ICARE
History of US Animal Welfare Oversight
September 24, 2021

>> SUSAN: Hello, and welcome. It is a pleasure to see so many new and old friends. My name is Susan Silk. I was the first Director of Policy and Education at NIH [National Institutes of Health] OLAW [Office of Laboratory Animal Welfare]. I retired in 2018 and continue to serve OLAW as a consultant and as the Director of the Interagency Collaborative Animal Research Education Project, or ICARE, which I have directed since 2015. The ICARE project provides training that empowers U.S. institutional animal care and use committees and their institutions to improve animal welfare and increase compliance with federal standards while minimizing regulatory burden.

In that spirit, ICARE is proud to present this panel discussion: “The History of U.S. Animal Welfare Oversight.” There are a number of cogs turning behind the scenes. I want to acknowledge and thank today Dr. Carolyn McKinnie, who is a member of the ICARE faculty. Give them a wave, Carolyn.

She is the USDA's [United States Department of Agriculture’s] National Policy Senior Staff Veterinarian for Exotics and Marine Mammals. For this broadcast, Carolyn is also the time czar, and will help the panel stay on schedule. Amy Chuang is the Director for Animal Care and Use Program at Virginia Commonwealth University. She is providing technical support to our panelist, Charlie McCarthy. And Erin Heath of Event Source Professionals is a member of our administrative team. She supports our technical and administrative aspects of our program.

During the live broadcast, you may text or private chat Erin through the software chat box if you have any technical issues.

Our panelists have many interesting stories to tell, and we have a full agenda today, so we will not be accepting live questions. And now it is my pleasure to introduce the moderator of our panel discussion, Ernie Prentice. Ernie is also a member of the ICARE faculty.

Ernest D. Prentice, Ph.D., is Professor Emeritus, Department of Genetics, Cell Biology and Anatomy at the University of Nebraska Medical Center [UNMC]. During his 45-year career at UNMC, he served as the Associate Vice Chancellor for Academic Affairs, the IACUC [Institutional Animal Care and Use Committee] Chair, the IRB [Institutional Review Board] Executive Chair, and the Institutional Official for both the animal care and use program and human research protections program. That's a lot of jobs, Ernie, and we are honored that you took on this additional job for us today.

>> ERNIE: Thank you, Susan. It's really my pleasure. Again, welcome, everyone. I'm really happy that you could join us. You know, history is a really fascinating subject. And I think this is going to be a really, really, interesting few hours for all of us. And we're fortunate to have our expert panelists who are really renowned in their career achievements. We have nine panelists. And I would like to now introduce each of our panelists.

But before I actually do, please recognize that I simply cannot do justice to their long and storied careers within the time allocated. So, I'm not going to mention items such as degrees, professional certifications, hundreds of publications which some of them have, service on prestigious committees, boards, and councils or awards.

Indeed, if I described all the awards our panelists have received, we would need another hour for their introductions. So, we have nine panelists in total. And I would like to introduce Dr. Pat Brown and Dr. Betty Goldentyer during their session at 4:40.

I will introduce the other seven panelists in alphabetical order with the exception of Dr. Charles McCarthy, who I would like to hold for last, because we have a special part of our program devoted to you, Charlie.

So, beginning with Taylor Bennett -- wave, Taylor. Taylor is in Hawaii, as you can see. He spent 36 years at the University of Illinois at Chicago, overseeing their animal use and care program. The last ten of those years he served as Associate Vice-Chancellor for Research Resources, where he oversaw 14 campus-wide research support core facilities. He currently is a management consultant in the area of program evaluation and regulatory compliance and serves as the Senior Scientific Advisor for the National Association for Biomedical Research. We all know that association as NABR. So, welcome, Taylor.

>>TAYLOR: Thank you.

>> ERNIE: Next, I would like to introduce Dr. Jerry Collins. Wave, Jerry. There you go. Dr. Collins is Professor Emeritus of Anesthesiology at Yale University School of Medicine. He served as chair of the Yale IACUC for 11 years. Congratulations, Jerry. That's a long time. Dr. Collins developed and served as the first chair of the Society for Neuroscience Committee on Neuroscience Literacy and worked closely with the National Association for Biomedical Research (NABR) in efforts to educate the public about the importance of animals in research.

Dr. Collins' research was primarily focused on the effects of anesthetics and analgesia on sensory processing in the central nervous system. Welcome, Jerry.

>> JERRY: Thank you, Ernie.

>> ERNIE: Next, Dr. Ron DeHaven. Wave. There you go.

>> RON: Good afternoon.

>> ERNIE: Dr. DeHaven has nearly three decades of experience with the United States Department of Agriculture. Of course, that's called USDA, the Animal and Plant Health Inspection Service, (APHIS). His positions within the Agency include serving as the Deputy Administrator of Animal Care 1997-2002. He was the Administrator of the Agency from 2004 to 2007. Dr. DeHasaven then served as the Chief Executive Officer and Executive Vice President of the American Veterinary Medical Association, AVMA, from August 2007 until September 2016. Welcome, Ron.

>> RON: Thanks, Ernie.

>> ERNIE: Next, it's my pleasure to introduce Nelson Garnett. Nelson, would you wave? There you go. Nelson has a long and distinguished career that spans the private academic and governmental sectors. Beginning in 1987, Dr. Garnett held various positions at NIH, and for approximately 12 years served as the Director of the NIH Office of Laboratory Animal Welfare, which we all know as OLAW. In 2004 after 20 years of combined federal service, he retired from the U.S. Public Health Service as Director of OLAW. Knowing Nelson, I'm sure that he has not really retired, nor will he ever. Welcome, Nelson.

>> NELSON: Thank you, Ernie.

>> ERNIE: Next, Dr. John Miller. John, would you wave to our crowd? Thank you. Dr. John Miller

served in the U.S. Army for 16 years, where he worked in and directed laboratory animal care and use programs. Following his Army service, Dr. Miller joined the Commission Corps of the U.S. Public Health Service and directed the Division of Animal Welfare at NIH's Office for Protection from Research Risks, known by the acronym OPRR, before being named Deputy Director of OPRR. During this period, he served as the lead representative for the PHS legislatively mandated consultations with USDA to harmonize their developing animal welfare regulations with the existing PHS policy in that area. Welcome, John.

>> JOHN: Thank you, Ernie.

>> ERNIE: Next up, I'd like to introduce Dr. Robert Whitney. Unfortunately, Dr. Whitney's schedule precludes his ability to interact with us today. I will however read his bio. And then Drs. Miller and Garnett will read his prepared remarks. Dr. Whitney was at the NIH from 1971 to 1992 and over that period he held many positions. Here are just a few.

He was the -- on the board of scientific directors. He was Director, the Office of Animal Care and Use. He was also Chair of the NIH Animal Care and Use Committee, from 1972 to 1992. Jerry, he's got you beat in terms of longevity as an IACUC chair. And, he was Chair of the U.S. Government Interagency Research Animal Committee, also known by the acronym IRAC, from 1984 to 1994. And you will probably find out later, that was an extremely important committee.

Then from 1992 to 1994, Dr. Whitney served as the Deputy Surgeon General, United States Public Health Service. When he retired, he decided to co-found an organization called Earth Span, a nonprofit organization providing advanced technologies for the conservation of ecosystems, biodiversity, and environmental health. We miss you, Bob, and we hope that we can do justice to your prepared remarks.

Next is one of my favorite parts of the program. And that is a tribute to Dr. Charlie McCarthy. It's actually the first of three. So, ladies and gentlemen, it's now my distinct privilege to have this opportunity to offer a well-deserved tribute to Dr. Charles R. McCarthy. Dr. McCarthy is a giant in the field of research ethics applied to human subject research, as well as research involving laboratory animals.

I'm really fortunate to have known this remarkable man since 1981. He has been a valued mentor to me and to many others. Charlie is a caring spirit who has always been unfailingly generous with his time and intellect. He knows more about ethics & regulation research than most of us will ever, ever know. Since time is limited, I will skip Charlie's formative years and move to the 1950s. Charlie was ordained as a Catholic priest in 1956, as a member of the Paulist fathers. Charlie was laicized in 1971, and then moved to NIH where he was appointed Chief of the Legislative Development Branch. For those of you who are old enough to remember the 1960s and '70s, there was a series of horrific exposés on unethical human subjects research, with the Tuskegee syphilis study topping the list. Clearly, at that time, ensuring adequate protection of human subjects was a major problem in the U.S.

Fortunately, Washington had Charlie. In 1978, he was appointed Director of the Office of Protection from Research Risk; we know that's OPRR. Under Charlie's leadership, OPRR was responsible for the prolongation and implementation of federal regulations and policies for the protection of human research subjects.

Charlie's office was also responsible for the development and implementation of the *PHS Policy on Humane Care and Use of Laboratory Animals*. Charlie, we all miss you. And I miss the Scotch, particularly when you were buying.

[Laughter]

>> ERNIE: On behalf of all of our panelists and hundreds of today's attendees, thank you for all that you have done for the humans and the animals that serve as research subjects to make this a better world. Now, Charlie, as we proceed through the history of U.S. animal welfare oversight, I hope you will correct us if we get it wrong. Because you have lived that history, which we will be talking about.

And now I would like to invite Dr. John Miller to say a few words about his friend and colleague, Dr. Charles R. McCarthy.

>> JOHN: Hey, Charlie. How are you doing? I realized when I started thinking about a tribute to Charlie McCarthy, a couple of things. One, I have four minutes to do it and that's impossible. But, when I

thought about it a little further, it came to me that all of what I was thinking about related to me -- how he influenced my life. But this is supposed to be a tribute to Charlie.

So, my second realization was, these days, we hear the term, well, the younger ones of us hear the term influencer. Charlie is no Ariana Grande or Kim Kardashian, but he is an influencer of the highest order and he was a major influencer long before that word became a noun.

So, I have my little personal tribute to my boss, my mentor, my colleague, my occasional golf buddy, my occasional Scotch-drinking buddy, but mostly my friend. Had it not been for Charlie and the U.S. Army's intransigence, Charlie bringing me on board, his wisdom, his shepherding me through ten years there, giving me the opportunities he did -- the opportunities [without which] I almost certainly never would have been a viable candidate for my next career step, the Director of AAALAC. So, I in fact owe over half of my career to Charlie McCarthy -- the non-checkered part is Charlie's part.

[Laughter]

>> JOHN: Charlie's -- his direct contributions to human subject protections are widely known. The National Commission, the Belmont Report, 45CFR46 Human Subject Regulations, and OPRR Guidance after that, they all not only have Charlie's fingerprints on {them]; they have his brain prints on [them]. Those were Charlie's. Now, his contributions to animal welfare, I feel, are less widely known, although just as significant. There was no national commission with its important, impressive reports. But for animal research and those who support animal research, the PHS policy that Charlie was behind changed just about everything. And Charlie's finger and brain prints are all over that, as well. Aside from the words of the PHS policy, Charlie's contributions to animal welfare came largely through his understanding and explaining how to implement the PHS Policy.

Explaining in speeches that he gave all over the country, through being a major focus in PRIM&R [Public Responsibility in Medicine and Research]. expanding from human protections only to include animal care and use issues, and responding to inquiries from IACUCs and investigators all over the place, especially during the early years of the PHS Policy. And this is where his influence really shone, because of his three characteristics that I'm going to deal with here. His wisdom, his wit, and his charm.

The wisdom came in his early recognition that you could not rebut passion and zealotry with reason and logic regarding the animal rights movement. You're never going to change the mind of a true zealot. What we needed to do in OPRR and in the larger community was to demonstrate to those passionate but reasonable people, Christine Stevens of the Animal Welfare Institute, for instance, that the government knows the issues, cares about the issues, and cares about animal welfare, and has the mechanisms to assure that animal welfare is dealt with.

Through assurances of compliance and IACUCs with a committee [community?] member, for instance. His wit, just one quick one. Charlie, when asked by someone in my presence how many people work at OPRR, he said, oh, about half of them.

[Laughter]

>> JOHN: Finally, the charm. I'm not sure if it was inherent or he learned it in academia or the priesthood, or as many would likely suspect, through his Irish heritage, but Charlie had the unique ability, (and many of you have heard this before but Charlie had it) the ability to tell someone to go to hell and have them look forward to the journey.

[Laughter]

>> JOHN: God broke the mold and threw away the pieces after he made Charlie. God bless you, Charlie.

>> ERNIE: Thank you very much, John. And next, I would invite Nelson to say a few words about his friend and colleague, Charlie McCarthy.

>> NELSON: Thank you, Ernie. I always hate to go behind John because he does such a thorough job of stealing all of the comments that I had, including some of the jokes.

[Laughter]

>> NELSON: However, I will abbreviate some of my comments and just adorn some of them with a few anecdotes. Clearly, I had the same issues that John had with respect to describing the importance of Charlie's mentorship and his influence on me both personally and professionally.

I could best describe Charlie as a cross between Obi-wan Kenobe and an Irish leprechaun. The cliche of standing on the shoulders of giants is overused, but in Charlie's case, that's really what I think of

when I think of him. All of the characteristics that he has demonstrated just -- I think are still alive today in the office and certainly in those people that have been influenced by him.

He taught us not to take ourselves too seriously. Good humor at all times. To understand that we're dealing with a human endeavor, human frailties. I think we also realize the importance of unintended outcomes and basically the effects of good luck. Many of you will remember the famous speech that Charlie usually gave at the beginning of most of his presentations. We referred to it affectionately as the pompom speech. And Charlie delivered that with such enthusiasm we never had the heart to actually question some of the details or the origins of some of the facts that he included.

[Laughter]

>> NELSON: Needless to say, we all remember that and I cherish those times. One of the other things that Charlie instilled upon us was, in fact, he asked us to be sure and tell him when it was time for him to retire. And the importance of retiring before everyone else knows that you should. So, those are just a few of the anecdotes that I would add to what John has said, which I agree with completely. Thank you, Charlie. Thanks for everything.

>> AMY: Do you want to say something?

>> CHARLIE: No, that's sufficient.

[Laughter]

>> ERNIE: Again, Nelson and John, thank you for all you've done, again, Charlie, for all of us in the field. Okay. Let me briefly go through the format for the day. We're almost right on time. We're about a couple minutes over. We'll make that up.

[Laughter]

>> ERNIE: We have 11 sections for our program, which is going to end at 5:30, with three short breaks. Each section has a topic and a time allocation for that topic. And as the moderator, I'm going to ask individual panelists questions pertinent to the topic. Other panelists may decide to chime in if they wish. The goal is to provide all of our attendees with both insight and appreciation for how the U.S. animal welfare system evolved over time, in order to promote good animal welfare and good science. You know it's up to the next generation, which is all of you younger folks, to protect and further evolve our system in this country, which is really the envy of most of the world. That said, we're going to move on to a section called “A Career Well-Spent.” I'd like to begin with John. John, what led you to become the first director of the animal welfare division of OPRR and serve in that role from 1986 to 1996?

>> JOHN: Well Ernie, thanks. It's one of those right-place-right-time stories, although it didn't seem to me at the time that that's what it was. I have a saying that my grandchildren all know, and it is the following, especially when they're upset like by really important things like the WiFi's not working right, or something like that. I tell them, “Listen. There are a bunch of big deals in life, and this isn't one of them.” However, I also have a second saying that is, “What first seems like the worst thing that could possibly happen turns out to be, if not the best, then a really good thing.”

So, with that as background, my planned 20-year career in the United States Army hit a snag at 16 years when I was directing a program in lab animal medicine and surgery, at the Uniformed Services University, the military's medical school, when the Army decided they needed to reassign me to Panama to inspect food, which is another thing veterinarians do in the Army, besides research and research support. Well, I argued with them that the Army had a really significant investment in me during the time I had 16 years and had received training in lab animal medicine; I got board-certified in lab animal medicine, [and] they sent me to graduate school at UC Davis for three years. But those arguments fell on deaf ears, as they frequently do, arguing with Army assignment people. So my options were few. I could either suck it up and do that, or the option of calling Bob Whitney, my old friend over in the Public Health Service to see if there was anything available in the commissioned corps so I could continue to be in the uniformed service. At first, no positions, he said. But almost immediately [he] called and said, “Hey John, I just heard about this. There's a new position for a veterinary officer at this office called OPRR. Would you like to go have an interview?” I said, “Absolutely.” So that led to my first meeting with Charlie. And we had our “interview”. I put that in air quotes because my memory of it is it was mostly storytelling and jokes, and very little interviewing in the standard traditional sense.

It's hard to describe how important it was to me at the time to have that meeting with Charlie, and to step into OPRR. I was offered the job. I became the Senior Veterinary Officer, actually the only

veterinary officer. There had been one veterinarian in OPRR earlier, but he was not a lab animal medicine trained person.

But with wider departmental and HHS PHS responsibilities, and higher public visibility, which led to more funding, they could add to the staff and create an education program to go along with that. So, in 1990, the Division of Animal Welfare was created. We had 6 professionals, 3 secretaries. Charlie retired in 1992 to go to academia and I became Acting Director of OPRR for nine months, one of my proudest moments. I retired in '96 as Ernie said, as Deputy Director, and that pretty much summarizes how I came to be and what I did at OPRR.

>> ERNIE: Thanks very much, John. Let's move on to Ron. Ron, what led you to nearly a three-decade career in leadership roles at USDA APHIS, a remarkable time period?

>> RON: You know Ernie, I was thinking about this and if I knew then that I was going to have to deal with the likes of Taylor Bennett and Ernie Prentice, I might have thought twice about it. And that's a dangerous thing to say, knowing that Taylor is going to be following me. But seriously, I, too, ended up in APHIS after a short stint in the Army. And at the time couldn't afford to buy a practice in small animal work, and couldn't afford to work as an associate. So I ended up working for APHIS. And what I found was that the mission of that agency, protecting and promoting animal agriculture, is so important. And the agency does it so well that all of the positions I held I found really rewarding. And that goes from a field veterinarian in Kentucky dealing primarily with cattle farmers and brucellosis issues to later as a senior executive with overall responsibility for a number of disease and pest control and eradication programs.

And of course, it's also true, that 12 years of those 28 years I spent strictly in animal welfare programs. I think during that period, and continuing today, there's been a huge impact in terms of promoting and improving the welfare of animals in a number of settings. Of course, APHIS has a role in overseeing the use of animals in biomedical research, but also commercial dog dealers and breeders, circuses, and zoos and the like, and transportation. It has a broad-reaching impact and I think the role that they play in the improvement and welfare that has improved in animals in those settings has been significant over the years. So, again, another rewarding part of my career.

Part of this influence of APHIS is the fact that even though they're a regulatory agency, they have a culture of working collaboratively with the industries that they regulate. So it's not an “I gotcha” mentality, but how can we meet the regulatory intent while at the same time meeting the needs of the industries we regulate, whether that be animal production, plant production, or in this case, use of animals in biomedical research. And so, I think we brought that culture really to the forefront, especially in the animal welfare arena.

We've all heard the adage that “I'm from the government and I'm here to help you,” but I really think that that old adage is true with the case of APHIS. Of course, it is a regulatory agency, and occasionally the need arises to use that enforcement authority. But I think we have learned and practiced over the years very well that voluntary compliance is easier to achieve, it’s longer-lasting, and it’s more effective. So, again, just all of the positions I had with APHIS I found really rewarding and truly believe that the agency focuses on promoting and protecting American agriculture in the broad sense of agriculture, which would include animal welfare.

And I'll end with just a short quote from my favorite President, Teddy Roosevelt, who said, “Far and away the best prize that life has to offer is the chance to work hard at work worth doing.” And that's what I found at my career with APHIS. Thanks, Ernie.

>> ERNIE: Thanks very much, Ron. Nelson, let me ask, what led you to become the director of OLAW?

>> NELSON: Well, the short summary is dumb luck and being in the right place at the right time. As you've already heard some of the others, some of the things that were going on in the background at the time we were making life decisions, keep in mind that was during the height of the Vietnam war. Some of our decisions to go into the service were influenced by that. And at that time I made the decision to stay with ROTC during my training. After a four-year service in the Air Force, I did return to my original life plan, which was to do the James Herriot thing: practice small animal medicine in my hometown.

After four to five years of that, one weekend I was counting the number of emergencies. I think they were right around 24 emergencies in one weekend. And a light bulb went off saying, gee, maybe there's something else I would like to do. And I called my -- one of my old classmates, Sam Adams, at the CDC at the time, to ask what's this thing about lab animal medicine all about. And he gave me a fair amount of encouragement, which led to a residency starting off at the University of Cincinnati under Steele Mattingly and later transferring to Johns Hopkins under Frank Lowe, John Stranburg, and eventually to the School of Medicine at the University of Maryland.

From there, I made the decision to take advantage of my military service and enter the public health service at NIH with Child Health and Human Development [NICHD], and the National Institute, NICHD as a monkey doctor, primarily. And it was about that time that I heard from John Miller, who was looking for some help, much-needed help, I assure you, to join him at OPRR. And I thought it was a little bit early in my career to be sort of shifting to what I considered at the time a mainly administrative sort of activity, but thought it sounded interesting, maybe it was worth doing for a year or two to gain that experience. And the rest is history. I ended up staying as Director of the Compliance Division, and then later as the Director of OPRR, and later OLAW. And that's the story.

>> ERNIE: Thanks very much, Nelson. I'm going to make an assumption that John never bothered interviewing you, just told jokes during the process, right?

[Laughter]

>> ERNIE: Okay. I mentioned earlier that Dr. Whitney, unfortunately, cannot interact with us today, but we do have an answer to the question as to what led Dr. Whitney to his career path. And Nelson, would you mind reading that for us?

>> NELSON: I'd be glad to. This was written by Bob, and it is his very brief definition of a career well-spent. He says, “When I graduated with a DVM from Oklahoma State University, in May of 1959, I knew I was going to be drafted. I had two choices -- either two years in the boots-on-the-ground grunts, or three years in the U.S. Army Veterinary Corps as a First Lieutenant. Easy decision.”

[Laughter]

>> NELSON: *[continuing] “*If that hadn't happened, I would now be burned out and retired from some small animal clinic in southern California. After a year at Boston Army base, which was a pier in the Boston harbor, I was offered a tour of Europe from Stuttgart, Germany. For almost three years I spent a lot of time in Switzerland inspecting lovely cheese factories in the alps and also other folks who sold, presumably food-related products to the U.S. forces in Europe.” And with emphasis, he says, “I am not making this up. One day while sitting at my desk in Stuttgart, I was thinking, God, I love this but I've got to do something else with my life. My sergeant handed me an official-looking pamphlet that contained opportunities for higher education paid for by the Army. One of those options was a two-year program for a master's degree. And then—get ready— training in laboratory animal medicine. It was UCLA, which you know where that is. I signed up, then learned that that program had lost its leader and I was being sent to Ohio State instead.” And I guess that's The Ohio State, for John and others.

>> JOHN: Thank you.

>> NELSON: [*continuing]* “On a lovely day in September 1963, I stepped into the OSU medical school vivarium, opened the door to a room full of single-caged raging rhesus monkeys, and that was it.” And then his final comment was, “See, I told you it wasn't going to be inspiring.”

[Laughter]

>> NELSON: Now, Bob is very modest and I would like to add that among other things, he was the first and I believe the only veterinarian to serve as an acting surgeon general of the United States.

>> ERNIE: Wonderful. Thank you very much.

>> CAROLYN: Ernie, we're about three minutes past.

>> ERNIE: I recognize that. So, Taylor, we all know you, okay.

[Laughter]

>> TAYLOR: At least Ron does.

>> ERNIE: If you could condense perhaps a little bit why you went into laboratory animal medicine, and why you hung out in Chicago for 36 years.

>> TAYLOR: That's a good question. Growing up I had an interest in science and scientific research. So, my junior year in high school I applied to a government program to expose you to a

research laboratory. I got accepted to a program at the local VA in Nashville, where my father happened to be chief of psychiatry. Because of my experience working on my uncle's farm, and I had a little bit of interest in veterinary medicine (even though both my father and grandfather were MDs) I chose to work in the animal facility with two physicians—surgeons— that were doing the early kidney transplant work. What I knew about my interest in veterinary medicine told me they didn't need more MDs doing research, they needed more veterinarians. So I decided, well, why don't I go to vet school? And I think I was the only one that went to vet school that was interested in research. In fact, had I known it was going to be so much harder to get in vet school than med school, I probably would have gone to med school. But, once I got in vet school I had a job working to support my family. And people kept asking me at the oil company why I wasn't going to make a real doctor like my daddy and my granddaddy, but during that time, Jules Cash started the lab animal training program. And I had never heard of lab animal medicine, at the Hines VA outside of Chicago. And my friends at the VA encouraged me to apply to it, which I did with the intent of going back and managing the program at the VA, which was affiliated with Vanderbilt at the time, where I'd actually started school. But then, as part of the training program, I was approved to get a Ph.D. at the University of Illinois medical school. And the plans just did not work out at Vanderbilt, so I ended up staying at the University of Illinois, where I, actually - my Ph.D. was in transplantation immunobiology. So, I kinda came full circle, and as John said I guess I just ended up being in the right place at the right time.

>> ERNIE: Thanks, Taylor. Appreciate that. And last but certainly not least, Jerry. You were at Yale and they convinced you to become Chair of the IACUC. How about that? Why? Why did you accept it?

>> JERRY: That's a very good question. I'm also asking myself why did I accept following all these great speakers. This is going to be tough. Unlike several of these folks, I was not at the right place at the right time, I was at the wrong place at the right time.

[Laughter]

>> JERRY: I had been a newly minted assistant professor in the early 1980s. I was doing neuroscience research. And because of the species I was working on, it was clear to me that the very active animal rights folks at the time would be targeting me. So, I went to the university administrators and asked them what plans the university have in place to protect investigators and help them, should that happen. And the answer I got was that's a very good question. Why don't you form a committee and chair the committee, and come back with some recommendations?

To make a long story short, as a result of that committee I ended up being the spokesperson for the university on why animals were used in research, ended up being very involved in the creation of a statewide organization. At the time there were four drug companies in the state, so there was a lot of interest in this issue. And we tried to come together and figure out what we could and should do. And one of the major issues was trying to educate the public about why animals were being used and how. And as a result of that, first at the university level, then at the state level, and eventually at the national level, I had a real good chance to interact with a lot of folks who -- as someone said, weren't livid in their beliefs but wanted to have better information about why animals were being used.

So, I had been doing that for a while. The first chair of the IACUC at Yale wanted to step down. I was asked to consider it. And although the animals were in great shape at Yale at the time, the whole IACUC process, perhaps the best way to put it is, er..., left a lot of opportunities for improvement. One of the big issues was that the administrators within the institution who had been interacting with OLAW, USDA, and AAALAC had really established an almost adversarial relationship with those organizations.

And in going out and talking to the public, it was very clear to me that we needed to be able to say there are rules and regulations and they're being followed. Fortunately, there was a change in administration at the time – they also recognized the need for those changes to occur. So, I felt that it was an opportunity for me to see if I could, in fact, help the institution get to a point where a spokesperson talking about what was being done there could honestly say there were rules and regulations in place and they are being appropriately followed. I was very lucky. I really didn't know anything about running an IACUC office or an IACUC, but we were able to recruit an individual from southern California who had run an office there, was very good at it, was known by all three of those organizations, by the representatives of those organizations, and known as someone who believed in

making sure these things were done right.

So as a result of that, over a period of a couple years, we were able to put together a reasonably good IACUC that really did demonstrate how it could be done well within the institution. That's it.

>> ERNIE: Thank you, Jerry. We are at 2:45, which technically is the end of the next section, which would be the canine influence. And that was assigned to you, Jerry. So is it possible for you to give us a minute and a half, two-minute overview of what happened with Pepper and Lucky, and really a succinct overview of what happened?

>> JERRY: I'll try. During the 1960s and before that, animal rights groups were warning the public about the fact that animals were being stolen and sold to research institutions for research purposes. Pepper was one of the animals that, it turns out was stolen from a farm in Pennsylvania. The people that lost the animal were really interested in getting it back, had some connections with the animal rights organizations, ultimately tracked the animal to a research facility in New York, discovered that the animal had in fact been used for research, and had been euthanized and cremated. That story appeared in Sports Illustrated, of all places, in November of 1965. Now, this was at a time when the use of animals in research wasn't necessarily a big focus, but the animal rights organizations were really trying to do their best to get some laws through Congress that would help protect against the horrendous things that were being done at the time. Subsequently, in February of 1966, Life magazine, for those of you younger than most of us here on the screen, Life magazine was basically Twitter, and YouTube, and all of that sort of thing wrapped into one back then. It was a weekly publication, and it was about 11 x 14, so it was a big magazine. And a huge number of people read it.

And in February of 1966, an article appeared basically saying there were concentration camps for lost and stolen pets. And that triggered a huge cry that got some members of Congress. And as a result of that, fairly soon afterwards, a bill was passed, a law was instituted that basically ended up ultimately being the Animal Welfare Act. The law was focused mainly on interstate transport of animals. Although dogs and cats were of primary interest other species were included as well. So, in many ways it really was the beginning of part of what we think about now as this protection for animals as far as the legal aspects of the process were concerned. A lot more information, but I think that's a nutshell.

>> ERNIE: Great. Thanks very much, Jerry.

>> JERRY: And I'll rely upon my colleagues here to fill in all the holes that I left.

>> ERNIE: Really appreciate that.

>> SUSAN: I think we should include that Pepper was a Dalmatian. You referred to him as an animal the whole time. He was a canine. He was a Dalmatian.

>> ERNIE: Yes, Pepper was. A beautiful Dalmatian from the Lakavage farm in Pennsylvania. Stolen in the middle of the night by dog-nappers. Okay. Moving on to section five, we are a little bit over now. We're three minutes over. We'll catch up. And perhaps --

>> JOHN: I can read fast.

>> ERNIE: Yeah John, you can perhaps catch us up. Now, the title of this section is interaction within and among federal agencies. It's really part one. And Bob Whitney graciously provided some information that John will read.

>> JOHN: Thank you. And, typical, before I read it, (typical of Bob) it's got almost nothing about his role in it, which was enormous, of course. And he's titled his presentation here, “Dr. Joe R. Held and the Rocky Road of Nonhuman Primates and Biomedical Research.” Dr. Joe, not Joseph, R Held, was director of the NIH Division of Research Services, and my boss from 1972 to 1984. His leadership and experience concerning nonhuman primates and biomedical research spanned four decades, from 1955 to 1995.

Here in his own word (Joe Held's) is his first encounter with rhesus macaques shipped right out of the wild from India, directly from the jungle onto a container & shipped here. Quote: “My first work with primates occurred in 1955 when I was a young epidemic intelligence officer in the U.S. Communicable Disease Center, known today as the CDC. The year 1955 was the first year in which the polio vaccine was licensed in the United States and thousands of monkeys were being imported for vaccine production testing. Over 200,000 nonhuman primates were imported that year. There were very

high rates of mortality amongst some groups of these animals and I became part of a team that was put to work to find the causes and to attempt to lessen the losses. My specialty became the epidemiology of zoonoses, and repeatedly, this caused me to become involved with primate diseases." Close quote.

Back to Bob's comments. Dr. Held's experience with nonhuman primates continued in 1962 when he was transferred from CDC to NIH in the then Division of Research Facilities and Resources. The NIH had received funds to develop seven regional primate research centers. He (Joe Held) was one of the individuals that helped make that happen. Each of the centers, including an eighth one added in 1999, are major scientific resources that are also committed to adequate breeding stock. By 1972, there were over 40 research centers devoted to experimentation with nonhuman primates in the U.S. and the rest of the world. Information about many of the larger centers can be found in the history of nonhuman primates in biomedical research in the book Nonhuman Primates and Biomedical Research Biology and Management. From 1967 to 69, Dr. Held was detailed to the Pan-American Zoonoses Center in Buenos Aires, known as PAHO, where he was introduced to new world monkeys. He found them considerably more genteel than old-world macaques, to say the least. [The year] 1969 brought him back to NIH and after a short time as Chief of the Veterinary Resource branch, he was named Director of VRB's home, the Division of Research Services. I (Bob) took that VRB job in 1972.

The '70s saw regulations in the U.S. and elsewhere on endangered species and conservation efforts that affected the supply of some wild-caught nonhuman primates. In 1973, the Indian government placed an export quota of 30,000 rhesus macaques, reduced that to 20,000 in 1974, and in 1978 banned the export of all nonhuman primates. That's the Indian government. By 1974, Dr. Held could see the train coming down the tracks and convinced the director of NIH and the U.S. assistant Secretary for Health to establish the Interagency Primate Steering Committee [IPSC] to provide a coordination between concerned federal agencies to assure the critical U.S. research and testing needs for nonhuman primates were met.

The IPSC was located within the NIH, chaired by Joe Held who led the government's effort to develop a plan for meeting the nation's nonhuman primate research needs. The IPSC was to develop a national primate plan. That was published in 1978. Another directive was to lay groundwork through a series of sponsored meetings and reports for a national chimpanzee management plan. The role of chimpanzees in biomedical research is absolutely worth the time to go into, but not for this short essay. We can say that almost all of these magnificent creatures are comfortably retired from biomedical research.

The IPSC plan promoted a number of projects to start breeding colonies here and abroad. These projects were and are helpful but have never been sufficient to meet U.S. needs. Well over 100 species of nonhuman primates are found in both the old world and the new world. None of these species is indigenous to the continental United States. By now you folks are thinking, all this monkey business is interesting, but what's the connection between it and the history of U.S. animal welfare oversight? That connection began soon after an NIH veterinarian, Thomas Wolfly, joined Joe and took the job as executive secretary at the primate steering committee. Along with his DVM degree, he had a Ph.D. in comparative animal behavior. Tom said that came in handy dealing with some of the members of the committee.

It was the early '80s and folks in Europe were developing international regulations and policies for all vertebrate animals in biomedical research. A forum was needed in our country to address these potential new international issues and their effect on biomedical research using animals here. Using the IPSC member agencies as a starting point, the Assistant Secretary for Health directed the Director of NIH at the time to expand the IPSC to include all interested federal agencies in the renamed Interagency Research Animal Committee (IRAC). You've heard that before, today.

The first issue that Joe, Tom, and agency members started work on would become -- get ready -- the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training -- AKA the "Principles." This was modeled largely after the Council for International Organizations and Medical Sciences principles which Joe Held brought first to the IPSC and ultimately to IRAC. Having every federal agency in the United States that uses or supports the use of animals working on a document and ultimately endorsing it carried a lot of weight. These principles were quickly incorporated in the 1985 PHS Policy and the 1985 *Guide for the Care and Use of Laboratory Animals*. They were here to stay.

Joe retired from the US Public Health Service in 1984 and Tom did the same a few years later. Neither of them abandoned their commitment to public health and the importance of nonhuman primates in biomedical research. Joe returned to PAHO serving as the coordinator of the veterinary public health program. Tom became the Director of the National Academy of Sciences Institute of Laboratory Animal Resources (ILAR). And IRAC eventually went the way of the buffalo. Joe, not Joseph, R. Held, died in October 2007. Thomas L. Wolfley [died in] June 2013. They were the very best of homo sapiens. Almost all the information in this essay and so much of its references can be found in the first chapter of the book, volume one, *Nonhuman Primates in Biomedical Research, 2nd edition*, CRAB editor 2012. The first chapter was history of the use of nonhuman primates in biomedical research, pertinent to today's subject by Dennis O. Johnson, David K. Johnson, and coming in third place in the authorship, Robert A. Whitney. Dennis and Dave, my colleagues and dear friends for over 50 years, carried the load for most of the 33 pages. And one last thing, almost all the source countries of nonhuman primates have banned their export. This country really needs a self-sustaining national program of breeding colonies of nonhuman primates for biomedical research. That's it.

>> ERNIE: Thanks very much, John. As you can see, the system that we enjoy now came from an awful lot of hard work and dedication of pioneers in the field who had the foresight and the energy to work to develop our system. And before I move to our break, one last comment. John mentioned the U.S. government principles. I would encourage everyone to look at those. They are in the PHS policy and you can also find them as an appendix in the *Guide*.

>> SUSAN: We have to go to break. And we will return at 3:04.

>> ERNIE: Okay. Enjoy your break, everybody.

[Break]

>> ERNIE: Okay. Welcome back, everyone. We are going to move on. With section 6, which will be a Part II of the interaction within and among federal agencies, which is not an easy achievement, for sure. And John, in your bio introduction, I mentioned that you were involved in the harmonization process. So, perhaps you could talk a little bit about that.

>> JOHN: I could go on and on and on about that. And first I must say I'm very disappointed that Dr. Dale Schwindaman was unable to be with us because so much of this story is his story. But as far as the key points in that time period, the first one had to be when it got dumped on me. I mean, the first look at the U.S. -- the initial proposed USDA regulations was stunning. Practically every element in them from our standpoint needed work. You've got to remember as Ron pointed out, they're a regulatory agency, so they have to occasionally take legal action. And practically every element was not congruent with the PHS policy. I had been at OPRR less than six months at that time, was right in the midst of reviewing one of two or three people who were reviewing the hundreds and hundreds of animal welfare Assurances, brand new ones that were coming into the office.

The PHS-proposed revisions needed to start with me. And it was just a huge undertaking, so that's obviously very memorable. But following that was the office had one attorney, Bill Dommel, who was (I think) Director of Compliance. That was an office at the time. And what we did was we sneaked a word processor out of the office. We took some government property off the property, took it to Bill Dommel's house, and in his kitchen took all of the edits, revised some of the edits, and created a marked-up copy, which leads me to the third key point. These all are kinda close together. Which is was my first meeting with Jim Glosser. I don't know, Ron, was Jim around? You knew Jim?

>> RON: Indeed.

>> JOHN: Jim Glosser was the Administrator of APHIS at the time. And Jim was a – he wasn't fat, but he was about as wide as he was tall. He was a rectangle. And he had this ambling way of walking. Think of a Pekingese at a dog show. I remember him rolling along. I remember vividly, meeting in his office (the APHIS administrator's office; a very nice, very nice office, Ron knows) and leaving that office [Jim] said, "I've got some people down in the conference room." And ambling down the hallway with Jim Glosser, getting into the conference room. (The Department of Agriculture building is only second to the Pentagon in the number, the miles of hallways it has. It was a long way.) We got there. He opens the door, steps in, [and] there's a conference table with at least 12 people. I think Dick Ristler was probably one of them, another veterinarian at APHIS at the time. The rest of them were all from the Office of

General Counsel. So we had at least eleven lawyers sitting around the table. And it had seemed to me -- so, we presented what we had to them, and I don't know if they were amused or bemused by what I suspect they saw as our audacity, but it was my first and blunt confirmation of what the major hurdle in this harmonization deal was going to be. And that was to convince the office of general counsel at USDA that performance standards were actually -- could actually be enforceable.

So that leads me to the next key point was a meeting with the USDA Undersecretary for Marketing and Regulations and the HHS Assistant Secretary for Health. These are big ones, now, that the Undersecretary for Marketing Regulations is very highly placed in the USDA and the Assistant Secretary for Health at HHS is, like, the top person for health, in Health and Human Services. So we had a meeting with the 2 of them. I was there, and I suspect Charlie was there as well. The USDA Undersecretary at the time (and maybe Ron knows her name) [was] a cattle rancher originally.

>> RON: From California, I think, yeah.

>> JOHN: She was a cattle rancher, head of the National Cattleman's Association, I think before she became the Undersecretary, [and] a no-nonsense sort of person. The HHS Assistant Secretary for Health was a wonderful, gentlemanly, scholarly physician who I later learned was a very highly-placed leader in the Mormon church *[Note: the correct name of the Mormon church is The Church of Jesus Christ of Latter-day Saints]*. And the meeting was very cordial, but it was a critical turning point in our discussions.

The undersecretary, the former cattle rancher person, made it clear to the department's Office of General Counsel to not stand in the way of what Dale and I were trying to do. And in so many words says, “Find a way to enforce performance standards.” So that's it, except for one. I gotta clear something up. Many of you may know the story about Dale Schwindaman and I being locked in a room somewhere and told we couldn't come out until we had a final product. You know, I don't remember that as being a key turning point. I vaguely remember it. But what I remember about it is that it was in a hotel and we weren't locked in. There was a lock on the door. But we were there for a long time. We ordered room service. I had a cheeseburger, and Dale had a cheeseburger, and I paid. And he has never paid me back for that cheeseburger.

[Laughter]

>> I think you should bill him, John.

>> With interest.

>> Yeah. Thanks very much, John. You know, we had the ‘85 amendment, the Animal Welfare Act, and the regulations weren't issued until '89, so you guys did a lot of work to get that harmonization in place.

>> JOHN: Fun times.

>> ERNIE: All right I'm going to move on to the next question. I'm sure that a lot of you recognize that there was a lot of animal rights activity during the 1980s. There were, you know, break-ins, protests, etc. So, I'd like to ask Ron and John, what was the impact of these activities on the development of the federal standards that we've been talking about and the public perception of animal research?

>> RON: Do you want me to go first, John?

>> JOHN: Go ahead, Ron.

>> RON: Thinking back to the 1980s -- this was really when I was first getting involved in animal welfare issues, and thinking about moving to Washington, D.C., and taking the national role in this. I do recall very vividly that over 50% of the correspondence and communication coming into the Office of the Secretary of Agriculture had to do with animal welfare issues. So here you have literally the smallest program out of literally hundreds of programs in the Secretary's portfolio that was generating more than half of the correspondence coming into his office.

At the time, the animal welfare oversight function (administration of the Animal Welfare Act) was within APHIS' Veterinary Services unit. So, at the time, APHIS was really focused (or Veterinary Services within APHIS) was really focused on livestock and poultry diseases. Brucellosis was a big-money project. A lot of the funding for other programs really was supported by brucellosis funding. We were [also] dealing with highly pathogenic avian influenza and those kinds of diseases. So here you had a cadre of field veterinary medical officers and animal health technicians whose day-to-day job was doing

brucellosis and TB testing, some export work, and the like. And so, I was one of those folks and literally, animal welfare inspections were something we did as a filler. So, if we did not have a herd lined up to do brucellosis testing, we would go to the local research facility or dog dealer, as the case may be, and do our inspection. So, at the end of the day, you had a cadre of inspectors, probably 500 or 600 at the time, whose primary role was livestock and poultry disease programs. And we kind of did animal welfare as a filler. And so, you can imagine that many of those folks were less than totally interested in doing animal welfare inspections.

And certainly, as it relates to oversight of animals being used in biomedical research, many of them were pretty uneducated or uninformed in terms of what went on in research laboratories. So ultimately it came down to the relationship between the individual inspector, the field veterinarian, and the facility manager at the research facility as to what kind of relationship you had. And you can imagine with some 500 people involved in that spread over the country that there was a lot of inconsistency in terms of the quality and depth of inspection, which led to really a lot of issues. And so [you] have this very important program that is increasingly getting more interest from the public, as evidenced by all the correspondence coming into the secretary's office, and it was pretty much buried in the program. So, Jim Glosser (the Administrator at the time) had the foresight to realize we needed to do something about this. He was looking at the rest of the APHIS organizational structure at the time as well.

And so, under his leadership, there was a reorganization and animal welfare was pulled out of Veterinary Services. [He] created this unit called Regulatory Enforcement and Animal Care. Regulatory Enforcement was the investigators that would investigate any violations of the laws that APHIS was responsible for. And the only reason for hooking those two units together was that neither one of them was large enough to be a standalone unit within the program. They later were separated and of course, now we have Animal Care. But Jim Glosser was getting a lot of heat from the Secretary's office as well as directly from the public, and one of the people that was really critical was the then-state veterinarian in the state of Michigan, Dr. Joan Arnoldi, and Joan was complaining to Jim Glosser that he needed to do a better job of enforcing the Animal Welfare Act. He said something to the effect of, well, if you think you can do it better, why don't you come in here and do it? So, in fact, Joan became the first Deputy Administrator of Regulatory Enforcement and Animal Care, a mentor to me and several folks.

So that's kind of how we got to where we still are today with the Animal Care unit, but going back to the '80s, I think, in general, the public was becoming increasingly concerned about the use of animals. The focus back then was clearly among the animal rights groups [on the] use of animals in biomedical research, but they still (for the most part) supported the use of animals in research. They just wanted to be assured there was better oversight. So, again, it made infinite sense to reorganize and set that function separate and apart within the Animal Care unit within APHIS. Clearly, the 1985 amendments to the Animal Welfare Act were being driven by the animal protection groups (not just the extreme animal rights groups) but I'll incorporate all of those that were interested in greater oversight and protection of animals in research.

And as John and others have indicated, a lot of emphasis [was] particularly with regard to use of non-human primates. So, the '85 amendments almost entirely focused on better oversight of use of animals in research, and that amendment, again, [was] driven largely by the animal protection groups. So, the '85 amendment required promulgation of regulations to provide for the psychological well-being of non-human primates, [and] exercise for dogs. It established within USDA the requirement for institutional animal care and use committees. A lot of emphasis on 3Rs, how are we going to minimize pain and distress in animals that are being used in research and particular emphasis on what we refer to as sensitive species: dogs, cats, and non-human primates. So really, that was the beginning of a dramatic decline in the number of non-human primates and dogs being used in research— and, at the same time, an exponential increase in the number of rats, mice, and fish being used in biomedical research. And so, I think, again, a lot of that driven by the animal rights movement, and ensuring that we had better oversight.

>> ERNIE: Anything to add, John?

>> JOHN: I think a lot of -- I agree with everything Ron said, but clearly the impact of the animal rights movement and the broader animal protection movement was very significant. I mean, 1981, the Silver Spring monkeys, that brought PETA [People for the Ethical Treatment of Animals] into the forefront. The University of Pennsylvania head trauma study which was less widely known was in

1985, but it should be widely known [that this] was the first instance in which an OPRR report found significant enough deficiencies that funding to that research project was halted. That's the first time that ever happened.

But looking back then, that's also the time CNN began in 1980. And in the early '80s we were in a recession. Towards the mid-'80s and later in the '80s recovery led to a boom. People had more personal time to deal with societal issues, and protests being newsworthy (when you got a 24-hour news cycle— it got a lot of publicity) which brought, as Ron said, a lot of Congressional attention. The Congress was clearly interested in this as well, largely due to that pressure. Dr. Bill Rob was the Acting Director of NIH at the time and he -- if you go back and Google hearings of Dr. William Rob with Congress, he's got tons of them. Most of them are about animal research during that time. The natural instinct of researchers, I think -- I know -- was to hunker down, try to cover/hide what we're doing and protect the laboratories physically if necessary.

And it was also natural for them to defend their research, to malign animal research supporters. The moderate voices, like Christine Stevens and the Animal Welfare Institute, the American Humane Association, and others were easily lost in those conversations. But the research community, largely led by NABR, Frankie Trull specifically, the founder of NABR and her troop [were] key in pushing for performance standards and encouraging researchers to explain their work to the public [that it was] critically important.

Finally, I'd like to think that the animal protection community and the research community have come to see the PHS approach along with AAALAC accreditation as being part of this demonstration that we are, in fact, committed to animal welfare.

>> ERNIE: Okay. Thanks, John. I'm going to move on. And you're up again, John. And I'm going to alter the question slightly. The question is: What do you believe has been the most significant outcome (not outcomes; pick one) of the 1985 PHS Policy and the subsequent harmonization of the -- with the AWA regulations?

>> JOHN: Number one, overall, it stood the test of time. That's the biggest outcome I see from that. That we're still living with it. Nelson's probably going to talk to this but the other major outcome was the shift of responsibility for animals in research, animal care and use from the individual researcher to the institution, [through the] acceptance of performance standards. I'll just read my bullets. And the bottom line [is that] institutional programs of animal care and use got better and animal welfare improved.

>> ERNIE: Okay. Thanks. I'm still trying to catch us up a bit. We can go back and revisit these questions in a moment if we need to. Ron, what do you believe to be the most significant impact, the number one impact of the AWA regulations in improving laboratory animal welfare?

>> RON: I'll go two bullets like John did because I don't know that I'm prepared to say one impact [statement]. Let's not forget too that the initial focus, as Jerry pointed out, for the 1966 act was to get a handle on dogs being stolen and ending up in research facilities i.e.,Fmorom the Pepper story. And then there was subsequently several amendments that expanded the scope of the act itself, and the regulations implemented because of it.

So, I think the biggest impact has been this -- two things, collaboration and coordination between NIH (specifically OLAW and USDA) and this emphasis on not just meeting the physical needs and the facility requirements, but going [on] to meet the more social/behavioral needs of animals through psychological well-being of non-human primates, exercise for dogs, and the like. And then the third thing (I'll copy John here): even from a USDA perspective where we would go in and do an inspection and really focus on the facilities and what was happening and hold individuals responsible, now those inspections largely focus on evaluating the effectiveness of the IACUC in being that primary -- having that primary role and responsibility for ensuring compliance at a facility.

So, all of those things collectively, I think, have ultimately led to far-improved animal welfare, but at the same time, doing it in a way that -- I won't say doesn't restrict biomedical research, because it certainly does, but minimizes that impact.

>> ERNIE: Okay. Thanks, Ron. Nelson, we've mentioned OPRR. We've mentioned OLAW. And at one time, the Human Subject Protection Division and the Animal Welfare Division were within OPRR;

then there was a change. And then what happened? Why did this change? Why did the Human Subject Division go up under DHHS [U.S. Department of Health and Human Services], and the Animal Welfare division become OLAW, and remain under NIH? What happened?

>> NELSON: I'd like to enlist your help, Jerry and John, and anyone else that would like to help me out in this explanation. I certainly have some opinions as well as some facts to deal with that. What was going on, on the human side, at the same time we were promulgating USDA regulations and coordinating them was the long evolution of the Common Rule and federal regulation dealing with human subjects research.

A whole series of events, departmental advisory committees looking at these questions. It was fundamentally different on the human side, from the animal side, in that human research subjects were protected by a regulatory structure. And there's a fundamental difference between regulation and policy. A decision was made to move the entire office, actually, animal and human at the time, to the Office of the Assistant Secretary for Health at the culmination of those studies of human subjects protection. And I believe there was a perception of conflict of interest on the human subject side where the institution, or institute rather, that was funding the research was also responsible for investigating and for enforcing those regulations. And again, because of the fundamental difference between regulations and policy, NIH is certainly not technically a regulatory agency. But I would like to get you to fill in some of the gaps if you will on the Common Rule and how that evolved. John, you may recall some of the issues during that period and during your tenure as acting director.

>> ERNIE: Well, what happened in the 1990s: the first shutdown of research by OPRR occurred in 1994 (I think October) at Rush Presbyterian St. Luke Hospital in Illinois. and that was a shocker. I mean, they shut down all federally funded research! And of course, I read about it. Indeed, we had some graduate students working on their PhDs in collaboration with folks at Rush Presbyterian and they had to halt their research. [Then] the biggie came not long after that: Duke University, and then there was a cascade of human subject shutdowns that went all the way to, really, the last one (which was the real biggie) and that was Hopkins. So, OPRR at the time was under Gary Ellis, who was the director.

Clearly, there was a lot of heat placed upon him, because, you know, there's something wrong with the effectiveness of the existent regulations, which at the time was the Common Rule. Apparently, IRBs left and right, according to [the] Feds, were violating these regulations. Although I don't know all of the politics, I made an assumption that it was felt that perhaps the human subject division should be now placed under DHHS as opposed to remaining under NIH. I also know that Gary Ellis was under a lot of fire for basically engaging in research shutdowns without consulting with his boss. So, [there were] lots of interesting things happening at that time.

Of course, I'm not privy to what was going on in [that] office. As to well, were there debates: do we remain in NIH or should we move up to HHS? I don't know any of those kinds of details. I just know it was these shutdowns that precipitated (in part) that move as well as NIH under [HHS Secretary Donna Shalala] requiring (under HHS) "[protection] of human subjects" training for any investigators with NIH grants that had human subject research components.

And that also led— John, you can talk about this— that also led to accreditation of human research protection programs, because prior to I think 2001, we didn't have any. It didn't exist, even though we've had AAALAC since (if I can remember my dates; John, correct me if I get them wrong), since 1965. So, John, perhaps you might want to comment on [what] was the pressure to now have accreditation?

>> JOHN: Well, thank you. I can't really speak to the issue of the separation of the human subjects and the animal, one going to the department and one staying. What Nelson said makes perfect sense to me. I think the fact that the Common Rule applied to so many federal agencies, several of which were under HHS, made it logical for HHS to be the place for it to be rather than down at one of those components [at] the NIH.

As far as accreditation, that started as an idea (I think) between Joan Rachlin at PRIM&R and I one time. Why [was] there no accreditation for programs for human subjects protection? Because, I mean, [human subjects research has] been around forever. It's accepted; seen as being productive, useful, and helpful. And so I convened a meeting and I had (actually, by that time) moved and was Executive Director of AAALAC. [I] had a meeting in the AAALAC office building conference room of interested parties and [it] ended up we had multiple of those meetings in that conference room. And

that's how the accreditation of human research programs started. [It] was seen widely at the time as something being needed to both help the institutions do a better job, and to provide a buffer— not coming up with a better term— between the institutions and the regulatory agencies.

>> TAYLOR: I can chime in here. I think it's important that this also changed the landscape at institutions. The IACUC, or at our institution, the animal care committee, barred a staff member from the IRB office. Between that and the animal care office, they ran the IACUC. And after the shutdowns, the IRB offices grew exponentially and all of a sudden the IACUC offices had to stand on their own. And it changed the landscape, certainly at academic institutions.

>> ERNIE: So, Taylor, I failed to mention the shutdown at your place, the University of Illinois-Chicago. I was part of the OPRR site visit. So, I have to take some responsibility for creating problems for you.

>> TAYLOR: You didn't. Actually, it helped. [Chuckling] Get our own --

>> ERNIE: I know it helped. But initially, what was the reaction, [at] Illinois when that happened?

>> TAYLOR: Well, when that happened, [they] brought in a new vice chancellor for research who actually came out of the chemistry department and didn't have a clue, what was, I mean, poor guy— he was thrown this— but they poured money into the vice chancellor's office to ramp up the IRB which went from a total staff of maybe five or six people, including the IACUC, to 25. And then there was a separate IACUC office. And fortunately, I had my finger in getting that first director appointed, who happened to be a PhD researcher, so it helped us a lot.

>> ERNIE: So, let me ask Ron a parallel question. The USDA has been involved in levying some fairly significant fines at academic institutions. Could you perhaps comment on the impact of those fines in terms of, “Okay, now we need more resources for animal care and use program, we need better caging, we need to change this and that”? Did those kinds of fines really work?

>> RON: Ernie, I think in some circumstances they really did. And not so much because of the monetary impact, but every time we levied one of those fines we went through the administrative law process and imposed a fine, far more impactful on the institution was the negative publicity that they got from that. So, while the fines in some cases were significant, I think the greater fear, the greater incentive to achieve compliance, was the negative publicity that would come out of any kind of action like that.

And anytime post-1990, say, when we were working closely with OLAW, we never took those actions single-handedly. It was always in coordination with OLAW. To the extent that it was a PHS institution, there was a double impact there. So yeah, I think it did have an impact. In the best of circumstances, we've had occasions where an attending veterinarian or someone senior in the institution would collaborate with an inspector to write something up so that they could get it fixed, to get the attention on it so they could get it fixed before it really got bad. So, I think to answer your question, Ernie, I think they did have an impact, but not so much because of the actual monetary penalty, but the negative publicity that went along with that.

>> TAYLOR: I would agree.

>> ERNIE: One final question, Nelson. Some folks at the time that the decision was made that OLAW would remain under NIH (but OLAW also exerts oversight over NIH) [felt] that might be a conflict of interest. Could you perhaps comment on that?

>> NELSON: Sure. And that's an interesting difference between, in my opinion at least, the human subjects oversight structure and the animal welfare oversight. At the time the decision was made to move humans, it was a foregone conclusion that animals were going with them. That really was an issue. I felt fairly strongly that OLAW really needed to stay at NIH and there were important reasons to do that. The most important of those reasons was purely statutory. And that was probably the argument that held the day. The Health Research Extension Act specifically states that “the Secretary acting through the Director of NIH shall establish guidelines” blah, blah, blah. That's pretty clear. I mean, that's the intent of Congress. And that I think, as I said, that probably carried the day in -- I did raise this issue at the time along with a number of other sort of arguments, or trying to be persuasive. I do think it gets back to some of the fundamentals of Grants Policy. And we'll talk a little more about that in the section 8 about the linkage between Grants Policy and PHS Policy.

But my opinion was that NIH was and is the appropriate home for OLAW. It is true that it's a

unique location and there are some parallel lines of oversight or authority over activities at sister PHS agencies. So that does create a little bit of a weird organizational chart if you try to draw it out. But I'd have to say I view the location as really not so much of a conflict as it is a quality assurance within the NIH granting mechanism and consistent with the NIH mission. So that's basically how I viewed it.

>> ERNIE: Okay. Thanks, Nelson.

>> JOHN: The farther away you are from a Presidential appointee, the better off you are.

>> NELSON: I'm sorry, I missed that.

>> JOHN: Organizationally speaking, the farther away you are from a Presidential appointee, the better off you are.

>> NELSON: That was one of the sub-arguments that— being hidden within the bowls of NIH administration has its advantages. Both in terms of resources as well as perhaps being shielded in some ways from direct intervention at a political level. So, I think those are [sort] of all factors. And the other thing, as Taylor mentioned earlier: I think the animal welfare oversight does far better when it's not competing with human subjects oversight for resources at the institutional level, and this is also true, I think, at the NIH level. We felt like we had the ear of our bosses in a much better way as an operation independent of human subjects oversight.

>> ERNIE: Okay. We're going to move on to the next section. And I'm going to alter the question a bit because I think that in some respects we have already answered components of the question. We've talked about when the revised PHS Policy was issued in '85. We've talked about the '85 amendment to the Animal Welfare Act, the birth of IACUCs, and the '89 USDA regulations that implemented the '85 amendment to the Animal Welfare Act. What we have not talked about is AAALAC, which was active during all of that time. So, I'm curious and I would address this question to both Nelson and John. What kind of interaction did AAALAC have with OPRR? And we can also ask Ron to comment as well if he wishes.

>> NELSON: Well, I can start off. And certainly, from a federal perspective and in keeping with administrative procedures acts, and federal advisory committee acts, and various things of that nature, the formal relationship was there and much more active between OLAW and USDA. But during that time, of course, the Animal Welfare Act regulations were being promulgated over a long period of time. During that time, we had active programs of education. We had all of the national scientific societies meetings where John and Ron and I would appear on the same podium at the same time to the point that we could probably give each other's speeches. I mean, it was that close. And during that time, we developed a level of friendship, a level of trust, an understanding that we had very common goals, what some of the limitations were for each other. And I think that all contributed; not just the three of us, but really down deep within our respective organizations, this idea of community that I think really, really helped when it came to approaching questions. Ron has already mentioned some of our other collaborations, including actual joint site visits where USDA and OLAW representatives would go together to an institution to address issues. And I think those were all very, very effective forms of cooperation, even to the point of coordinating answers to questions coming from the community where we wanted to be sure that our answers were not only correct but that they were consistent or not incompatible with each other. So that effort was a conscious effort and I think— I believe— it still continues today.

>> ERNIE: So, John, I'm curious. You weren't the executive director of AAALAC then? That was a later position. Did AAALAC have influence on this whole process we're talking about?

>> JOHN: You know, that's a fascinating question. I never thought about that before, amazingly, given what I've done before. But as I'm thinking about it, just as the discussion is going on here, very little. The interaction – Gene New was the director of AAALAC at the time, and Gene and I were long-time personal friends and we would see each other, but as far as AAALAC involvement directly or even indirectly with the promulgation of the harmonized regulations and all that that was going on. But there's a good reason for that. The thing that AAALAC and PHS policy have in common is the *Guide for the Care and Use of Laboratory Animals*. I mean, without the *Guid*e there would be no AAALAC. And so that's -- those are the standards that AAALAC uses. Those are the standards that the PHS Policy refers to and applies as well. So it was very difficult for there to be any sort of conflict because we were using exactly the same standards from our perspective.

>> ERNIE: Okay. Thank you.

>> RON: I'd just comment a minute, Ernie if I could. (I apologize; my computer, for whatever reason, just decided to restart itself, so I got logged off and I'm back.) So I missed some of the conversation. I hate it when that happens. But, you know, I think from a USDA perspective, we have to take into -- or understand the fact that at that point in time ('80s and early '90s) USDA probably had about 10,000 dog dealers, many of which you'd classify today as puppy mills that consumed a huge amount of resources. We had a number of roadside zoos, fly-by-night circuses, and all of that. So, trying to provide oversight and administer [and] enforce the Animal Welfare Act on those kinds of institutions with 120 inspectors while at the same time there were probably 1200 USDA registered research facilities, there were really workload issues.

So, it was back then that we initiated the first iteration of our risk-based inspection system. And at the time I don't think we could legitimately acknowledge AAALAC accreditation as one of the factors that we would use to reduce the frequency of inspection on those facilities. So, if you have limited resources, then spend your resource where is you're likely to find the biggest problems and less emphasis and less oversight on facilities that have a good compliance record and typically those that are PHS-Assured and AAALAC-accredited. So, I think there's been – and Betty can fill us in on this perhaps later.

But there is a formal recognition of that and a subsequent lawsuit that's pending because of formal recognition of AAALAC accreditation as one of the factors to consider in determining inspection frequency for a particular facility. But I can't emphasize the importance and how much I appreciate what John and Dale Schwindaman did in terms of getting a consistent set of requirements so that institutions weren't trying to meet two totally different ones, and then the collaboration that the three of us had later on in terms of dealing with individual situations. We typically spoke with one voice and I think at the same time [we developed] a real collaborative relationship with the research community by participating in meetings, conferences, and explaining the regulations or the current interpretation of whatever the hot issue was at the time. So, a really positive collaborative relationship there that I think served everyone well.

>> ERNIE: Okay. Thank you. I'm going to skip around because I'm a little bit worried about the time and I want to turn to Jerry. Jerry, obviously you were doing research way before there was a requirement for IACUC review and approval. What kinds of changes did you observe as a result of their implementation? And was there a transition period that took time for investigators at your institution to adjust to these changes, and were they receptive, or were they in opposition?

>> JERRY: And how many hours do I have to answer that question?

>> ERNIE: You've got about one minute.

>> JERRY: Okay.

>> ERNIE: A little bit more than a minute, okay.

>> JERRY Let me, first of all, go back to something that Ron and John and Nelson said. And that was the role that the institution now had to play in making sure that things were going well. As an individual investigator, if I had a concern about occ [occupational] health or I had a concern about veterinary care, without the institution now being required to be involved in that process, I was on my own and not very much was going to happen. So, I think that was a huge, huge effect on overall scientific processes throughout the institutions.

As far as the kinds of change that happened, let me go to your last question first. Was it quick? Was the ability of investigators to adapt to this quick or was there any pushback? And the answer is no, it was not quick. There was some pushback. And I would argue that it's still going on and there's still some pushback. Fortunately, we have basically a new generation of individuals who have grown up understanding that this is the way the process will be done.

One of the challenges that I certainly saw was the sense of— it was buried under academic freedom— but the sense that the investigator, that he or she was the person in charge, and they were responsible and they could do everything that they wanted to do. And I would suggest going back to the question about the dog, the Dalmatian that was stolen, that attitude was unfortunately reinforced and resulted in something that exists still today, the idea of the mad scientist going into a laboratory, closing the door, locking it, and doing whatever he or she wants to do back there.

So, we still face the issue of not trusting science, but again, the cohesiveness of the attempts to make sure that oversight was broad-based, I think, helps us in being able to say there are rules and regulations in place. We understand they're going to be followed everywhere and we're going to try to make sure they go as well as they can. As far as real differences -- and I'm going to go back to the 1970s when I was graduate student and compare with what's happening now.

I'm going to talk about two species -- rats and rhesus monkeys. As a graduate student, I initially worked with some rats and I can tell you that there were three failings that I now identify in how I did that. First of all, I received no training in how to handle the animals appropriately. Secondly, I received no training in how to restrain them. Thirdly, I received no training in how to adequately anesthetize them for non-survival surgery procedures. It was simply, go in, somebody told you what to do, you did it. Clearly, that's not the case now. Likewise, with rhesus monkeys, I spent several years working with rhesus monkeys, training them to perform behavioral tasks, but also performing surgery on them to attach recording chambers to their skulls. If I think back to how things were done, first of all, there were issues of occupational health and safety. Clearly, we know that rhesus monkeys carry B virus. It was known back then. But in the training of the animals and in working with the animals for four years, the only PPE that we ever wore were welder's gloves and we did that only when we thought the animals might scratch us.

And this points out the fact that we're not just looking at the changes that have been implemented as a result of IACUC oversight, but there are also changes in the environment, in the world and how things are being approached as well. So, we shouldn't assume that everything that's come out of this that's good has necessarily come directly from those regulations. Also, with occupational health and safety, we initially anesthetized these animals with halothane, an inhalation anesthetic agent that is known to cause halothane hepatitis. And as we did that we were sucking in all sorts of that halothane as we were anesthetizing the animals. Again, no care whatsoever as far as occupational health and safety was concerned.

We did surgery on these animals. I never received any training in appropriate surgical technique or in appropriate tissue handling. It was a matter of watching two, scrubbing in for the third one, and doing surgery the fourth time around. And again, we know that's not going to be happening now. We know that there are requirements for people to be appropriately trained in order to undertake those things. There was no post-op analgesia at that time, but in reality, within veterinarian medicine, post-operative analgesia was really not a big issue. If we took our pet dog to the veterinarian and had surgery it probably would not have received it as well. Even in the human environment if we go back and look then, neonates who underwent cardiac surgery frequently received very little anesthesia and not very much analgesia post-op because there was a fear the drugs were going to kill the babies.

So again, increased knowledge has made huge differences in how we deal with it. And then finally, vet coverage. I had worked with these animals for four years. If we thought the animal didn't look well, we would go to the refrigerator and draw up some penicillin and give the animal an intramuscular injection. I saw a veterinarian once in the four years that I worked with these non-human primates. So, those are the kinds of things that I personally experienced. Part of it might have been where I was at the time. Part of it certainly was that's how things were being done. When I would tell similar stories during IACUC 101 training programs or during SCAW [Scientist's Center for Animal Welfare] training programs, there were always a couple heads out there nodding yes. I would speak to them afterwards. They'd say that's how they did it as well. Clearly, there have been huge, huge changes that have greatly improved animal welfare, have improved occupational safety and health for the humans, but those changes have also improved research as well, because they have helped to reduce a lot of unknown variables that we simply didn't appreciate at that point in time.

>> ERNIE: Thank you, Jerry. I want to continue with you. You know, when I was the IACUC Chair at Nebraska I wasn't the most popular guy around. I had a lot of investigators accuse the IACUC of impeding their research. So, let me ask you the question, are there any really negative effects on research that are valid?

>> JERRY: Yes.

>> ERNIE: Comment on those?

>> JERRY: Let me follow up that answer, however, with an explanation. And somebody -- I think it might have been Ron -- alluded to this early on. And that is the fact that the necessary regulatory

environment that we live in today must have associated with it a period of time in which applications can be filled out, submitted, reviewed, and approved. So, there's a natural period of time that has been established where, rather than working on the research, you're taking care of the bureaucracy associated with it. The real negative part of that as far as I'm concerned relates not so much to the IACUC but to the broader picture of the entire environment. When we take a look at investigators who are working both with humans and with animals, and we begin to think about the various agencies that they have to get clearance from before they can actually do their work, we see that it's very large. It's a significant amount of time.

So, each of us associated with whatever particular regulatory group it might be has a responsibility to make sure that we are staying within the guidelines and also doing everything we can to minimize the size of the hurdle. And not just the people on the committee, but the institutions as well. Part of that really relates to individual IACUCs. Over many years, seeing many different places, the one thing that always struck me was if an IACUC is really being effective in doing its job well, the amount of slowdown attributed to it as it relates to animal research is fairly minimal. However, it's not uncommon for an IACUC to either not understand what they should be doing, or they let one person command the IACUC and tell the IACUC what it should do. As a result of that, the IACUC suddenly is doing more and more and more. Actually, it's requesting that the investigators do more and more and more, asking more questions. There may be a question put into the form 15 years ago that was needed then that's no longer needed. It's still there because that's the way we've always done it.

Let me give a real solid example of this. We know that veterinary verification and consultation, VVC, came out a few years ago in an effort to reduce the amount of time between the idea for a modification to a protocol and that modification being approved. That process, if the institution has the appropriate policies in place, can run very smoothly. Typically, the veterinarian takes a look at what the request is. All of the necessary boxes have been checked for that request to be approved. The veterinarian says it's okay and the work can begin. I happened to be at one institution, and the institutional IACUC had allowed one person to tell them what they should be doing with this. And that one person had told them that, okay, once the veterinarian has approved this, that approval must now go back to the IACUC for full committee review and approval at the next scheduled meeting.

So, the whole purpose of VVC to shorten that time had been changed and yet in consultation with the folks from that particular organization, their argument was no, we've been told we have to do it this way. So frequently the problems that arise as a result of the IACUC process are not the result of doing it right, rather, the result of the IACUC itself doing it wrong. Members of the IACUC not paying attention to what their responsibilities are, not knowing what they're supposed to be doing.

>> ERNIE: Okay. Thank you, Jerry. So, the message here is IACUCs should not create undue administrative burden.

>> JERRY: Absolutely.

>> ERNIE: I want to turn to Taylor. I want to go back to when the regulations were issued, the 89, the PHS policy in '85. You're a lab animal vet. What impact did it have on you and your job, and how you had to deal with investigators?

>> TAYLOR: Actually, you know, the regulations didn't have any really impact in terms of how we managed the animal care and use program at UIC because one of the first things that I did when I started having responsibility was sit down with our veterinary staff and supervisors and the 1972 copy of the *Guide* and go page by page through that thing and figure out where it was we needed to improve our program. And as part of our runup to the budget process every year, we'd sit down and review the program again, and the veterinarians and the supervisors would prepare program improvements for their area of responsibility, which we would then work into the budget process. So, by following the *Guide* as actually a living document, so to speak, the regulations in terms of the day-to-day management didn't have a lot of impact on us, I don't believe. Where it did have a big impact was in my role working on the NABR [National Association of Biomedical Research] board and on the NABR federal regulations committee, because I did get involved with— along with the other organizations in preparing— NABR's comments for the '85 amendments. And one of the things that I've learned in a job I had was (while going to vet school which was working for a Texaco distributor driving a truck) was that you needed to know the regulations better than the people that regulated you because they would pull you over on the

side of the road and want to see if you had your fire extinguisher and all this kind of stuff. That was a kinda a message I passed on to the people who came through our post-doc program. If you're going to be regulated, you need to know what's in the regulations. In fact, Ron mentioned the training of the VMOs. The NABR committee was meeting with folks in the USDA on a regular basis. One time I held up what was then the regulations and said can I put together a training program for VMOs that's no longer than the regulations? Because if I need to know the regulations, can't they have a training program that's no longer than the regulations? I don't think they thought it was as funny as I was, but I think that was the big impact. I somehow got sucked into the regulatory process. Ron and I had our dog and pony show at various meetings over the years.

>> ERNIE: Thanks, Taylor. Yeah. Let me deviate just a second. I first got involved with IACUCs in 1985. In my office, the chancellor's secretary called me up and said, "The chancellor wants to see you." And I went up to his office. I think that was the first time I had ever been in his office, in that rarefied place in the medical center. And he said, "We've got a problem. We need to have an IACUC because this thing called the PHS Policy requires an IACUC." And my response was, "What is an IACUC?"

This guy was a rather progressive chancellor. He knew what it was. He said, "I want you to develop an IACUC for us." And I said, "I don't know anything about it, I'm a basic science researcher." And I'm working with rodents and, you know, my research was like Jerry's. No oversight whatsoever. He said, "I'm going to send you out to California." It was one of the first PRIM&R meetings on the PHS policy and IACUCs. It was at the -- I can't remember the name of the center, but it was in Monterey, California. And, I knew Charlie. And, you know, I met Charlie there. And we, once again, went out and had a few scotches and he sort of educated me about what this PHS Policy really meant.

That was my first introduction. Then I had to go back to the medical center and literally create an IACUC, and I've been very, very fortunate in that over the years, I've been able to participate in so many different conferences like PRIM&R and SCAW and AALAS [American Association for Laboratory Animal Science] and the IACUC 101 series. So, I want to turn the question to all of you. What about all of these partnerships, shall we say, that these organizations I just mentioned really have with OLAW and with USDA Animal Care -- they really are all partners. So, what's been the impact of that on how we have evolved in terms of our understanding of what really needs to be in a robust, valid animal care and use program?

>> TAYLOR: You know, I think the PRIM&R, SCAW, and IACUC 101, as you mentioned, the foundation of that, was the traveling roadshow that Charlie put on from OPRR. I was fortunate enough to speak at several of those. But at the same time that he was starting that, there was another meeting that Steele Mattingly, who was mentioned earlier, had in Cincinnati called CONMED [a continuing education forum on laboratory animal care and use]. CONMED looked at a lot of these things before there ever was a PRIM&R, or a SCAW, or an IACUC 101, and each spring we would get together and have a little meeting there. [A] couple of times they had to sneak us out through the parking garage into school buses to go to dinner because the animal rights people were picketing the CONMED conferences.

I think one of the other things that happened was Frank Lowe, who was also mentioned previously, at the time was, I think the chair of -- I can't remember what his involvement was. But, he had the idea of putting out a book called the Biomedical Investigator's Handbook for Research Using Animal Models. It was put out by FBR. This was in 1987, before there were any of those things taking place. So, I think Charlie, and Steele, and Frank Lowe deserve a lot of credit for starting this educational process that then turned into quite a number of meetings every year, having been to many of them. [Chuckling]

>> JOHN: I would just add that the relationship, when I was at OPRR, the relationship between OPRR and PRIM&R was critically important during that period of time when we were trying to harmonize the regs and the Policy and get buy-in to the new Policy for a number of reasons. Number one, Joan Rachlin was an amazing driving force for whatever it was she felt needed to be done. With your encouragement, away she went. But they had in place the framework for bringing together individuals from institutions prior to the animal -- it being the people at institutions who were involved with animals, it was the human subject protections people. They knew all those people who ended up being the people over the IACUCs. And so, when they devoted themselves partially, when they started having the animal welfare conferences, they already knew how to contact the right people to get the right people from those institutions to come and hear what Charlie had to say, what I had to say, what Taylor

had to say, and what Nelson had to say. That was already in place. Plus, PRIM&R has always been open to and they don't reject any members. If an animal rights person wanted to come to the PRIM&R meeting, they were never blocked. Animal welfare people weren't blocked. So, there was exposure, hopefully, to the more moderate of those groups to us, to the people who were trying to come up with oversight mechanisms, and hopefully, they saw that we were, you know, regular, normal human beings. We weren't the type that locked the lab door and went in and tortured the dogs and the monkeys behind there; [we] really wanted to do good. So I think that, especially, the OPRR/PRIM&R interactions, their relationship was critically important to getting done what got done in as short a time as it did.

>> NELSON: And I would say the OPRR/OLAW mission has always included a major commitment to education, and I think that's consistent with what you're saying. It grew out of Charlie's influence, I think, and the PRIM&R experience. But to the almost endless list of organizations that we sponsored or partnered with, collaborated with, coordinated with, all of that really was an intentional effort and part of the fundamental mission.

>> RON: And I think it was important that all of that was well-established by the time the new regulations were published in '89 and subsequently in '91. That USDA was incorporated into that fold and provided a non-threatening environment where members of the research community could ask questions, get policy interpretations, and all of that before they had that inspector on-site who was writing them up. So, it provided an opportunity for—and because of the graciousness of Charlie and John and Nelson— to incorporate us into that and be part of that educational role instead of just the compliance role.

>> JERRY: The audience for many of those [was] someone who needed to learn what this thing was all about. It was absolutely invaluable and continues to be so, because the reality is that as we all know this is not a simple issue. It can take a fair amount of time for someone to become truly fluent in the language and in basically understanding what's best for the animals, what are we doing for the animals, because a lot of the verbiage kind of loses in translation the bottom line. And that bottom line is it's about the critters. Ultimately, that's why all this has been written. That's why all this is being done. So, I think that collaboration that the three of you and others were involved in really was essential to helping people understand what this was about and helping the expansion, the appropriate expansion, of the IACUC oversight.

>> TAYLOR: One group that hasn't been mentioned, within AL [Agricultural Library], the regional AWIC [Animal Welfare Information Center] was very important in pulling together resources. They had a really excellent staff. And I know I worked with them a lot on things. They provided us with a lot of support.

>> NELSON: [Nodding] Uh huh.

>> SUSAN: Taylor, can you tell those who don't know what the acronyms are?

>> TAYLOR: The National Agricultural Library [NAL]. Part of the '85 amendments established within the NAL, the Animal Welfare Information Center, or AWIC, which served as a gathering of resources and today I know they cosponsor the 3Rs Symposium every year. They put out a ton of information that was very useful to IACUCs and others.

>> SUSAN: Thanks.

>> ERNIE: You know, being a professor (I guess I'm kind of like a former professor) I've always believed in the value of education. And I wonder what the panel thinks would be the best way for institutions to help educate their investigators and their IACUC members. I'm well aware of the fact that CITI [Collaborative Institutional Training Initiative] is a common program, as well as AALAS's program for education online. But is that really enough? Should we be doing more? And if so, what? What are some ideal educational ways to accomplish what we want to accomplish? For the entire panel.

>> TAYLOR: We took a little different approach at USC. We thought if we educated the next generation it would make life easier on all of us moving forward. And so, we had required courses for graduate students who used animals; [these] actually sprung up because the President and Vice President of the Graduate Student Council came to us to wanted to know, during the animal rights movement when it was being so vociferous at various types of big meetings, wanted to learn so they could respond and have a better feeling for it. And so, I think having required courses for graduate students takes it away from what Jerry was talking about where some poor graduate student is trying to figure out how to do something in their lab. That's one of the key takeaways. And we also had a graduate

student, a representative from the Graduate Student Council, on our IACUC from the get-go.

>> CAROLYN: Just a comment, Ernie, we are at five minutes before the break and Elizabeth Toby from AWIC also made a comment that they're around and happy to help everyone. They're updating their resources on their website and updating bibliographies and offer assistance in literature searches for alternatives. So, it's NAL.USDA.gov/AWIC.

>> ERNIE: Okay.

>> JERRY: Ernie, if I could make a brief comment? Clearly, educating the investigators and the members of the IACUC is important, but I think we also need to try to educate the investigators about the importance of explaining to the public, to their neighbors, to their friends, to their family, what they do and why they do it. We know about all the things that happened in the '80s and '90s that have changed somewhat, but if we look at what is happening to vaccines right now. Perhaps 80 million Americans, some of whom have very valid reasons for being afraid to get vaccinated, but an awful lot of them don't believe science, don't believe scientists. In 2018, the Pugh Research Center released a study basically saying that support of using animals in research in about 50/50. So, although we can do everything we can within our institutions, there is a huge, huge deficit in people understanding why animals are being used and how they're being used. And the number of investigators who are ashamed to even discuss with their family members what they're doing is really quite frightening.

>> ERNIE: Okay. We have exactly three minutes left. And I am going to pose a question to the panel. One of you can choose to answer, not all of you. We can't do it in -- now we have two minutes.

[Laughter]

>> ERNIE: Within two minutes, what do you think is the most important advancement that we should make to foster good animal welfare and good science within the next decade? One important advancement. Somebody choose to answer the question…. The clock is ticking. Now you've got a minute and a half.

>> TAYLOR: I think the key to animal welfare is the quality of the training of the front-line people who are taking care of the animals on a day-to-day basis. And I really think, you know, through the AALAS certification program, anything you can do to turn that into a career opportunity will in the long run benefit the animals.

>>Begin Break

>>SUSAN: Jerry, you know what I was thinking as you were talking, is that because IACUCs are organized and government-mandated and staffed, it is easy for institutions to add additional duties on to them. And that is not a criticism of universities, it is just an observation that everyone is trying to stretch a dollar and get more done. So, some of the burden that IACUCs turn around and impose on people have to do with dean's offices and chancellor's offices trying to make the best use of the resources they have.

>>JERRY: It can but in my experience, surprisingly few places allow that to happen.

>>SUSAN: Really?

>>JERRY: There have been some places where I have been consulting and suggested to them that these are 3 things that are not within your purview, not your responsibility; this is somebody else's job. But yeah, I didn't see a whole lot of that. You would think it would be there. Really what they do is not so much giving them more, they just don't [frequently] give them the staff that they need to actually meet the requirements as they exist now.

>>SUSAN: Because, [the] idea that an IACUC requiring full committee review of VVC, that kind of falls on us to educate them, and it falls on them to trust us with the education that we put out there.

>>JERRY: But it also falls on them. This was an interesting situation where the person pushing this was fairly high up and they weren't interested in listening to anybody else. There were several people there at the time all of whom were fully aware, and actually, some of them had worked with you folks as that was being developed. They didn't want to hear it. One of the things that always amazed me was that the number of times, when there is a situation like that where the IACUC it's almost painful for them to say, "Oh gosh, maybe we are wrong?".

>>SUSAN: Well, what they often say is, "We don't trust you guys." And you've heard me tell this story before where I told somebody at PRIM&R who asked me what does "advanced in writing" mean. I said it means before you do it, you have to have a policy written down and she said, "I don't believe you, and I don't trust you." I said, "I wrote it, that's what it means." But, that's a different

problem and needs a different solution. I mean somehow you have to tease out the problem and address it. And, the hardheadedness of human beings, that's a problem that's existed for a long time.

>>JOHN: I never fail to be (well I guess I am not surprised anymore) at the ability of people in our community to self-impose regulatory burdens on themselves.

>>TAYLOR: Amen.

>>NELSON: You're reading my mind, John.

>>SUSAN: And that's what, you know, ICARE is interested in.

>>End Break. It's time for us to start again.

>>ERNIE: We're a little bit over. Welcome back, everybody. We've moved on to section 8. It's "Impact In and On the Community." And let me clarify when we say "community" we're really talking about the research enterprise community, not the community at large. So, I'd like to ask John to respond to this question and then Nelson the next one. I'm altering the schedule just a little bit.

The '79 and '85 PHS Policies that required institutions and organizations to submit Animal Welfare Assurances for the first time – why was an Assurance even [required]? I can remember, and this was a painful process for me, and I certainly asked myself, "Why do I have to go through this?" So, John, perhaps you can enlighten me.

>> JOHN: First of all, I need to correct you. Animal Welfare Assurances were first required by the PHS in 1971.

>> TAYLOR: Correct.

>> ERNIE: '71? Okay.

>> JOHN: Believe it or not. And they essentially -- I'm not 100% sure of this, but pretty certain that all they required was— [well,] they didn't require a committee.

>> TAYLOR: But the *Guide* did.

>> JOHN: What did you say, Taylor?

>> TAYLOR: The 1972 *Guide* started requiring a committee.

>> JOHN: So, '71 was the first Assurances.

>> TAYLOR: That was within NIH, right? And that expanded to PHS later.

>> JOHN: Well, maybe. But it was all awardees. This all goes back to the origins of OPRR in the animal research grants area of NIH. So, the first requirements [for] Assurances were just a simple "you assure that you are taking good care of animals and you write it down and you send it in." There's an anecdote: Bill Robb, (I mentioned him before) Acting Director of NIH gave a ton of hearings in Congress and at one of those hearings he addressed the fact that that's how we, the NIH, deal with this issue of animals being appropriately used and treated in things that we fund, and it's through these Assurances. And the speech obviously had been written for him. So, he gets back to NIH and goes to Charlie and says, "You know, are we sure that these Assurances are doing – that they're working?" And so, at the point, there was one elderly lady (already elderly at that time in OPRR) who was responsible for Assurances, Helen Gordon.

>> TAYLOR: Helen Gordon. Yes.

>> JOHN: Charlie went to Helen Gordon and he said, "So tell me about these Assurances. How do we handle these Assurances?" And even at that time, it was probably well in the hundreds; I would guess, well in the hundreds. "How do we deal with them? She said "It's very simple. I receive them, I log them in, and I file them over there in that file cabinet." Charlie said, "Do you read them?" She said,"No. [I] receive them, log them, and file them."

[Laughter]

>> JOHN: That was when Charlie had his "Houston, we have a problem" moment. And from that time on, that was not how Assurances were handled, trust me. But they were and continue to be collegial, based on trust that the institution and research would actually do what they said they would do in their Assurance [and] that they would do it.

In 1983, a fellow named Lou Sibel (some of you remember Lou Sibel [who] led eight site visits through awardee institutions essentially to see if this Assurance program was working). And back to the AAALAC linkage— one of the ways that OPRR has always recognized AAALAC at the time was, back then, you had to have – the Assurance had to either describe in some very minor detail what you did, or if you were AAALAC accredited you just had to tell them you were AAALAC accredited and what [component]

of your organization was accredited. So, when Lou did his eight site visits, number one, I was amazed to see that NYU, and Washington University, were on the list because they were eight awardee institutions who were not AAALAC accredited in 1983. So AAALAC always got favored nation status at OPRR. After the '79 *Guide*, one of those *Guid*es, when I got there in '86, the -- we had to have all the '85 *Guide* and the '85 *Policy*, all brand new Assurances. And while they're not the size of AAALAC preparation documents, the program description, they are rather extensive.

And we had to review every one of them. [There] were three of us doing that, but we did it. We reviewed them, we contacted institutions to get explanations and corrections, and we actually did, in fact, have some more reason to believe that institutions were living up to what their Assurances said.

>> SUSAN: John, Jim Taylor just wrote in to us and said early on they only required animal care committees, not animal care and use committees.

>> JOHN: Right, and it was like three people had to be on it. And it was fairly, – fairly vague. It was the '85 policy that really specified that there had to be an outside member and veterinarian.

>> TAYLOR: Yes. It was just a one-pager at one time, your letter of Assurance. It was just a one-pager.

>> ERNIE: Okay. Thanks, John. I did come to appreciate the value of these Assurances, but not initially when I had to put them out.

[Laughter]

>> ERNIE: I want to turn to Nelson now. Could you talk about the linkage between the *NIH Grants Policy* and the *PHS Policy on Humane Care and Use of Laboratory Animals*? I think it's an important linkage. Could you give us some insight on that?

>> NELSON: I can start us off. I think this would be a good subject for further discussion and certainly would want to bring in Pat as well if she's willing to do that. I do think that there is a fundamental difference between regulation and a policy. And I think we've kind of touched on some of this before. It's not all that different from the difference between USDA's and OLAW's approach to oversight, in that one is fundamentally a law and there are [potential] civil and criminal penalties associated with it. The other is a condition of eligibility for funding. And again, that is – I think that's essential to understanding the different approach. PHS animal policy is an integral part of NIH and PHS Grants Policy, and I would go a step farther in saying that compliance with animal welfare standards really helps to guarantee the quality and reproducibility of the science.

And I think we can kind of expand on that a little bit. Getting back to Jerry and some of the issues that investigators might face, I remember being a little bit puzzled and maybe a little bit in disagreement with some of the charts or the posters that were big circulated at NIH in my time there where one of the posters showed a scale, a balance scale where you had science on one side and animal welfare on the other, and it was like maintain the balance.

And I'm thinking, you know, there's something wrong with that, at least in/from my perspective. The animal welfare component is really an essential part of sound science. And in eliminating variables in controlled studies, basically, you can't have one without the other. And so, I think in that sense it sort of amplifies what I was trying to get at earlier about agency quality control or quality assurance as part of the NIH grants research support program. I'd be interested in hearing other opinions, other comments on that.

>> ERNIE: Okay. Thanks, Nelson. I think we're really over now, so we're going to have to move on to the next section and then maybe cut some time back in a little bit later on this afternoon. So, I would like to take this opportunity to move it to section 9 and introduce Dr. Patricia Brown first, and then Dr. Betty Goldentyer second.

So, let me tell you a little about Pat Brown. She currently serves as the Director of OLAW. OLAW oversees the use of animals in all PHS Service, National Science Foundation, and NASA-supported research by providing guidance and interpretation of the PHS Policy. They also monitor compliance with the Policy, evaluate allegations or indications of noncompliance with federal animal welfare requirements, and support educational programs that further the humane care and use of research animals, and certainly, Pat, we certainly recognize the value of that support. We've talked about that earlier.

And our second panelist is Dr. Betty Goldentyer. Dr. Betty Goldentyer currently serves as USDA's Deputy Administrator for Animal Care – Animal Care's Deputy Administrator. Betty joined animal care in 1988, and over the next 30 years held a succession of important positions, culminating in her appointment as the Deputy Administrator in 2019. I think it's important to note that Betty leads USDA's response to the 21st Century CURES Act. This is an ongoing effort to reduce regulatory burden on scientific researchers while maintaining scientific integrity and humane animal use. So, welcome to both of you.

And the title is -- there's really no title. So, I'll go to the first question.

>> PAT: It's "Policy."

>> ERNIE: Okay. I see that. You're correct. We could have come up with a better title than that, okay.

[Laughter]

>> PAT: I didn't write it.

>> ERNIE Okay.

>> SUSAN: My fault. I like policy.

>> ERNIE: So here is the first question. How has -- this is for both of you. How has the IACUC evolved and what role did it play in implementing animal welfare policies and regulations, and in gaining investigator buy-in for improved animal welfare? Now we've already heard from Jerry and Taylor because they were back in the trenches: PI, IACUC chair, and lab animal vet. So, from the perspective of OLAW and Animal Care, what do you think about gaining investigator buy-in to improve animal welfare? Was it a tough row to hoe, so to speak?

>> BETTY: Thanks Ernie I'm going to start on this one and I feel like I was in the trenches back then, too [chuckles]. So, back in the late '80s, early '90s, I was inspecting, [over] in Taylor's neck of the woods. And I can tell you, you've heard a lot about how long it took, how many proposals. And this was so new to us. I had no idea at the time how this was going to work out. It wasn't what we as inspectors were used to doing at all. It wasn't anything that we were seeing in the institutions we were inspecting. And really, I feel like it could have gone other ways than what it did. I really credit you leaders on this panel and your colleagues. In my opinion, the IACUCs have evolved really into the centerpiece of a community-wide culture of animal welfare and compliance. And that is so important, because as Nelson said, it's vital for good science. It supports the research. But it's also inspectable. We can regulate it. And that's critical because we need credibility and public support for what we all do. So, I think really, the evolution of the IACUCs has been really extremely successful on both sides.

In USDA, we work with a lot of regulated communities that do not have any formalized system to manage welfare within their communities. And it's a completely different world. They don't have the kind of buy-in and sort of industry-wide support for continually improving and exceeding the minimum standards. And so it really is a tribute I think to the IACUCs and to the regulations that got us here. Pat?

>> ERNIE: Thank you, Betty. Pat?

>> PAT: Well, before I answer your question I just want to say how humbled I am to have these giants of animal welfare among us today and to hear first-hand their reflections on this history, and how our current system came about, and how it's evolved. I just want to thank you all for taking the time and for really putting your heart and soul into telling us where we all came from.

So, as John said, the PHS Policy has really stood the test of time. And it's remained pretty much unchanged concerning the responsibilities of the IACUCs. But over this time that I've had in OLAW, I've been able to really see the influential changes that have been driven from input from IACUCs as we have fine-tuned the information and the guidance that we provide to keep IACUCs operating effectively to maintain and improve the oversight of the research and also to engage the investigators. So I have just a few examples that I just wanted to put forward that kind of tie the past history to where we are now.

The first example is designated member review [DMR] subsequent to full committee review [FCR]. And we offered that idea back in 2009 because we had been observing in our review of Assurances from certain institutions that they had developed this process and they wanted to make sure what they were doing was okay. [We] reviewed it, and we said yes, this is fine; we need to share it with the rest of the community so that they can take advantage if they care to. And as you all know if you're involved with IACUCs now, DMR subsequent to FCR allows the IACUC to have a policy that allows the streamlining of the review process after the committee has met and wants changes made to a protocol

that they've just reviewed. So that whole process [as] I said, is meant to streamline it so the PI is getting that follow-up and that okay to proceed in a quicker timeline.

Another change that was spurred by comments we received from IACUCs and resulted in a joint notice between us and USDA was us officially acknowledging the use of alternate members. And in that guidance that we issued back in 2011, we provided details on the flexibilities for how to use alternates and the benefit of that was it not only ensured the continuity of IACUC functions and helping IACUCs to maintain a quorum; it also, from the PI standpoint, [helped it so] the protocols didn't get delayed because the committee meeting didn't happen because there wasn't enough members there. So that's just another one of the examples of when the 8th edition of the *Guide* came in. Well, there were a lot of new requirements in that *Guide*.

They did emphasize performance standards. But what we did see was there was a lot of concern about how much detail they had to follow. So that allowed us to get input from the community, from the IACUCs, before we required institutions to start using the *Guide*. And based on those comments then we proposed what the flexibilities were. That whole idea of performance standards for such things as housing and environmental enrichment and social housing. All of those, as I said, made the transition easier for programs and also hopefully continued to support the research.

And then the last one is the one that Jerry already mentioned, Veterinary Verification and Consultation. Again, we proposed guidance on significant changes to protocols. We put that out there and asked the community if what we were proposing was good or not. They came back, and came back with the idea that then, (Betty and I sitting across the table, similar to our previous colleagues that were talking) came up with the idea of Veterinary Verification and Consultation for IACUCs. That if they already had a policy, or standards for changes in anesthesia or certain kinds of changes to the protocol, that that could be a streamlined process using the veterinarian to confirm that the information in the protocol met the IACUC's policies.

So, as I said, all of those are just examples of how that cooperative process between the IACUC community and the regulators like OLAW can really end up benefiting the whole process and advance the whole efforts.

>> ERNIE: Okay. Thanks, Pat. Let me comment by complimenting you and OLAW, and Betty, and Animal Care. All of these policies that you developed like VVC, DMR subsequent to FCR, that certainly reduced the burden placed upon IACUCs and helped investigators immensely. And to go back to one of Jerry's comments, [I] would hope that institutions would avail themselves of these time-saving avenues to complete their reviews.

Also, I want to comment on, when I first began in 1985, I think the internet had barely been developed. I don't think that OLAW had a website, or OPRR had a website, not that I can remember. And there was no guidance.

>> NELSON: We didn't even have a fax machine.

[Laughter]

>> ERNIE: So consequently, you know, I'm in a situation where as you said, Pat, the PHS Policy hadn't changed. It stands – stood the, you know, time, okay, memorial. And I'm trying to figure out what does all of this stuff mean, and to try to develop some kind of guidance for our investigators. So, it's so much better now than it was then in terms of all of the guidance provided by OLAW and USDA.

>> SUSAN: Ernie, I think we have to include Carol Wigglesworth [among] the people that developed the Policy, because the superb quality of the writing was hers. The ideas came from many of you.

>> ERNIE: Yeah. That's true. Okay. I remember Carol very well.

>> SUSAN: So well-written.

>> ERNIE: Yes. Now, we've kind of moved into that second question about reducing or minimizing regulatory burden, so I'd like to change it if I may. I'd like to ask you to perhaps --

>> PAT: You're going to throw us a curveball.

>> ERNIE: Oh, I won't throw you a curveball. I never do that, Pat.

<<Laughter>>

>> PAT: Oh, no, you never do, do you, Ernie?

>> ERNIE: You know, the 21st Century Cures Act. I mentioned that Betty has you know, taken

the lead in Animal Care to, you know, to try to move that through government. Can you all comment on that?

>> PAT: Sure. So, I just want to give a little bit earlier history because I want to give credit to Susan Silk because she was the brainchild back in 2015 to come up with the idea of the ICARE project and the whole mission of the ICARE training workshops that we have for IACUCs is to not only improve animal welfare and compliance with the federal requirements but to minimize regulatory burden to researchers. And that was, we were/she was going through that process well before the law got passed that required us to do the harmonization that we did. So, I really want to, as I said, call out Susan for recognizing that and implementing the activities that we as OLAW and Betty and Carol Clarke and others that were from USDA grabbed onto and said, "Yes, let's do this. Let's move this forward." And then we've had six other federal agencies that are all part of the ICARE project and providing support to it, and in some cases also providing faculty to the program.

But back to the 21st Century Cures Act. So, as anyone who has been around the last few years knows, we were required by Congress to harmonize [and] make revisions to reduce burden on investigators while maintaining the integrity and credibility of research findings and the production of research animals. So, it has been a balancing act, in that we have to look at what can we do to look for refinements, where are our flexibilities that are already built into the regulations, where can (as Betty will tell you) [they] change the regulations to harmonize with some of the requirements that NIH has. So, we are currently at the point where we released our report back in 2019, following listening sessions and repeated input from the IACUC community and the public. That report has a laundry list of actions that we're now taking. We're working on continuing to work on the policy guidance for a number of different topics and as you can see, every single time we do this we have a -- currently we've been having 90-day comment periods to get your input from the IACUCS, from the animal programs about what we're proposing, as I said, to enhance what you do and also to give more flexibility to the scientists have less burden.

>> ERNIE: Okay. Thank you. All right, Betty?

>> BETTY: Okay. On the Cures Act, I first want to [give] tons of credit to Pat. She has really been the lead over the whole thing and just done an amazing amount of work. I got a little tied up with Tiger King and she just stepped right in and took care of everything so it's been great working with her. I think we've made [really] good progress and accomplished a lot. And it's kind of like a model for how to go after regulatory burden. Like, it's not easy, because you know the public has these expectations and they keep moving the target on you. They want you to do more and more and more. And it's awfully hard to get rid of a regulation. It's a lot easier to add on to already all the regulations we have. But I think the Cures Act, just the working group worked really well together and you have to just go at it kind of with the idea of, you know, where is the unnecessary burden. You can't sit down with each other and find those unnecessary burdens and find those places where you can harmonize unless you have a really good professional working relationship. And so [we] are lucky that you all started this, working this closely together so we could just follow in and then we can get to some of these burden issues.

>> ERNIE: Okay. Great. Thanks very much. I appreciate that.

>> SUSAN: Ernie, we have a comment from Steve Niemi– thank you, Steve—, about burden. So this is a good time to read it. There's a related question to self-imposed regulatory burden. Despite the oft-mentioned concept of performance standards on this agenda and by this panel, why are we still so beholden to engineering standards and the inefficiency and obsolescence they sustain? This applies across the entire spectrum of U.S. institutions, U.S. regulators, and accreditation.

>> ERNIE: Good question, Steve. Anybody on the panel want to respond?

>> PAT: I will just say the 8th edition of the *Guide* opened the door for performance standards at the local level. And I would – too bad we don't have someone here from AAALAC to talk about that, too, unless any of you that are still actively involved with AAALAC could comment— that they also are focused on performance standards at the local level when they're doing site visits. And we are, too, when we do site visits, although we haven't done any in this last period because of the pandemic.

>> BETTY: I can maybe add that, you know, we read a lot of comments that come in on different regulatory proposals. And there's just a lot of pressure to have minimum standards, like engineering standards. The public wants to be able to look at what we do and make sure, you know, we are holding regulated entities to these minimum standards. So, I think [what] we have now is a balance,

and that might be partly because that is what the public needs to have confidence in the regulators.

>> RON: I suspect that you also have some institutions who simply want to know black and white, tell me what to do and I'll do it. Where it takes more ingenuity to develop and implement performance standards. Some institutions are kind of minimalist, and just say tell me what to do and I'll do it.

>> TAYLOR: Yeah, it's kind of interesting. You take a group of assistant professors, professors, associate professors who will fight to the death for academic freedom, and put them on a regulatory committee, and they want everything in black and white, a checkbox approach. It just makes life easier. John's laughing but I mean, some of these IACUCs just go crazy. [Laughter]

>> You're muted, John.

>> ERNIE: I had a very senior investigator who had his protocol tabled, and I met with him after it was tabled I think three times. And he said, "All right, tell me what to put in. Whatever you want, dictate it to me. I'll put it in there." I really didn't have any confidence that he would follow any of those directions.

>> PAT: Could you read – could you read Jim Taylor's comments about AAALAC since he is a long-standing AAALAC emeritus?

>> JERRY: He says, "AAALAC absolutely supports and embraces performance standards and the use of site-specific evaluations that validate the performance standard is meeting the 'requirements' or needs of the procedure practice seeking positive results that satisfy animal welfare needs."

>>PAT: And that's what we would argue; that's exactly what we would expect too. That's a very well-written way to say it. Yes.

>>ERNIE: Absolutely.

>> ERNIE: Okay. I think we all agree with that. So, let's move on to section 10. We are going to go until about 5:25. And this is kind of like unstructured storytelling, comments, and discussion among participants. You all know one another very well. You have interacted with one another over the years. I would assume that you have stories that you would like to tell that are interesting; that are funny. Please do so.

>> JOHN: One of the points that I didn't get to make (that I would like to) is that I mentioned the meeting between the USDA higher-level person and the HHS higher-level person. And the fact that that was the turning point when the USDA Undersecretary told the OGC [Office of General Counsel]: "Don't impede progress here."

On the way, -- I got to that meeting by riding with the Acting Director of NIH, Bill Robb, at the time, in his car. It wasn't a limousine, it was a big black sedan. And it had one of the very first (this is dating how old many of us here), it had one of the very earliest car phones, which for those of you who don't remember was a gigantic box sitting in the front with this big brick. I mean, it was in fact the size of a brick. That was the phone. Driving back from that meeting, talking to Dr. Rob, the phone rang. He answered it, and he said, "Here, John, it's for you. It's Jim Mason" who was the assistant secretary for health. And so I took the call. [The] important thing about that is that it demonstrated to me that what I was doing was being noticed, and more importantly, that I really – I had – OPRR had -- we had the support of the highest level of HHS in doing what we were doing. He also called me at home one time and I had to have him hold on because I had to go get the dogs back in.

[Laughter]

>> NELSON: Talking about regulatory burden, I would like to take this opportunity to claim full credit for why we don't have to have air conditioners built into our armpits. In reviewing the regulations early on, I was the one that picked up the probable typo that was requiring axillary ventilation for outdoor housing facilities. And so I changed that to auxiliary. And as a result of that, we have prevented a huge burden.

>> JOHN: I remember that. I remember that. Yep.

>> ERNIE: Nelson, do you remember the time that you called me up and you said you know, I've got a problem with your -- how you hand me your case studies. You are inciting noncompliance and I need to talk to you about it. Remember that?

>> NELSON: Which time was that, Ernie?

>> PAT: Every time you were at SCAW with him.

>> ERNIE: And I was on my way to D.C. I think you called me in the airport and I said, “Okay, Nelson, I'm coming to D.C. I'll meet you at…” it was OPRR, then. I think. And we promised to talk about it and I promised to be good and to not ever again, okay, incite noncompliance. Do you remember that?

>> NELSON: Bless you, my son.

[Laughter]

>> SUSAN: Ernie, when I first took my job at OLAW, Nelson said to me, “Those are really good guys but you've got to hit them upside the head every now and then.” That was good advice, Nelson.

>> NELSON: That goes back to the real reason that John hired me in the first place. Which was, he knew a lot about my background and being an old farm boy himself, he picked up on the fact that I had successfully interacted with mules for a long period of time. And that was the qualification that got me hired into OPRR.

>> JOHN: Absolutely correct.

>> SUSAN: We have a comment here from Barbara Williams and she says, “This has been so interesting. I remember from the olden days that…” sorry, guys. She called it the olden days “…that OPRR started as the Institutional Review Branch in the Division of Research grants, now CSR [Center for Scientific Review]. That office was transferred to the OD [Office of the Director] at OPRR. The director was Dr. Don Chalky. Dr. McCarthy was appointed director of OPRR when Dr. Chalky retired.

>> JOHN: She is correct.

>> JOHN: It was actually, at one point, called the Institutional Relations Branch, or office or something like that. I found the names to be fascinating as I went back through and saw what they were called back when they meant simple things. Office for Protection for Research Risks. They kind of muddied it up a little bit there. We all know now what it means but I imagine people were scratching their heads about what in the world they were talking about.

>> ERNIE: I'll tell you a quick story about Charlie McCarthy. He told me one of his first assignments when he moved to Washington and became laicized was given to him by his boss. Apparently, his boss, and I don’t know who he was, walked into his office with a big box filled with documents and he said, “Charlie, I want you to write the government's defense.” Well, in that box were the documents pertaining to the syphilis study— the Tuskegee syphilis study. So, Charlie, according to what he told me, he spent about a week or ten days and he read them all. And then he wrote a one-line response and took it to his boss. And the one-line response was, and I quote, “There is no defense.”

[Laughter]

>> TAYLOR: In the beginning of this Carolyn was talking about how we go back a ways. Well, I met Betty and I think it would be right after you started with the USDA. I was asked to give a talk on the new amendment at the Wisconsin AALAS meeting. And I have a copy of the federal register with her name and number I wrote, took down that night, sitting over here in my file cabinet, though the paper is a lot yellower than it was when I first wrote it down.

>> BETTY: What's really funny about that is we weren't very good about communicating in animal care in those days. I didn’t have a copy – I hadn’t seen it. Taylor let me look at his copy.

[Laughter]

>> ERNIE: Taylor, I bet you've never thrown any papers away in your life.

>> TAYLOR: Yeah, I have. I do have going back to the original Animal Welfare Act and all that in my files plus all the NIH documents. Every once in a while one of these regulatory agencies tries to sneak something by you so you have to go back to the original files and see what they actually said. [Laughter]

>> JOHN: Taylor, did you ever meet Bennett Cohen?

>> TAYLOR: Oh Yeah. Remember, he was -- Bennett was at Northwestern before he went to Michigan.

>> JOHN: For those of you who don’t know, Bennett Cohen was actually the grandfather, the original god of laboratory animal care and use as we know it. He started the small group of eight, five, veterinarians?

>> TAYLOR: Four in Chicago. And he and Bob Flynn -- I worked with Bob and Nate Brewer, Ella Hue Bond, who was actually the director at the facility I ended up directing. So, it's a small world.

>> JOHN: I am so honored. I have AAALAC's Bennett Cohen award back here just out of view. But my Ben Cohen story is [this]: A brand new diplomat in the American College of Laboratory Animal

Medicine, 1979, I went to my first AALAS meeting and ended up sharing a hotel room with Ben Cohen. That was fascinating to begin with. What I remember most, is that although I grew up on a dairy farm, I never liked early mornings.

[Laughter]

>> JOHN: Early one morning, [I heard] this funny sound coming from the floor on the other side of the other bed in the room. I raised up and looked over and there was Ben Cohen. I don't know how old he was at the time. But he was doing his morning 100 pushups before he got up.

>> TAYLOR: He and Nate Brewer.

>> ERNIE: Are you all out of stories?

>> PAT: I have a story.

>> ERNIE: Go ahead.

>> PAT: Okay. So, I was doing my lab animal medicine training at Hershey Medical Center under C. Max Lang. Yes. Paid for by the U.S. Air Force, I'll have you know. And they were talking about well, there were going to be these changes in how institutions got money from the government, from NIH, because of course back then, Hershey was one of the grantees.

And I just thought, "Well, why don't you just make everybody get AAALAC accredited if they want to get the money?" That was the very juvenile thought that I had was, isn't that easy? Because, of course, Hershey was AAALAC accredited and they had a very good program. But that just goes to show you (that did get incorporated into the plan) [that] people— institutions– that were AAALAC accredited are on a different level of oversight in terms of the information they provide and the Assurance agreement. So. I wasn't quite right, but at least it was going in the right direction.

>> NELSON: Good idea.

>> JOHN: In the first -- the process of reviewing all those Assurances that came in subsequent to the '85 revisions, because they all came in at once, there was no -- whoever got -- they rolled in. In they came. Every day there was another stack of them. And so very early on they made the determination that the AAALAC-accredited institutions, organizations, would automatically go to the end of the line. They would be reviewed last. We would go through the rest and get them approved before we did the AAALAC-accredited. So there has been recognition from OPRR for a long time that AAALAC accreditation means something.

>> PAT: I did -- before we were getting ready for this, I started looking through the history and it looks like even in the earlier versions of the Assurance, just the NIH Assurance agreement, indicating you were AAALAC-accredited was one of the ways that you could provide information in the early, very short versions of the Assurance agreement. I guess probably in '73 or '79 version, I think.

>> TAYLOR: That's true. I remember.

>> SUSAN: John, you have a message from Monte Matthews. He says, 'Wasn't the effort for OPRR and USDA working together to harmonize the policies and regulations under the broader Congressional directive to reduce regulatory burden under the Reagan administration?" And here we are again, Pat.

>> JOHN: The harmonization was directed by the USDA legislation.

>> TAYLOR: Yeah. It was in the Animal Welfare Act.

>> JOHN: I don't think it was in the Animal Welfare Act. I'm sorry, I think – It was -- you're right.

>> NELSON: The consultation requirement.

>> TAYLOR: Yes.

>> JOHN: Because the PHS Policy came into effect like 60 days, days before the USDA regulations, before the Farm Act, the changes to USDA in '85.

>> SUSAN: Was all that during Reagan?

>> JOHN: PHS policy proceeded it. The harmonization was required by statute. That was during the Reagan administration. And the Reagan and Bush years had a really heavy focus on reducing regulatory burden. Bush headed a task force under Reagan and then subsequently Quail headed a similar group under Bush whose main emphasis was to ferret out undue regulations. The office that did that was the Office of Management and Budget. They have one level down from the top is the Office of Information and Regulatory Affairs.

The head of that organization was a bona fide character. I suspect he was a Presidential appointee given as high up in the organization as he was. But he was absolutely rabid about

performance standards and reducing regulatory burden. And every time USDA had to provide a new set of proposals based on the comments they got in Dale and my harmonization efforts, every time they did that they had to do a new (it was essentially a cost-benefit analysis) economic impact analysis every time. That was clearly a part of it. I would have loved to have been in the room. When I met with this guy, I really wish I could remember his name. It was just he and I but he also had those meetings with Dale or somebody from USDA. I would have loved to be in the room when he was talking to them. He and I – it was like good old boys talking about yep, we agree. We agree. We agree. I doubt that was the case when the USDA person was there.

>> TAYLOR: It's interesting that it wasn't brought up, though I noticed that you sent out a notice of the meeting ten years ago celebrating the 25th anniversary. But the 1984 NIH symposium on the properties of animals, there's a meeting at the National Academy, [that] kicked all of this off where the investigators were there, the folks from the protection agencies were there, and it set a tone that you had to be there to appreciate.

>> SUSAN: That is -- we're closing in on the end of our time together. And I want to mention that we had a symposium in 2010. It seems like it was a long time ago and it also seems like it was yesterday—25 years of animal welfare and scientific research. You can find a link to transcripts from that very interesting meeting. Many of the same speakers are here today; some are no longer with us. Those are interesting and wonderful stories, and I recommend that if you enjoyed this that you go to OLAW's website (I think it's in the education section, right, Pat?) and you can find those transcripts. I also want to say we've had some inquiries on the chat line. Thank you all for what you contributed to the chat line. If you need and want a certificate, if you can write to Erin or to me we'll arrange to get you a certificate of participation. We're not going to send them out wholesale because so many of you don't need them.

And then I just want to say what an enjoyable and wonderful afternoon this has been for me. It makes me remember how much I've missed all of you.

>> NELSON: [cows mooing in background] It's dinnertime on the farm.

>> I was going to say.

[Laughter]

>> That's an interesting way to end it.

[Laughter]

>> SUSAN: Thank you to all the panelists for all the time that you put into this. We had meetings. We planned and we discussed. So, they gave us a lot of time, and we appreciate all you've done for us in the past and all you've done for us today. And we hope that the coming generations behind us will come to understand some of the work that we did, and they did, and why we all did it, and that you will carry on in the tradition that these fine leaders have started. So, I'd like to invite (and Mary Lou James has put the link in the chat for the 25th-anniversary symposium)— if you click on that right now while it's up on your screen, it will load onto your computer. And then when you sign off you'll have it. So, Jim Taylor says it brought back many, many memories.

We're getting so many nice thank yous and comments. So, I would like to invite the participants to go ahead and log off. And if the panelists would like to just stay for another minute, that would be great. I was looking at all these things coming in. You've got a lot of fans out there. We should make baseball cards. Thank you for joining us, and from all of the ICARE faculty, thank you.

[End of Session, 4:30 p.m. CT]