AN INTERVIEW WITH JOHN F. SHERMAN, PH.D.

BY STEPHEN P. STRICKLAND, PH.D.

ON THE OCCASION OF

THE 100TH ANNIVERSARY IN 1987 OF

THE NATIONAL INSTITUTES OF HEALTH

and the

150TH YEAR IN 1986 OF

THE NATIONAL LIBRARY OF MEDICINE

SEPTEMBER 1986

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Introduction and Biographical Sketch

This interview with Dr. John Sherman is one in a series of "oral hsitories" focusing primarily on the origins and development of the extramural programs -- most especially the grants programs -- of the National Institutes of Health, beginning with the establishment of the Division of Research Grants in 1946. Like Dr. Sherman, most of those interviewed had critical roles in the development of the extramural programs.

John Sherman is, in the view of colleagues at the National Institutes of Health and the Association of American Medical Colleges, "the man in charge of making things go." Since his retirement from federal service, he has been Vice President and more recently Executive Vice President of the mentioned Association. At NIH, he was for more than five years Deputy Director of NIH, for part of that period also serving as Acting Director. Before that, he had run the extramural programs of NIH, as NIH Associate Director. Earlier, the extramural programs of the National Institute of Arthritis and Betabolic Diseases and the National Institute of Neurological Diseases and Blindness. John Sherman is a statesman in the biomedical research enterprise, and one of the most dedicated public servants in recent times.

This oral history project is being carried out, in 1986 and 1987, under a grant from the National Institutes of Health, administered by the National Library of Medicine.

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WASHINGTON, D.C.

Interview with Dr. John Sherman by Stephen P. Strickland, Ph.D.

September 5, 1986

SS: I am talking this morning with Dr. John Sherman, Executive Vice President of the Association of American Medical Colleges, former Associate Director and Acting Director of the National Institutes of Health, and an old friend.

One impression I get from talking to the pioneers of the NIH grants programs, those great builders and enthusiasts, is that the whole thing was simple at first, but the structure was so sound that the grants program has continued from 1946 until today with things being absolutely rosy most of the time. This may be true, but it seems improbable. I wondered, in your years at NIH, if you could help me identify some landmarks of change, development, division of authority, and how new situations were dealt with.

JS: I would say that the basic element in that context was the simple yet elegant nature of the research authority enacted in the addition to the Public Health Service Act in 1944. To my mind, few people appreciate how that extremely innovative and broad legislation provided the framework for the whole program in those early years. This was, of course, before the establishment of most of the categorical Institutes. But it is a significant landmark in the biomedical research enterprise, and it ought to be so viewed with respect to any other landmark pieces of federal legislation.

Given that, however, there were indeed, as you implied, some periods of contention or uncertainty as to either the pace or the direction in which the program should evolve. For example, most of the early people involved were not academics, but were old-time Public Health Service officers who had little or no exposure to research. In this sense, it is somewhat remarkable that the extramural program came out as well as it did in its relationship to academic activities. I guess in part that was due to the fact that both sides were learning. The academic community hadn't had much responsibility to or relationship with the federal government except in time of war. Therefore, it was all new to them. And the program was small, which made for an ease of communication even though the environments and traditions were markedly different. That, I think, in turn is partially explained by the fact that when NIH started to expand after the war, there were a lot of people coming in from the academic environment who tended to "balance off". For example, James Shannon and C.J. Van Slyke came from totally different backgrounds, but both of them played a major role in the early years.

The establishment of the relationship between the academic community, in particular the academic medical community, and the NIH was not always smooth. There was a great deal of concern, as you know, centered not only over the enabling legislation for the National Science Foundation, but also the evolution of programs at NIH as to what the various roles and responsibilities ought to be. I think it came out in a very useful way; the academic community didn't control the process, and yet they were highly influential in helping to keep it from becoming a typical federal bureaucracy. The exception that I've reflected on was the myth that many of us promoted and believed -- the myth

that we could disprove the contention that federal funds meant a substantial degree of federal control. That, I think, has proved over time indeed to be a myth. In the early days we had sort of a Camelot in distributing funds. But I am also convinced that even though our conviction wasn't valid in the long haul, nonetheless at the time it enabled the NIH to accomplish what it did, both in substantive as well as managerial senses.

SS: Are you saying that the pervasive acceptance of this notion that federal influence wouldn't be controlling made it possible to do as much as you did?

JS: I think so. It brought the two "cultures" together, because otherwise the inclination of the AMA and of many people in academic medicine would have been to fight the NIH activity. The very wise move to bring in outside experts who, of course, were concentrated in the academic community, served wonderfully to facilitate everything that's happened since. That was very signficant.

SS: One thing that Ernest Allen said in an interview 25 years ago was that he and Dr. Van Slyke were surprised at the number of research proposals they got after they had released a circular saying, basically, that the NIH was taking over wartime contracts and would have some extra money, so please submit any good research proposals. Missiles came over the transom in surprising numbers, too many to handle. They started looking through "Who's Who in American Science" and other such sources to see who knew about a particular aspect of biochemistry, etc. But Dr. Van Slyke had come out of a medical school, had he not?

JS: He had been in the Public Health Service for a long period involved with venereal diseases, so he was much less an academic than he was a federal bureaucrat.

SS: And Jim Shannon was out of industry, although he had served as chairman of a study section.

JS: His formative years were in academia, before he went to Squibb. There was some military orientation for the malaria program, but it was influenced by an academic attitude.

Balancing Expert Judgment and Government Accountability

SS: Another thing that Ernest said 25 years ago and repeated in the case of my interview with him recently, was that once the study sections were set up, Van Slyke and Dyer and Shannon were very watchful to make sure that nobody on staff who was acting as executive secretary, or in any other capacity, tried to second-guess the experts. There was a deference to experts in the academic institutions on the part of the bureaucrats.

JS: That's right. But there was also, through the wisdom of that two-tiered system -- the study sections and the advisory councils -- a recognition of the two important features of that whole relationship: one, the dependence on experts for evaluation of scientific merit, and at the same time, the larger view from the councils in terms of the relevance of projects recommended for approval in the study sections process to programmatic objectives of the Institutes. Still a semblance of control had to be there since it was federal money; the Surgeon General didn't have to make an award just because of the

recommendations of the councils. I know several instances where Jim Shannon put his foot down and said he didn't care whether or not there was a recommendation for paying a particular grant; he, as responsible federal official did not feel it should be done. There was a most ingenious arrangement there that emphasized quality and merit, and yet didn't unduly diminish the authority of the responsible federal official, regardless of what some of the people in the Bureau of the Budget — and in political science -- used to say.

SS: I agree. And basically that balance still seems to be there.

JS: I think it exists in a very productive and reasonable fashion, respecting the need for flexibility in the management of the scientific enterprise, and also in the preservation of those things that result in reasonable accountability for public funds. I put it that way because I still find myself frustrated and dismayed that we haven't been able to find a better approach to demonstrate real accountability than to use an elaborate system of financial auditing as a surrogate.

SS: Is that an example of a major change from the early days to the present day?

JS: We like to say that NIH ran the grants program for about 15 years before it realized it was supposed to have some regulations! That's an oversimplification, but not by much. The programmatic objectives and the means to accomplish those were established -- setting up the instruments to distribute the money -- then we worried about cleaning up things with respect to regulations. I think that's the only way the process could flourish. And it did so with amazingly few major mistakes.

SS: I would say so. But what did the application of elaborate regulations in reporting requirements and auditings do to the process? I am sure it made it more expensive.

JS: Right. And to a significant, but not lethal degree, it frustrated researchers and program managers because of the fact that, like many other activities in our society, it became overly elaborate. Therefore the amount of effort that goes into "processing" the project grant system is unnnecessarily complex. The result of that is that you develop, both in the institutions and at the NIH, an elaborate bureaucracy with a lot of second-guessing or levels of clearance.

Individual Investigators, Scientific Infrastructure

SS: The grants in the first instance were inspired by the wartime experience and focused on the individual. Back then the grants process really did reflect the philosophy that if you picked a good man with a good idea and equipped him with the right resources, the grant should let him do what he decided was important to do in the broad context of medical science. Later, other kinds of grants were created.

JS: The next major consideration was Shannon's concern about an adequate infrastructure for research. That created an element of controversy both within and outside NIH. First, other than just the simple project grant system,

there was an emergent threat to the growth of the enterprise in the fact that there needed to be better and more facilities. We also had to worry about training. Another question was, if there were increasing amounts of money, could we continue to let the so-called retail approach dominate the system, or did we need to find some ways to complement that by packaging activities in blocks that permitted larger chunks of money to go out.

I think the first area of disagreement occured over NIH's role in training. If you recall, the Cancer Institute in 1937 had received authority to make research fellowships. After World War II, however, it was properly perceived that if anything was going to be done about categorical illness through research, there had to be an expansion of people who knew something more about those particular diseases. Despite the expansion of those cadres during the war, in the chronic disease area particularly — oncology, diabetes, rheumatology and so forth — there was a real paucity, not only of trained individuals, but also of places to train them. So a major feature of the early expansion of the NIH training program, beyond just the research fellowships, was a series of clinical traineeships that were frankly created to permit the expansion of better trained diabetologists, and endocrinologists, and oncologists, and cardiologists, etc. It was largely a non-research effort, although it was hoped that there would be some research involved. Then came the graduate training grants, and it was there that I believe the biggest point of tension ocurred. There was then a constant battle with the academic clinicians who were thwarted by not being able to find ready sources of money support for graduate medical education. In many instances, they converted the NIH graduate training grants to residency training support rather than the provision of some clinical exposure at the graduate level in order to become a good clinical investigator, to complement the basic research. That was one of the reasons for putting a special payback provision in the National Research Service Award legislation.

SS: Which requires what?

JS: It requires that if the individual doesn't go into essentially a research activity after the training, he/she has to pay back whatever amount was involved.

SS: Who were the "contenders" in this issue?

JS: There were two different forms. For example, the people in the mental health field were able to pursuade the Congress and the Executive branch that the need for a larger number of better trained psychiatrists, particularly to staff the public mental health hospitals, was a justification for a straight-out clinical training program, with research being completely supplemental, off to the side. Neurology took a somewhat different approach. They contended successfully for awhile that they were a so-called academic discipline, that is, all neurologists were practicing within academic medical centers in contrast to those such as internists in private practice. They went so far at one time as to almost require that an institution wouldn't get a neurology training grant unless it was willing to set up a department or division within the medical school with a neurology designation.

That situation caused consternation, both within the front office of NIH and also in the dean's offices. The aftermath of that was a growing sense of

imbalance in the ability of the school as a whole to maintain a well diversified, high-quality training program in medical education because you had then, as you may see now for different reasons, an increase in the automony of the program directors and department heads at the expense of the cohesiveness of the educational program as a whole. We've gone beyond that kind of impact from the impact of research funding. Now the problem is what results from the faculty practice plans. The power within the schools resides in a series of departments. In the early days it was research and training money that was coming in, and now it's the faculty practice money that's coming in. The consequences are much the same.

Peer Review of Training Grants and Fellowships

SS: How did the review mechanisms work with respect to training grants and fellowships? It's fairly easy to see how a scientist (or group of scientists) with a project gets reviewed by peers, since the only question is whether the science is good science, and the scientists competent, and in the second round, whether the project is in accord with program goals. But how did the review process work in these other areas?

JS: In the fellowship area it was simple. Like a research project, it concerned a single individual who was proposing a research project under a designated sponsor. So the fellowship component of the whole training effort flowed rather smoothly. It was in the training grant area that one ran into the uncertainties and difficulties because, on the one hand the agency was trying to build a capability for clinical investigations in categorical areas, and the people involved in the institutions were still confronted with this desire to expand the specialties and subspecialties of medicine, fully aware that research was important, but staying more concerned about the overall educational program. So, first of all one had a set of guidelines for the program objectives that were not contradictory, but a little confusing in terms of the objectives, since it didn't say right out that it was only for research. The guidelines used to say that the grant was for "academic medicine", but you couldn't be a good clinical teacher without having a firm grounding in your specialty or subspecialty. You also couldn't be a good clinical investigator unless you had some very good research training. In the area of clinical investigation, that research training was dependent on a thorough grounding in the subspecialty of choice. Thus, there were dual, separate but related purposes which permitted the people in the institutions to pursue their interests, and in other respects, permitted the agency to achieve its primary purpose of getting on with the research enterprise.

SS: So that was one tension. But who are the "peers" who review whether, say, Washington University gets a training program or not?

JS: They are the same types who, say, in St. Louis are wearing one hat as the chairman of the department of medicine or surgery, and another hat when they come to Washington to look at how we expand the manpower pool of clinical investigation. Given the lack of funding elsewhere for other desirable purposes, residency training, for example, NIH had to be pretty creative.

Let me give you a specific example on this: At the time that Secretary Caspar Weinberger decided to do away with the training grant program in 1973, the Neurology Institute set out a specific set of objectives for a training

grant program saying that they were training people for research, basic and clinical, in the neurological diseases. Weinberger essentially said, "Look, this whole idea of NIH-supported training is for the birds." The letters that came in to the Bureau of the Budget all complained not that research training in general was going down the drain, but that the termination would destroy the specialty of neurology. So there was a constant tension which derived from the fact that a good clinical investigator had to have training in both sectors: research and his or her specialty.

SS: But was there no difficulty in finding people who were objective about the capacity of a given institution to have such a clinical training program so as to provide the right setting for carrying out the research? I would have thought that the competition would have been a little keener, and make it harder to be objective if you had to bring people in from one medical school into a study section to look at whether another medical school would qualify.

JS: There was remarkably little of that, Steve.

SS: Could you discuss the Shannon research and training grants illustration?

JS: Jim Shannon certainly recognized and vigorously defended the importance of the project grant system as the keystone of the whole extramural enterprise. But at the same time, he was concerned about the infrastructure and, interestingly enough, about help to medical education. He wanted to find some way that the institutions could exert greater control over their own destiny. So he devised the idea of what he used to refer to as the "general research and training program" which is now called the Biomedical Research Support Grant, as a means by which the institution would be granted, on a formula basis, additional money dependent on its success in the project grants system. The purpose that he had in mind was to balance the institutional impact, the internal impact, of a heavily emphasized project grant system with some flexible money, research-oriented, that would be under the control of the institution and thereby permit the institution to balance off internally its research activities and overall strategy. That initially created two sets of tensions, one within the institution, where the faculty frequently described those funds as "the Dean's kitty", with a considerable amount of resentment. They saw it as draining off money from the project grant system. The other area of tension was within the NIH, where the Institute extramural staffs, including myself at the time, felt that this was a threat to the categorical concept and therefore to the individual Institute's categorical programs. So, this is a good example of tensions that resulted from an effort to do something other than just simply support research through project grants.

SS: Your other point was that this was a Shannon idea based on Shannon's perspective of possible adverse consequences to the institution as a whole, and to medical education, if project grants were the only way in which the NIH could support research and research training.

JS: Shannon's attitude was exemplified by an experience we had with MIT. Back in the early '60s the engineers at MIT had decided that they ought to organize a medical school at MIT and apply engineering concepts and approaches that they thought could straighten out the health care system at the Cambridge Hospital. There was much talk about the possible establishment of an MIT medical

school. Jerry Weisner was close to Shannon and asked him to come up to explore this on a retreat with some of the senior engineers and others on the MIT faculty. Jim, Joe Murtaugh and I spent about three days with them. Jim gave one of the most lucid explanations of what is involved in a medical center in terms of research and education and patient care. The thing I've always remembered about that, which I think is an absolute truism, was when he outlined on the blackboard a message that in the area of research and education, you can "call the shots" fairly well from an institutional point of view, and therefore control your destiny to a large degree. Even though Shannon felt at times that medical schools had taken on more research than was justified for their education program, nonetheless he accepted it because he felt that there was reasonable control. He told us, basically, "Once you get into patient care, the control of your destiny shifts to the community, or to those consumers who look to you for the provision of care". I've often thought about that from my position here, because the schools and teaching hospitals try to compete with community hospitals and therefore the faculties are now increasing primarily on the basis of service needs rather than for educational requirements. That broad sensitivity and vision of Jim's was absolutely crucial to the quality and productivity of the research program, as well as how it fit into a broad scheme of health activities.

SS: Well, he certainly did have that enormous range of view.

Expanding National Capacity

JS: When Shannon realized that the money was going to continue to flow, and in relatively copious amounts, and he and others in the science field felt that there could and should be an expansion of the nation's scientific capability, he devised a program called "health science advancement awards". This was an effort to upgrade an ill-defined group of institutions that weren't quite in the first rank of research-oriented academic institutions. He decided to set up a program that would try to identify that group of institutions and give some large sums of flexible money with the express purpose of upgrading the research and research training capability of that group of institutions. This was the first instance in which one couldn't define the process clearly; how to set up review criteria, for example. I remember the National Health Council meeting where Harold Enarson, then president of Ohio State University, just gave Jim hell because this was "a bureacratically dominated, poorly defined program that was giving money to a favored few", and so on. It was finally abolished with only a total of eleven grants awarded. The objectives were reasonable and probably desirable, but the ability to make the effort into a real operation was never realized.

SS: What kinds of grants did the NIH have the most control over? Looking at the review process, we know that, even though there was always the two-tiered review, experts had the most influence on project grants. But I assume that some of the other efforts you've mentioned were designed in such a way that made it easier for the agency to achieve its objectives.

The Role of Contracts

JS: There really wasn't any grant instrument available in that area, Steve.

That's why the contract played an important role and should play a more important role than it does now. The only problem was that the contract mechanism was at least confused if not ill-used in some instances. There were allegations of favoritism, especially in the relationship between the use of the contract mechanism and intramural scientists. Originally the contract had been used at NIH solely to provide additional resources, like the provision of chemicals that weren't necessarily available on the open market. When the cancer program started to expand back in the mid to late 1960s, some of the intramural people, having access to the contract mechanism, built huge empires -- only about four or five of them -- but there was a lot of criticism that the intramural people were placing the extramural people at a disadvantage because the latter had to compete through the project grant system. The contract instrument was solely under the control and authority of the bureaucrats -- the intramural scientists or Institute directors -- and many felt it was being misused.

SS: I never knew that contracts were made with intramural scientists.

JS: Not with them directly. But they controlled the process and thereby controlled a good deal of money.

SS: But the National Cancer Institute didn't make a contract with an intramural scientist?

JS: No. It was the fact that the intramural scientists' program had access to external capabilities through the contract mechanism. In my mind, a good Institute director needs an instrument of that sort to which he has access, in contrast to the grants program whose scientific direction is primarily in the hands of the biomedical community. I think the system ought to provide a capable program manager with a degree of managerial flexibility that the grant system denies him. Therefore, the contract could serve the overall strategy of the program manager well, and it has. I don't think that it is conceivable that one could run a good grant program and have it as something other than a passive instrument for the program manager. Although an Institute director is in charge of a program, he has little control over the direction of the grants program. He has little control over his intramural programs also, because the intramural program functions largely like the extramural component as far as its scientific content is concerned, even though the monies flow differently. Therefore, if the director takes a look at his overall program, perceives an area that offers promise and needs to be pursued, the only way he can do that on his own initiative is through an instrument under his personal control, like the contract. Thus I have always felt that ideally the NIH program would consist of a small but strong contract program in addition to the intramural and large extramural components.

Means and Tools Available to Institute Directors

SS: There are some other means by which a director can influence direction, I would assume.

JS: You have "RFA's", requests for applications.

SS: Would he have any authority or money to call a conference like they used to do in earlier years?

JS: No, not a great deal. Most of the conferences are supported through grant money, but on the other hand, a whole galaxy of mandated advisory bodies have grown up that are statutory bodies. I don't have intimate knowledge of how they operate, but I have the sense that they're controlled as much by the community as they are by the director, just because of the fact that they have been put in legislation by virtue of the pressure from lobbyists on the outside.

SS: Are you saying that the intramural scientists still have the greatest control over the contract program?

JS: No. The alleged abuses resulted in considerable changes. In previous days, there was a virologist whose research was funded probably 90% with contract money, quite in contrast to the usual intramural scientist and his access to resources.

SS: Obviously there has been some push and pull over that. I have always thought that the director of an Institute should be in a better position to see research needs than anybody else in the country. Even if that is true, but they have no authority or money to do anything about it, that would seem to be a waste.

JS: I think an NIH Institute director these days has surprisingly little authority over what happens in his Institute. That is further exacerbated now by something we're trying to explore, namely the apparently lessened degree of managerial flexibility at NIH. Restrictions are imposed by such things as Congress specifying a fixed number of competing grants to be awarded, which is established at the NIH level, but then has to be divided up among the 12 Institutes. Also, the Office of Management and Budget has now changed its apportionment process. Instead of the simple one that obtained for years that said, "Here's the appropriation for X Institute divided into four parts of relatively equal magnitude," and then said to the Institute, "O.K. You have this much money to spend and no more than that for this period," now it is my understanding that they require an internal allocation of that quarterly apportionment by activity, that is, research grants, training grants, contracts, ets. The combination of the two types of specifications is very restrictive.

SS: And they're making this kind of division each quarter?

JS: Right.

SS: That would mean the director has very little control. Pretty soon we could put it on "automatic pilot"! That's an unfortunate situation. Can you think of other examples of difficulty where the established mechanisms simply didn't encompass a new situation, or where controversy arose?

JS: One issue had to do with the training area, with a period between the completion of traineeship on a training grant or fellowship, and the individual's established role as a researcher within the institutional framework. There is often a gap of a few years there that is very crucial in the transition for the individual. There was a great deal of concern in the late '50s and early '60s about how you stabilize investigators and faculty members. The first effort was in the form of "career professorships", which went well until

some of the institution people felt that it was a threat to their autonomy in terms of faculty management. Who would do the appointing? The federal agency or the school, in the normal academic process? And so the desirable objective of finding a way to provide the institution with some money for designated individuals on a career basis wound up causing a great concern, to the point that there was finally a meeting where Sidney Farber got up and walked out, back to Boston, because this concept had been largely his brainchild, and he was seeing his idea go up in flames because of the criticisms. That program just barely got off the ground before it was halted (except for the commitments that had already been made). In that case, an attempt by the NIH to do something for the institutions to fill a very real gap in faculty support got a very negative response.

SS: Apparently only the Pope has the authority to intervene in institutions of higher education in this country!

JS: Of course, NIH has maintained a career development award which is time-limited. They also introduced a series of other clinical investigator awards to try to bridge that gap, and those have worked well as far as I know.

Geographical Distribution

SS: How were discussions of geographical distribution handled? There had to have been some, because members of Congress put pressure on every agency of the government to spend money on their states or districts. Was there a sense of the inevitable evolution of a major biomedical research program, financed through the extramural program, that would finally encompass all good institutions in the country?

JS: No, there was remarkably little political pressure at NIH, Steve. It raised itself as a worrisome spectre once in awhile, but the only area where geographical distribution was a factor was in the construction program, where there was a general sense to try to spread the money across as wide a geographical range as they could. There weren't definite allocations on a regional basis, but geographic considerations entered into the review of the awards. In other areas, in contrast to other federal programs, there wasn't more mention about the distribution in Congress, due in large part to the attitudes of people like John Fogerty and Lister Hill and a willingness of people like Bill Carey of B.O.B. and Jim Kelly and various secretaries of HEW not to contaminate the NIH operation by that requirement. I think a perfect example of that is Fogerty. He really didn't try to do a lot for the state of Rhode Island as far as NIH was concerned.

SS: You can't say the same for Lister Hill.

JS: True, to some degree. But you know, it's interesting that Senator Hatfield, during the "pork barrel" debate cited Magnuson's contributions to the University of Washington, but except for a couple of non-university activities out there, the Hutchinson Cancer Center, and maybe one or two other things, those things all went through the regular process. Though Maggie took great pride in what went on out there, I don't think there is evidence that his influence and position resulted in much unwarranted diversion of funds to the University of Washington.

Impact of NIH on Education and Research

SS: Can we talk now for awhile about the impact of the National Institutes of Health, particularly the grants program, on the development of a national network of health science education and scientific research centers? Where would we be in 1986 if we had not had for 40 years a growing program of grants to individual researchers and institutions in biomedical sciences?

JS: I don't think there's any question about the impact of the NIH grants program on the institutions. The network of academic centers would hardly be of the same size and same quality as we have now. If one reviews the history of the evolution of these institutions, it's fascinating to ponder the probabilities. First, the acceptability of the NIH grants program and the way that it emerged in a non-institutional nor individual threatening way paved the way for the developments in biomedical research, and for later support by the federal government for the expansion of the production of physicians and other health professionals that certainly wasn't politically acceptable earlier. We had at least two major benefits as a consequence of the NIH grants program not only being created and growing, but also in its operating withing a framework that was non-threatening.

I think it is important to make a distinction between substantial influence and dominance. There was a myth for awhile that there was not going to be much influence except in the scientific sense of quality, and an increase in the output of new knowledge. But it certainly avoided any kind of domination.

SS: As you suggest, that made it easier than for the federal government to support medical education in a variety of ways. The old argument was even in the 1950s that once you let the federal government get a toe in the door it would take over completely and dictate everything. You've been at the AAMC for twelve years and were at the NIH a long time before that, so you've seen this growth from both sides. Over the last twelve years, has the role of NIH grants changed as a part of an institution's overall activities?

JS: I think it's changed in a couple of major ways. The most prominent one is the fact that the rise of practice-plan income on the part of clinicians in these institutions is now the fastest growing source of revenue within the total institutional budget, replacing the NIH money in the total operating budget.

SS: In the '60s and early part of the '70s was NIH the dominant component?

JS: Yes. It varied tremendously from school to school, but in the aggregate at the national level, it was a dominant feature of those operating budgets.

SS: To that extent, schools planned for the expansion of their research activities, or at least made it possible for them to expand, and I take it today that is not the case. There is only stable if not static support. Are institutions struggling to maintain the appropriate level of biomedical investigation?

JS: Oh yes. I don't know of any institution that doesn't aspire to have a stronger biomedical research base than it has, but you are correct in viewing

the situation as one of considerable stability at the moment, not only in terms of the size of the enterprise, but more importantly in terms of which institutions within that group command the largest part of the NIH extramural budget.

Financing Clinical Trials

SS: Has there been any shift towards more clinical research as opposed to more fundamental research?

JS: No, I don't think one can say that. As a matter of fact, one of the big concerns a number of us inside and outside NIH share at the moment has to do with the question of program balance at NIH among the various types of activities and what that means to the institutions. As you know there has always been, particularly in the last fifteen years, a growing debate on how, for example, clinical trials ought to be financed: Should they be financed by NIH or by some other source? In those areas questions are still unresolved.

SS: For medical schools and their teaching hospitals, with the new, most important growth element being payment plans, the dominant element consists therefore of patient care?

JS: I find myself a bit ambivalent about that, Steve, because of, first of all, the success of medical research funding in the last few years; research has struck a responsive note in the Congress and we've had better increases, even in very difficult fiscal times for the federal government than was true in the late '70s and early '80s. Second, it seems to me that there remains, even despite the fact that the only real expansion that's taken place within medical school faculties has been for clinical purposes, recently there is still a very strong emphasis on research in those institutions. It still figures very prominently in such things as promotion patterns and things of that sort. What changes will take place will probably be marginal in the size and other characteristics of the research programs. It is still unclear what's going to happen with respect to industry. The uncertainties range all the way from the impact of the tax legislation to attitudes within the institutions as to how to sort out the relationships between academia and industry. Again, I think the impact will not be major. We're still looking to the federal government as the primary source of support for biomedical research, and those institutions are still going to do whatever they can to promote it.

For-Profit Hospitals

SS: Another new element is the for-profit hospitals, particularly the large chains. Some of those have now become affiliated with university teaching hospitals. Is that something that will have an affect?

JS: I think that has pretty much run its course. There was a big move a few years ago that was a matter of considerable interest to our Assocation, because with the effect of the prepayment system and concept, and the growth of the for-profit chains, we wondered how many of our flagship hospitals would be taken over or would be managed by for-profit organizations. All of a sudden the whole situation within that community changed. They stopped buying

hospitals and went into insurance programs and other pre-paid activities. Now some of the major ones run have been running into hard times. I don't think that in itself is going to be as much of a change agent to our institution as we perceived.

SS: If a major research proposal was received by a group of clinical researchers at, say, St. Luke's, which was being managed by a for-profit group, would that make any particular difference?

JS: I don't think so. The bigger concern that we had was in the education field, which would suffer because the relative stability, in the sense of being able to count on the federal government, is not really matched by a similar commitment except in some of the states through their institutions for the education purpose. Since the late '40s, education funding has been the "third element" in these institutions; patient care, and research revenue always expanded before education, even with the flux of federal money. So, when those developments started to move to the profit groups, we were more concerned about the impact on medical education, particularly in the clinical group.

Role of Industry

SS: So, today you would say that the NIH grants program is in fact a stable element in health science centers' planning in medical education. It causes the balance among the teaching, research and service functions to be as it has always been, with only marginal changes, and is still a major element in medical schools, but not the dominant ruling one.

Can we talk more about industry? It is still amazing to me to see elaborate stories about new breakthroughs -- including the most recent one dealing with an AIDS-restraining chemical -- as if they were the exclusive province of Burroughs-Welcome or some other pharmaceutical company, without any mention of the role of NIH in supporting the basic research or helping coordinate the overall nationwide effort going on right now. Is that changing? Is industry surging ahead with chemical breakthroughs?

JS: Of course they are always trying to do that. I don't know of any major leader in the pharmaceutical industry who, if questioned, wouldn't say that they are truly dependent on the basic research supported by the federal government. Certainly, Ted Cooper of Upjohn and Bill Hubbard and a number of the other pharmaceutical company leaders are on record that their well being and advances depend on that base. I think they are just as supportive, for example, as the Packard-Bromley Report of academic science, although that is broader than just the biomedical field. There is a recognition there that not only should the country's academic science flourish, but that those companies' economic well being is dependent on that.

SS: You don't see that as a changing dynamic then. And specific advances or patented products are not indicative of a shift in the relationship between private enterprise and the fundamental research supported by NIH?

JS: There is a statistically significant increase in the amount of money that industry is putting into the pot that is outside of its own laboratories, but

I don't think that presages any change in the relationship. However, the big area of change that is still unfolding is biotechnology, which has a lot of potential as far as application is concerned, in agriculture, medicine, etc. That is now where the action is.

SS: Who was in control of the clinical trials relating to AIDS?

JS: It has been shared, with the Allergy Institute funding roughly nineteen treatment evaluation units in centers scattered around the country. That is a good example of how industry and government and the institutions can work together under the pressure of a very highly publicized public health threat. From what I gather, all three of these groups mobilized quite rapidly in the cause of an AIDS cure.

SS: We were talking earlier about the question of who supports clinical trials. Has the balance shifted there more to industry?

JS: It depends on the area. Burroughs-Welcome has put a lot of money into the clinical trials, but I think the system is still heavily dependent on the federal government. Tom Chalmers, who used to be at the Clinical Center, and recently retired as President of Mt. Sinai Medical Center in New York, has for a long time pushed the idea that clinical trials ought to be funded by a tax on either the pharmaceutical industry or somewhere other than the research budget. I am inclined to agree with him on that. In the first place, they are big and expensive -- to carve that out of the NIH budget almost exclusively doesn't seem to me to be good public policy.

SS: To carve out an increasingly large portion of an increasingly stable, stationary budget, is problematic. It's amazing that so many things now seem ready for clinical trials. It strikes me that one measure of progress is the number of clinical trials going on right now.

JS: I think there is a good indicator available, and that is that, for example, in our ad hoc group, which is composed of about 150 organizations that support a single figure recommended for NIH, about 2/3 of those are categorical organizations, and what they worry most about is the fact that there isn't enough money somewhere else, so they concentrate on the NIH budget for more clinical trials. Yet, they are very supportive of a diversity of activity within the NIH framework. But they want to see more in the way of clinical trials.

SS: Is there any demand or interest in making major modifications in the grants program on the part of institutions?

JS: Every once in awhile you get some cry from the have-nots that there ought to be a different way, but for the most part, even among those institutions that aspire to more research activity, there is very little pressure, except maybe once in awhile over facilities, to go outside of the present system for funding. It's remarkable to me that these institutions are willing to play the risk of the peer review process in a competitive grants program. Even though I am sure every one of them would like to get more money, they aren't bucking the system in order to do it.

There has been a valid desire to find some way of getting a little more money into the biomedical research support grant, which was the formula grant

tied to the success of competition for projects. But again, the amount of money involved isn't great. That program is funded for maybe $50-60 million per year, and I don't know of anyone who would propose doubling that. It was started by Shannon back in the early '60s.

SS: The program project grants are still intact?

JS: They have waxed and waned, in part over the concern about quality, and in part because sometimes it is an artificial forcing into a package that doesn't make clear sense. Nonetheless, as far as I know, every Institute still puts a fair amount of money into program projects.

New Issues

SS: What, in your judgment, will be the next round of issues from the medical schools' point of view regarding NIH and the grants program?

JS: First of all, I think they're going to be overshadowed by what happens with respect to the outcome of reimbursement patterns of patient care on these institutions and the attention that is going to generate. For example, one of the questions in my mind is how you sort out, in terms of control, whether the practice plan revenue goes in an academic or purely economic direction; whether it remains largely in the school or in the hospital. That becomes a much greater institutional issue that still needs to run its course. In the research area, it seems to me the concern will be in manpower uncertainties. It could be that what people are referring to as a "glut" of physicians -- the output is still climbing -- may overcome the current problems of the perception that there are too few physicians being trained for careers in research, particularly as clinical investigators. The proportion, as well as absolute numbers of M.D.s who are principal investigators at NIH, on NIH grants, has steadily fallen over the past decade. Most people feel that that represents a major area of concern, if that surplus of physicians doesn't turn that around, something else will have to be done to increase the number.

A second problem is indeed the question of how far you go in expanding that research enterprise -- what is the optimal size, the ideal size? That is a perennial issue. A third one has to do with the question of technology assessment and the transfer process. My sense is that the institutions are going to be the source of that type of activity. The Institute of Medicine is now establishing a council on technology assessment. That may bring some order to what is now an uncertain situation as far as how the transfer process occurs.

My fourth candidate would be the relationship between the Congress and the NIH regarding macro versus micro management. There are two new bills now pending in the Congress, one on Alzeheimer's Disease and the other on pulmonary diseases. It's another manifestation of Congress' desire to exert more control over medical research: every time you enact one of those pieces of legislation, despite the general agreement on the objective, you further impinge on managerial flexibility in the agencies. So that is a very significant issue.

I must say, I get mixed signals about this. In that article that appeared in the Times a few months ago on the Hughes Institute, centered on the

change of attitude at Yale, the Yale people, after negotiating with Don Fredrickson, felt much more at ease about the Hughes approach to their funding biomedical research than had been the case before. On the other hand, I have heard from other places that the new adminstration at Hughes is getting more dictatorial, more insistant about following their pattern of how they want the relationship to be.

SS: How do they fund? They are apparently trying to concentrate their resources in certain areas, but what more?

JS: What they do is, in effect, set up within an institution (a non-federal one usually) a little Hughes operation; the investigators and staff are on the Hughes payroll, not the institution's, yet they sit in the midst of the institution and the institutions go after that money because it is reasonably stable. How that will all play out in terms of the stability of the funding and the relationship between those individuals and that activity and the rest of the institution is one relevant question.

SS: Do we know what the timing is for the burgeoning of their resources?

JS: It is starting now. I think the money that they had to dispose of this year was about double that of last year -- although I'm not sure which 12-month year that included, but it went up from roughly $100 million to $300 million or so.

SS: That is substantial, but it's not anywhere near the $5 billion that NIH has, except that I think that only about 60% of that actually goes to the medical schools.

JS: I think the other dimension, however, is the fact that Hughes tends to concentrate by amount and scientific area.

SS: This has been enormously helpful. Thank you, John.

CURRICULUM VITAE

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PERSONAL

Date of Birth: September 4, 1919

Place of Birth: Oneonta, New York

Marital Status: Married, Two Children

Education:

February 1946 - June 1949
Union University College of Pharmacy, Albany, NY
B.S. - June 1949 (Cum Laude)

September 1949 - January 1953
Yale University, New Haven, CT
Ph.D. - June 1953

PROFESSIONAL EXPERIENCE

February 1987 - present	Executive Vice President, Assoc. of Am. Medical Colleges
March 18, 1974 - February 1987	Vice President Association of American Medical Colleges, Washington, D.C.

(March 18, 1974 to June 30, 1976 - also Director, Department of Planning and Policy Development, Association of American Medical Colleges)

November 1, 1968 - March 15, 1974	Deputy Director National Institutes of Health, Bethesda, MD

(January 22, 1973 - May 29, 1973 - also Acting Director, National Institutes of Health)

January 1, 1964 - October 31, 1968	Associate Director for Extramural Programs National Institutes of Health, Bethesda, MD
January 15, 1962 - December 31, 1963	Associate Director for Extramural Programs National Institute of Arthritis and Metabolic Diseases, NIH, Bethesda, MD
July 1, 1961 - January 14, 1962	Associate Director for Extramural Programs National Institute of Neurological Diseases and Blindness, NIH, Bethesda, MD
October 8, 1958 - June 30, 1961	Deputy Chief, Extramural Programs National Institute of Arthritis and Metabolic Diseases, NIH, Bethesda, MD
August 8, 1957 - October 8, 1958	Assistant Chief, Extramural Programs National Institute of Arthritis and Metabolic Diseases, NIH, Bethesda, MD

July 1956 - August 1957	Assistant to the Chief, Extramural Programs National Institutes of Arthritis and Metabolic Diseases, NIH, Bethesda, MD
January 1953 - July 1956	Research Pharmacologist, Laboratory of Tropical Diseases National Institute of Allergy and Infectious Diseases, NIH, Bethesda, MD

MILITARY AND UNIFORMED SERVICE:

Private to Major, Army of the United States
February 1941 - 1946

Commissioned Corps - U.S. Public Health Service,
Assistant Scientist (Lieutenant J.G.) to Assistant Surgeon General (Rear Admiral)
January 1953 - November 1968

HONORS-AWARDS:

Decorated Bronze Star, Army of the United States
June 1945

Meritorious Service Medal, U.S. Public Health Service Commissioned Corps, 1965

DHEW Distinguished Service Award, 1971

DHEW Secretary's Special Citation Award, 1973

National Civil Service League Award for Distinguished Career Service, 1973

Honorary Sc.D., Albany College of Pharmacy, Albany, NY
1970

Distinguished Alumnus Award, Union University Pharmacy College Council, Albany, New York, October 1974

Fellow of the American Association for the Advancement of Science (AAAS), 1982

OTHER ACTIVITIES:

1976 -	Member, Panel on Clinical Sciences (National Research Council - Commission on Human Resources/National Academy of Sciences)
1976 -	Member, Institute of Medicine, National Academy of Sciences
1978 - 1982	Member, Membership Committee, Institute of Medicine, National Academy of Sciences
1979 - 1981	Member, Committee on Federal Research on Biological and Health Effects of Ionizing Radiation (National Research Council - Assembly of the Life Sciences/National Academy of Sciences)
1980 - 1982	Member, Advisory Committee, Five-Year Outlook Project, (American Association for the Advancement of Science)
1976 - 1978	President, Coalition for Health Funding, Washington, D.C.
1978 - 1983	Member, Board of Directors, Coalition for Health Funding, Washington, D.C.
November 1975 - December 1976	Member, Board of Directors, National Society for Medical Research, Washington, D.C.
January 1977 - November 1979	Vice President, National Society for Medical Research, Washington, D.C.
December 1979 -	President, National Society for Medical Research, Washington, D.C.
July 1976 - June 1979	Member, Biomedical Library Review Committee (National Library of Medicine), Bethesda, Maryland
July 1979 - June 1980	Chairman, Biomedical Library Review Committee (National Library of Medicine), Bethesda, Maryland
January 1985 -	Member, Research Programs Advisory Committee, National Multiple Sclerosis Society

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