

Comments by NCTR Leadership on the Occasion of the FDA Centennial

Acting Director's Comments:

William Slikker, Ph.D. (2005-present)

A Successful Past and a Promising Future



Have you ever stopped to think how lucky we are? NCTR researchers, both contractor and federal, continue to benefit from the excellent facilities, the synergy of the energetic and talented staff, and the financial advantage of government or equivalent salaries in the beautiful land of opportunity here in Arkansas. As we celebrate the 35th Anniversary of this great institution, we need to appreciate the opportunities before us and the challenges that have been met, time and time again, by our excellent scientists.

Excellence in research is the key to our past successes and promise of the future. Behind each scientific achievement is the resourcefulness and brilliance of our researchers. Our ability to lead the scientific revolution in the application and integration of the post genomic world with traditional toxicological endpoints continues to provide our competitive advantage.

Supporting our researchers are the highly technical and efficient research facilities. With over 700,000 sq. ft. of prime laboratory space and many special purpose structures, including the Phototoxicology and Testing Facility, the Nonhuman Primate Research Facility, and the Biosafety Level 3 laboratories, NCTR is a model toxicological research center. In fact, NCTR's facilities and organizational structure have served as a model for the development of a

toxicological research center in South Korea and continues as the premier toxicological research center in America.

Over the years NCTR has also benefited from the enthusiastic support from the local Jefferson and Pine Bluff Arsenal community, the Pine Bluff Alliance, and the local, state, and national political figures. The high degree of interaction with the colleges and universities, within the state of Arkansas, has been critical to the success of many research endeavors. The rural setting has been a blessing for the laboratory research efforts of our scientists, and the comfort of the piney woods and unlimited parking has always been appreciated.

It is the excellence in science and the cutting-edge research that is the real heart and soul of NCTR. The achievements are too numerous to list here (see our [website](#)), but suffice it to say that when it comes to toxicology, NCTR scientist have provided leadership time and time again. It is this cooperative spirit, the willingness to form teams of researchers with diverse but complementary training and experience to solve toxicological problems that sets NCTR apart from other institutions.

So as we look back on our 35 years of research accomplishments, let us congratulate our fellow scientists and enjoy the fruits of our labors. The history of NCTR has set the stage for the integration of the new biology with traditional endpoints and paved the way to a promising future. We are posed on the threshold of providing personalized nutrition and medicine to the American public, and NCTR scientists are ready and able to lead this endeavor to enhanced public health.

Director's Comments: Daniel A. Casciano, Ph.D. (1999-2005)



I guess my tenure as Director was more accidental than intended because I decided only after I was Acting Director for seven months that I wanted to lead this institute. I initially was interested in the Deputy Director for Research position because I felt that I could influence the use of molecular tools in the various toxicological disciplines that make up this Center, and because I felt that I had accomplished the goals I had set as Director of the Division of Genetic and Reproductive Toxicology. Little did I know that Bern Schwetz would leave one month after I was selected in that position. Jane Henney was the Commissioner at that time, and she required that principals be present at the weekly headquarters staff meetings. Consequently, for approximately two years, I was traveling to Parklawn weekly, representing the NCTR, and becoming familiar with the mission of the FDA and the rest of the centers. These interactions were extremely valuable because I was able to determine the future scientific directions that the NCTR should be engaged in to support these missions. Additionally, I had the great pleasure of working with some highly skilled and dedicated individuals whose prime motivation was promoting and protecting the public health. This dedication became more evident after September 11, 2001. The entire leadership of the Agency came together to convert chaos into order.

It was essential for us to integrate the new technologies with the traditional toxicological tools we had been developing and validating mainly for preclinical studies. It became evident to me that these emerging technologies finally provided us with the means to determine the relevance of the rodent surrogate bioassays we had been using because they were applicable to evaluating the human. I felt if these surrogates were not as predictive as we'd like, these new tools would help guide us in the development of new surrogates. We finally could become major players in understanding toxicology in humans and assist the FDA in designing more meaningful clinical studies. To accomplish this, we needed to build an infrastructure that could support the development of methodology in genomics, proteomics, metabolomics, and bioinformatics. Using supplemental funds, the infrastructure was developed and recruitment of trained staff was begun.

We were extremely fortunate to be able to recruit highly talented individuals to lead in these specific areas. This was due to our international reputation in the toxicological community and the infrastructure we had in place. In order to be successful, we needed a strong computer science and informatics staff to help us translate the myriads of data produced using these technologies into biological significance. Fortunately we had statisticians in Biometry interested in the challenge, and we had in place a skilled computational science staff that were well hidden under the veil of the Endocrine Disruptor Knowledge Base. I think that the most important contribution of my administrative career, in my opinion, was the recognition that systems toxicology was the next discipline that needed to be integrated into the fabric of the NCTR.

Director's Comments: Bernard H. Schwetz, D.V.M., Ph.D. (1993-1999)



Friends of the NCTR,

During this 35th anniversary year of NCTR and the 100th anniversary year of the FDA, I am pleased to share my thoughts about the Center during the years that I was the Director, 1993 to 1999. Let me declare my bias up front—I have said often that being the Director of NCTR was the best job I've had. I am grateful that Dr. Jane Henney selected me as the Director even though she later asked me to leave the Center to help her in the Office of the Commissioner while she was the head of the Agency.

Why was it the best job? Lots of things came together for me and NCTR. Art Norris, Ron Coene, and Pete Attwood were the best management team that any Director could ask for—the best that I've ever worked with. With Dave Gaylor added to the team, we were even better able to handle scientific issues as well as the personnel, budget, and facility issues in a way that was good for everyone. We reconnected NCTR to the FDA. Without that stronger tie, I am not sure that NCTR would have survived the tough financial years that followed. During those lean years, we reached a peak of support and involvement with NIEHS/NTP that allowed us to be more fiscally independent and at the same time created the opportunity to work on some very important projects. One example was the capability of conducting phototoxicity studies in large numbers of animals. This remains a unique and significant resource for conducting studies of great importance to Americans. The studies, conducted with the support of NIEHS/NTP, examined drugs, cosmetics, environmental chemicals, and contaminants of food and beverages, studies that are seminal to risk assessment throughout the world.

Bringing ORA on site and changing the name to the Jefferson Laboratories of the FDA was a large step forward, one that reinforced that NCTR was really part of the FDA. In response to concern over chemicals in the environment that had estrogenic or other hormonal activities, we developed capabilities for computational biology techniques that set the stage for NCTR to be a

leader in the “-omics”. That area of research has come to be a particular strength of the Center and a magnet for attracting young scientists from all over the world.

If this was such a good job, why didn't I stay? Beyond the change at Dr. Henney's request, in my opinion directors of research laboratories should turn over every five to six years. The science changes so rapidly these days that it takes new leadership to keep an organization out in front. My years in “the corner office” were good years for the Center and were certainly good years for me personally. Thanks to all of you who helped to make that true.

Acting Director's Comments: Arthur R. Norris (1991 – 1992)



I offer these recollections for the short period of time that I was Acting Director of the Center. Not only was it a short period, about two years, it was nearly 15 years ago. Memory fails in general, and memory fails specifically in trying to single out that short period of the 18 years I was privileged to be a part of NCTR.

It was quite a surprise to suddenly be in the position of Acting Director. It wasn't anything I saw coming, and it seemed more like a continuation of what we were all doing as a group than anything enormously different. The privilege of working more closely with FDA leadership under Dr. Kessler was rewarding, and reporting to Dr. Henney as FDA's Chief Operating Officer was a singular privilege. She was a strong supporter of the Center and its people.

The most memorable event was the fact that FDA's first Science Advisory Board issued a report on science in FDA. It was quite complementary of the science, the staff, and the productivity at NCTR, but there was a powerful statement that seemed at the time to turn our world on end. It said that although the science was very good, unless the work at NCTR could be made more relevant to the regulatory mission of FDA, NCTR should no longer exist as a part of the FDA.

The response by the scientific staff, especially the division directors, was immediate and powerful. Many of you spent much more energy traveling to the

D.C. area and interacting with other FDA centers and other FDA scientists. In very large part, it was a matter of letting the others know, in more detail, about your work. It was also a matter of seeking their collaboration in design and conduct, not just within FDA, but also strengthening the relationship with the National Institute of Environmental Health Sciences and the National Toxicology Program. So many names and faces of people who did so much for the Center are firmly in my mind. There's no way I could start to list them individually. There would be no logical stopping point. There was a common devotion to preserving the Center that prevailed

over and over. In my view, those efforts were successful in changing many attitudes; in letting others in the Agency know of NCTR's contributions and in paving the way for the fresh, new leadership brought to us by Dr. Bern Schwetz.

I also remember fondly some of the nondivision director leaders. You were the people who raised voices for those whose voices were too often not heard. Your passion, your concerns, and your abilities continue to impress me. The contractor staffs who so strongly identified and adopted the NCTR mission as their own were always inspiring to me. It was a time of new energy and talent in the area of the information management contract, thanks primarily to Dr. John Young's vision and oversight.

I suppose, as I look back, my over-riding set of feelings are those of gratitude—gratitude for the opportunity to have been a part of this group of people and what they have accomplished...gratitude for being able to learn so much in the process of earning a living...gratitude for knowing so many of you. I thank all of those who made this possible: Dr. Hart for selecting and supporting me and, most definitely, the NCTR government and contractor staff who made the experience so valuable and made such a profound difference in my life. I don't believe there was ever a day when I didn't learn something and gain insight from those of you who were and are NCTR. It was a unique privilege for which I always shall be enormously grateful.

Director's Comments: Ronald W. Hart, Ph.D. (1980 – 1992)



I arrived in Arkansas during the heat wave of 1980. For over 45 days in a row the temperature exceeded 100 degrees each day without a drop of rain. The Center had a combined budget from EPA and FDA of less than six million dollars, and the EPA had just announced that based on the negative report from the National Academy of Sciences and the failure of the Center to meet the expectations of the EPA, it would be withdrawing its financial support. Only approximately 35,000 square feet of the Center's potential space had been renovated, with many areas lit by bare bulbs, having roof leakages and scorpions running across the floor. On top of all this, Mr. Myers, then Deputy Commissioner of the FDA, called me to Washington and informed me that it was his belief that if the Center could not be turned around within the next two years it would have to be closed. Emergency action had to be taken.

First, it was imperative to establish support for the Center within the FDA, the USPHS, and the DHHS. Despite the observation that the administration was about to change from Democratic to Republican, it was obvious that the senior Civil Service personnel would not change. Based upon this observation I recruited the support of key senior administrators in helping to create a new administrative staff for the Center, thus establishing the connections needed between the Center and Washington. With a new Washington-trained staff in hand, the next step was to significantly alter the perception of the top-level decision makers in the FDA and other agencies relative to the Center and its productivity.

The Scientific Division Directors were informed they had to be responsible to their customer base, and that this had to be done in a fashion that could be documented. Productivity indicators, both qualitative and quantitative, had to be established for scientific productivity, and these would form the basis of each employee's performance review. The Division Directors in charge of support services were charged with reducing overhead costs, while maintaining product quality. It was further stressed that their employment reviews would be based in part upon the feedback from the scientific staff and in part based upon documented reductions in overhead costs. The managerial staff directors were informed by the newly recruited senior managers that

they would be required to ensure that the plethora of changes were smoothly carried out and documented.

The successful implementation of the above goals led to the Center's recognition by a number of federal review groups and private professional organizations thereby permitting the next step in organizational development to take place—the national and international recognition of the Center as a whole vs. recognitions of the expertise of one or two key members of the scientific and engineering staff.

Local and national outreach programs were established with a number of historically black colleges and institutions, international training programs were established with various nations including Taiwan, the Peoples Republic of China, the (then) USSR, Egypt, and others. Scientific staff was identified and recommended by management to serve on a number of departmental and interdepartmental committees, task forces, etc. Housing was established to aid in the implementation of these programs and scientific programs and facilities expanded.

Local programs with various colleges, universities, and state organizations were initiated leading to a minority program in regulatory sciences at UAPB, the creation of the Arkansas Science and Technology Authority, and creation of the Arkansas School for Mathematics, Science and the Arts. With the support of local and state-wide elected officials, the budget of the Center was rapidly expanded leading to the renovation of several hundreds of thousands of square feet of additional facilities and several millions of dollars in operating budget at a time when other regulatory agencies were either being reduced in size, scope, and budget or eliminated altogether. These activities placed the Center and its staff on a solid footing to succeed. In 1992 with the advent of a new Commission and facing certain personal issues, I was appointed Distinguished Scientist in Residence and resumed my studies on the role of nutrition and diet in degenerative disease processes including cancer and aging. Out of these programs, thanks to a really great group of associates, several hundred peer-reviewed publications, scientific presentations, a number of patents, and millions of dollars of research support from NIH were transferred to the FDA and in particular the NCTR, thereby further strengthening the Center and its reputation. I retired in 2000 after twenty years of government service.

Director's Comments: Thomas Cairns, Ph.D. (1977-1981)
The NCTR Directorship "A Wonderful and Glorious Burden"



Dear FDA Colleagues: As we prepare to celebrate the 35th anniversary of NCTR and the 100th anniversary of the FDA, I am proud to have been a part of your history. In the late 1970s my arrival at the gates of NCTR with the then FDA Commissioner, Donald Kennedy, to assume the leadership role was not exactly under the best of times. Looking back on those early years during the infancy of the Center stimulated me into a deep reflective and retrospective mood obviously recalling the achievements of the past, but much more the maturity the Center has achieved on the present-day global scientific stage of toxicology in the service of humanity.

It is the very essence of our human emotions to perform this mental task weighing achievements with assignments as yet not accomplished, for the true definition of legacy is those tasks yet to be performed. Directors are capably supported by a team of scientists who perform the fundamental tasks of research and promote advancements in our understanding of toxicology. For without them the burden of office would have been tremendously complicated. To the scientists who served during my tenure as Director to help build the Center into the fine scientific institution it is today, I offer my sincere appreciation to all you have accomplished for the FDA in the last 35 years.

As you all know, it is somewhat difficult to be self critical. Above all else, the basic decree, inferred in the oath of office, is "to faithfully execute the duties of the Office of Director". This honorable vow still reverberates within my mind these some 30 years later. During the five years that ensued there were many moments of disappointment brought about by cynicism and pessimism. But an NCTR Director must overcome such difficulties often in the face of adversity and always look forward. Patience under adversity is a demanded quality for a Director. I found that instant action was rarely ever successful. It was far better to ponder the issues, then respond. But some decisions did bring a feeling of achievement.

In many respects the NCTR Director becomes the Center in the eyes of the scientific community. Your behavior is largely controlled as indicative of the consensus of the Center controlling your every action and the effectiveness of your delivery of speeches. Words by themselves are not persuasive without the accompanying logic and understanding. Directors are molded by the burden of responsibility and must possess that rare commodity, that of being of a facilitator not an autocrat. For leadership is the art of guiding and maintaining consensus without strong dissent or the unsavory consequences of politics. All these concepts I struggled with during my term. I leave the task of judging performance to future historians.

As the second NCTR Director, I have taken a historical look back in time to honor your former Directors. This honorable list contains the great names of our past history, triumphs, glories, and most of all your rise to current day status. Each of them has, with their personal wisdom, added substantially to the NCTR collective strength. Each represented your accumulation of will power to improve and measure your tenacity to survive in an ever increasingly complicated and complex world. They have been triumphant. To learn from the past is honorable, but to succeed in the future requires a competitive mind and a willingness to try new ideas, to adapt to changes, to use new technology, and most of all to use people skills to the benefit of the FDA.

The responsibilities of NCTR Director I have characterized as a glorious burden. Let me briefly relate a little of the glory part. While in office I had many cherished memories - ED01 Study, NTP, Peer Review, Mass Spectrometry Laboratory, Science Council, EPA Cooperation, the Monkey Colony, etc. But the most honored memory of all is the progress and maturity of the many fine young scientists who have dedicated themselves to the NCTR and, in the process, making outstanding professional careers featuring the core sciences conducted at NCTR. These achievements have pleased me so much in the last 30 years as I watch their growth and success. As a lover of Gilbert & Sullivan, I remember a lyric that goes "If in this world you wish to success, you must shout it and stomp it and blow your own trumpet".

All of these events have had a significant effect on the stature of NCTR on both a national and international level. They provide synergistic evidence of FDA's commitment as custodian of the public health. Many perceptions wash through my mind at this time as I recollect my years with passion and pride in a scientific institution I have always admired and supported. Memories last a lifetime, and I have an ample supply to dwell upon in future years.

And so, my fellow FDA scientists, as we embark on the 35th anniversary, I have enjoyed this brief recollection of my wonderful years at Jefferson. Your invitation to allow me relive the pride of tenure as NCTR Director has been a rewarding process for which I am grateful and pleased. The burden of responsibility was a wonderful experience and a glorious feeling of achievement.

Director's Comments: Morris Cranmer, Ph.D. (1971-1977)



In 1969, President Nixon banned the United States' participation in the production, storage, or use of biological weapons for military purposes. Early in 1970, the Biological Operations function of the Pine Bluff Arsenal became available for reassignment. Two of the driving forces behind the continued use of the facilities were Senator John McClellan, Chairman of the Senate Appropriations Committee and Congressman Wilbur Mills, Chair of the House Ways and Means Committee. There were several steps that needed to be accomplished to provide the facility. It needed to be demilitarized, transferred from the Department of Defense, and provide jobs for the previously employed workers.

My involvement with the idea of a sword-to-plowshares opportunity began in 1970. The Office of Management and Budget (OMB) had organized a team of scientists and administrators from various departments to organize a research and development plan for the newly established Environmental Protection Agency (EPA), and I was privileged to serve as the leader of the Health Effects Task Force. It was the activities of that task force that determined the research needs that were to become NCTR's mission.

The early OMB concept was that NCTR would be funded as a dual project between the EPA and the FDA with input from the National Cancer Institute (NCI). A policy board was formed consisting of scientists and administrators from these agencies, OMB, and myself as chair. Early on it was determined that one agency should have the administrative responsibility. Dr. Charles Edwards, then FDA Commissioner and later Assistant Secretary for Health of the Department of Health, Education and Welfare (DHEW), asked if I would accept the job as the first director of NCTR, and I accepted.

Our first task was to develop a detailed research plan and establish a supplemental budget request, a five-year operations budget cycle, and a seven-year facilities plan. This was tricky since the facility would not be available for nearly a year. The establishment of a science

advisory board was a priority. Another priority was the establishment of a long-term relationship with the University of Arkansas. A MS degree in pathology was set up to retrain microbiologists, and the nations first Interdisciplinary Toxicology MS and PhD programs were established in 1973. The early days seemed like a continuous set of special expert committees of the Science Advisory Board, testimony before OMB, headquarters, and congressional committees. For the first six years, at least two days a week were spent in DC.

Those formative years were very exciting. NCTR was at a frenetic pace recruiting, planning, building, and initiating long-term research. The barrier, conventional animal rooms, breeding colony, as well as teratology, chemistry, microbiology, pathology laboratories, and computer center were early additions. The 29,000 animal ED01 carcinogenesis dose response experiment was initiated. The budget doubled every year for five years, and the number of employees expanded from 20 in January of 1971 to 600 by 1976.

Bill Allaben, Karl Baetcke, Dan Casciano, Larry Fishbein, Charles Frith, David Gaylor, Fred Kadlubar, Charles King, Ralph Kodell, Bill Slikker, and John Young were just a few of the key scientists we recruited. Administrative leadership that have given their all for NCTR, and who were on staff during my tenure as Director, include, but are not limited to, Glen Achorn, Jeanne Anson, Pete Attwood, Maureen Brooks, Terry Genz, Sandy Holland, and Vicky Ross-Barsh.

It was a privilege to participate while NCTR transformed itself into a world class research institute. I gave it my all and have been rewarded with the Award of Merit, Distinguished Service Medal and, most importantly, with many friends. My heart will always be with NCTR, and I will always be appreciative of how the FDA stepped up and caused NCTR to happen.