnosis of disease, college members recognize that genetic testing is an area of growth and change for pathology and medical practice in the decades to come. Pathologists, therefore, have a keen interest in ensuring that gene patents do not restrict the ability of physicians to provide quality diagnostic services to the patients they serve. Gene patents pose a serious threat to medical advancement, medical education and patient care.

When patents are granted, subsequent exclusive license agreements, excessive fees and other restrictive licensing conditions prevent physicians and laboratories from providing genetic based clinical testing services. As a consequence, patient access to care is limited, quality of patient care is jeopardized, clinical observations as the basis for new discoveries are compromised and training of health care providers is restrictive.

Throughout history, medical discoveries have progressed from the discovery of basic anatomy and histology and cytology, none of which are patented, to the more recent discovery of genes. The recent trend of using patents to monopolize gene-based testing services is a radical departure from historical precedent in clinical laboratories and it works against the goal of making these procedures widely accessible and affordable for the public. Especially troubling is the fact that under patent protection, the increasing understanding of the utility of the test, as well as the underlying disease process, also becomes proprietary, thereby imposing a profound change in how the profession and the public acquire knowledge about these rapidly evolving tests and the clinical utility in diagnosis of disease.

Physicians and scientists can easily and rapidly translate fundamental information derived from mapping the human genome into diagnostic genetic tests and use them for patient care. Because information about gene sequences is so fundamental to understanding specific diseases, patent holders can essentially gain ownership of diseases. Exclusive or restrictive license agreements on gene-based tests have been used to prevent physicians and clinical laboratories from performing genetic tests as diagnostic medical procedures and ultimately patients suffer because these services are less readily and affordably accessible.

Medical education and research related to laboratory testing are also threatened. In fact, college members have received cease and desist notification letters from patent holders or exclusive licensees indicating that continuing their patient testing would be patent infringement. Examples of diseases where testing has been halted due to patent enforcement include breast cancer, Alzheimer's disease, canavan disease and Charcot Marie tooth.

The college, like SACGHS, was awaiting completion of a study by the National Academy of Sciences Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation and subsequent recommendations and provided testimony to this NAS committee.

The study recommended that policy makers take appropriate steps to prevent the increasingly complex web of intellectual property protections from impeding potential breakthroughs in genomics and proteomics research and the access for the public to those findings. Specifically, it recommends that congress consider legislation to exempt research on certain aspects of patented technologies or inventions from patent infringement liability with a goal of promoting scientific discovery. The report also recommends that owners of the patented technology of certain gene based diagnostic tests should establish procedures to allow others to validate these clinical test results. If these patent holders do not take these steps voluntarily, the report suggests that congress consider in the interest of public health whether work to validate such results should be shielded from liability. This single clinically focused recommendation falls short of recommending specific protections for physicians and other providers of clinical laboratory services against gene patent infringement enforcement.

The college has supported policy recommendations and advocated for legislation in congress that would extend protections to laboratory physicians. Information provided to the NAS warrants the need to provide protection for the medical use of genetic information, including that derived from laboratory testing. The NAS report clearly outlines concerns regarding the negative impact of gene patents on medical practice. However, it did not provide recommendations to address the data gathered. We, the college, therefore, ask the SACGHS to carefully review the information in the NAS report on the clinical impact of gene patents, consider further investigation of this impact and develop recommendations for the Secretary of HHS to address the growing negative impact of gene patents on clinical testing in the United States.

In summary, we are facing the unprecedented situation in which a single patent owner can prevent physicians throughout the country from performing diagnostic procedures that use certain gene-based tests. This sets an extraordinary and dangerous precedent for patients and actually all of medicine and strays from the constitutional and social purpose of the patent system to promote progress.

Therefore, the college believes that current practices in patenting and licensing of genetic sequences must be reexamined to ensure that gene-based diagnostic tests are widely available and affordable for the greatest public benefit.

Thank you for your attention to these matters.

DR. TUCKSON: Well, thank you. Let me just say that we are—as hopefully you'll have a chance at least to either stay or hear about the discussions tomorrow because we really are in agreement that we need to look at very carefully that gap between the NAS report and clinical issues.

DR. RAUCH: That one is bigger than a crevice.

(Laughter.)

More than spackle.

DR. TUCKSON: All right. I particularly appreciate having the American College of Pathology weighing in on this and what I really hope is that you, through your presence here, are signaling that the college's resources and its intellectual experience is available to this committee.

DR. RAUCH: Absolutely.

DR. TUCKSON: As we work through this. I think that one of the things that we have identified as a committee as being exceedingly important is having the role of physicians in these issues more substantive and more involved in the process. Quite frankly, we don't get enough of it and so I just want to make a special note, and if you would take it back to the college, that we appreciated your taking the time to be here and that we hope that you'll keep those lines of communication open as we try to work with this in the subcommittee level going forward.

Are there any other questions?

One of the things that we are comforted by is that Dr. Leonard is very much involved in your work and that's helpful.

MR. DANNENFELSER: Well, I just wondered maybe while she's here if I could ask, we had a discussion earlier about co-development with the private sector and the public sector, and to the extent that there is significant government dollars involved in the development of certain products, what can be done in terms of limiting patent protection in that case that might not already be done? I don't know if you could address that.

DR. RAUCH: Put in a quarter and you'll get a long answer.

MR. DANNENFELSER: Maybe you could get back to us.

DR. RAUCH: With all due respect, I think I would monopolize quite a bit of time addressing that but I would like to commit our full support on behalf of the CAP and know it's one thing to identify the problem and another entirely to work out the optimal solution that meets everyone's needs.

DR. TUCKSON: Well, if there's a way that you can—again, I think that you—as we work with you, if you could be prepared for helping us with that.

I guess the other thing would be just as you go back to your colleagues at the college, your message is very clear about what you don't want. I think what would be helpful to us again is if you were to put yourself in our situation and sort of look at some of the testimony or some of the discussions that we've had to sort of say here are the concerns that we have to work through.

By the way, we have your written comments, I'm sure, available to the committee.

DR. RAUCH: Yes.

DR. TUCKSON: The real issue now is to go beyond that to, okay, here is how to address the issues that we have to grapple with at the level of granularity.

DR. RAUCH: Right.

DR. TUCKSON: You put a marker down but now the question is how do we work through it and we would really, really appreciate that kind of guidance as we go forward.

I know we're close to needing to move on. Did somebody else have their hand up? Did I miss somebody?

See this is again Joe Telfair tries to get me to recognize people that aren't there.

Thank you very much.

DR. RAUCH: Thank you.

(Laughter.)

DR. TUCKSON: That goes without saying.

(Laughter.)

Michele Schoonmaker?

DR. SCHOONMAKER: Schoonmaker.

(Laughter.)

DR. TUCKSON: I started out going down hill.

I do know you're with the Association of Molecular Pathology.

DR. SCHOONMAKER: Yes. Thank you. Good afternoon. My name is Michele Schoonmaker and I'm here today as a member of the Professional Relations Committee of the Association for Molecular Pathology, that's AMP.

AMP is an international medical professional association representing over 1,400 physicians, doctoral scientists and medical technologists who perform genetic testing as well as other testing based on knowledge derived from molecular biology, genetics and genomics.

AMP members practice their specialty in academic medical centers, community hospitals, independent clinical laboratories and federal and state health facilities.

On behalf of our membership, the Executive Council and the Professional Relations Committee of AMP has reviewed the SACGHS document entitled "Policy Issues Associated with Undertaking a Large U.S. Population Cohort Project on Genes, Environment and Disease." We would like to take this opportunity to applaud the committee's efforts in such an important undertaking.

AMP supports the concept for this project. We anticipate debate about many of the issues identified in the committee's report but are hopeful that the information derived from a large population study will facilitate clinical applications. We believe that the policy and process issues identified must be thoughtfully and actively pursued. We will provide detailed written comments before July 31st, which will include our concerns regarding scientific and technical issues of the project. However, today we would like to focus our comments on two facets of this

report of great concern to our membership, clinical validations of research findings and patient safety.

As molecular pathology laboratory professionals, our members will undoubtedly serve as the interface between the public and scientists in any such endeavor. Consequently, policy decisions regarding the study that touch on the HIPAA privacy rule and CLIA are of great concern to us. While the draft report states that an investigator has no therapeutic relationship with the subject, there is no doubt that our members do have a relationship with their patients with all the attendant clinical, legal and ethical responsibility.

AMP members direct CLIA certified laboratories that would be appropriate locations for clinical validations of research results prior to reporting to subjects. The members of AMP are prepared to engage in substantive discussions to define the clinically relevant information which should be returned to the individual subjects and in what manner.

In addition, we also recognize our obligation to pursue the best interests of our patients. We note that the draft report focuses heavily on the scientific aspects of this project but our experience as clinicians and scientists leaves no doubt that the clinical importance and applicability could be immediate. Recognizing the very significant role our members will play in this effort, AMP strongly recommends that the processes and policies relevant to clinical implication and, importantly, patient safety must be specifically addressed now rather than later.

AMP appreciates the opportunity to address the committee on this very important endeavor. We reiterate our commitment to participate not only in pursuing the success of this project but in translating the results of this effort for the betterment of public health and patient well-being.

We invite you to contact Dr. Wayne Grody, the chair of the AMP Professional Relations Committee, if we can provide additional information. Thank you.

DR. TUCKSON: And, just for the record, you said that we're going to get some—a more-another set of more detailed comments by July 31st?

DR. SCHOONMAKER: 31st, correct. Yes.

DR. TUCKSON: Terrific. Thank you very much by the way.

Hold up. I've got to look around the table first before you go. All right. Thank you so much. I appreciate it. Thanks for taking the time.

Well, I know I won't get the last person wrong because I actually know Judy Lewis and I actually can say her name.

DR. : We had planned that just with you in mind.

(Laughter.)

DR. TUCKSON: Judy, International Society of Nurses in Genetics.

DR. LEWIS: Yes, sir.

DR. TUCKSON: I got it right.

DR. LEWIS: Very good. My name is Judith Lewis. I'm a professor of nursing at Virginia Commonwealth University in Richmond, Virginia. However, today I'm here to present testimony on behalf of the International Society of Nurses in Genetics, which is an international nursing specialty organization dedicated to fostering the scientific and professional growth of nurses in human genetics. We are pleased to submit comments to the committee regarding your document, the draft report on policy issues associated with undertaking a large population cohort project.

ISONG supports the document's intent to support preliminary and intermediate questions, steps and strategies in the five areas identified. The policy areas identified in the draft are appropriately focused and the issues are organized in appropriate categories and addressed in such a way as to give policy makers sufficient understanding of the importance of considering a large population cohort project on genes, environment and disease.

ISONG believes it's essential to involve and engage the general public and the nursing community before moving forward on such a complex and expensive endeavor and we'd like to make the following recommendations that will strengthen and clarify the document.

The first one won't surprise you at all, Reed, which is to broaden health care providers, to providers and patient care personnel, including nurses, social workers and psychologists, and other health care professionals;

To reword the following statement regarding the public's engagement to make it strong and that statement is "the public's willingness to participate in a large population project will be assessed before embarking on such an expensive endeavor." It is essential that the public be engaged before the initiation of such a project. Additional measures to assess the public's interest and willingness should include focus groups with representative community-based agencies, including lay health care workers.

Since nurses are present throughout the health care system and provide care, education and management to individuals, families and communities, it is essential to seek engagement and input from nurses and nursing organizations, especially around recruitment, approaching, educating, informed consent, privacy and confidentiality, and enrolling various subpopulations. Nursing associations such as the American Nurses Association, the National Black Nurses Association, the National Hispanic Nursing Association and others must be approached.

Please include nurses in ongoing consultation with the international community and the private sector to explore opportunities for collaboration.

Please specify nurses and nurse researchers as important members of a multi-disciplinary team approach for such a project.

And, finally, please include nurses in an independent standing committee for the duration of the project.

Thank you.

And, just as an aside, it's very, very heartwarming as a member of the original Secretary's Advisory Committee on Genetic Testing to recognize that our work didn't fall into a great black hole but that some of it is actually being resurrected and used again. It has been very satisfying to sit there and it has been hard to keep my mouth shut.

DR. TUCKSON: By the way, it's not falling into a black hole. It's falling into a crevice, the dimensions of which we are unsure.

(Laughter.)

DR. LEWIS: Thank you.

DR. TUCKSON: That was really terrific. Thank you, Judy.

Any issues here? I'm sure we've got the written comments. I think the key thing is you make the point—oh, good, I'm sorry. Agnes?

MS. MASNY: Thank you very much, Judy. I just also wanted to draw to the committee's attention sort of supporting Judy's statement about the involvement of nurses. Steve mentioned earlier about sort of doing a systems approach and I think the nursing community really has taken this to heart as making a systems approach. With the efforts of HRSA and NHGRI nurses, a major endeavor was made to actually implement competencies for nurses across the board and, to date, from what I understand there is over 40 professional nursing organizations that have endorsed the competencies for genetics in nursing care looking at how genetics will impact all of patient care. So, I think, yes, nurses should be involved at all levels.

DR. LEWIS: That's true, Agnes, and thank you for mentioning that. The other thing is that if you look at the surveys that are done around public trust, nurses are out there and only in 2001 were we second to firefighters in terms of the profession that is most trusted by the general population. So if you're looking to gather engagement and have people who the public see as trustworthy, it's the 2.8 million nurses who can help you the most.

DR. TUCKSON: Judy, thanks an awful lot. Really appreciate you taking the time and we'll definitely be obviously following up, and I know you won't let us not follow up.

DR. LEWIS: Absolutely, you know I'm watching you, Reed.

(Laughter.)