

Thoughts for the Kellogg Pharmaceutical Clinical Scientist Program

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My thoughts on the Kellogg Pharmaceutical Clinical Scientist Program arise from what I have observed in the last 20-25 years as an outsider in the health professions, looking at and sometimes being asked to comment on and to help within the fields of medicine, dentistry, nursing, pharmacy, and nutrition. I have found it necessary to try to create for myself a conceptual model of what I am observing, to understand it in the broad picture, and to try to relate all that I observe and all the conclusions I reach to that model.

The Study Commission on Pharmacy was a remarkable experience for me; after two years we were thinking almost as one individual. The most obvious criticism of the present health care system was its capacity for generating a reverse flow of knowledge from the point of experience and understanding back toward the preceding parts of the system. It became evident in studying pharmacy that this was the most severe deficit—and it was nowhere nearly as pronounced in the field of medicine. The one thing that flows through the system in pharmacy is products. Knowledge gets thrown in the wastebasket (with the exception of reporting adverse reactions). No one in pharmacy is in charge of feedback, and this must be accomplished with people; hence, the concept of the clinical scientist.

Historically, the starting point of knowledge in the system we

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call health care has been the biomedical sciences—good old trusty subjects called anatomy, pathology, physiology, pharmacology, and biochemistry. But what has happened is that inexorably the width of this spectrum has been increasing. That is, the physician/scholar has found something in physics that is important to the doctor. The pharmacist has found something in behavioral psychology or social psychology and cultural anthropology that is relevant to pharmacy. How people react to the pharmacist and drugs is not only a personal experience but also a group experience—it is a cultural, a societal, phenomenon. We've known right along that economics has something to do with it. Suddenly, we find out that to serve society we not only have to give health care that is effective, but we also have to give health care that is efficient. Cost containment is now the motto of every professional. It has to be. We also found out that the communication sciences are important, and we found out that the managerial sciences are very, very relevant. Suddenly we're faced with the fact that rather than dealing with a rather narrow spectrum for the acquisition of knowledge, we have an entire spectrum involving all of these areas.

I want to draw some maps so that you know where I am in the hope that you will be with me and we won't be talking off and against each other. First, I want to tell you that there is a tried and true method I always use, a set of steps. I always want to get from here to there in an orderly process if there is to be a chance of any final success.

A number of times I have been asked to think about certain problems in the field of medicine—graduate education, for instance, or, more recently, evaluation of the national boards—or nursing, where I have worked over several years, or pharmacy. Over the years it has occurred to me that there is a pattern, a similarity, a parallelism, whether one is working in genetics or in medicine or in nursing or in pharmacy, that allows one to design a generic diagram that describes the system.

This model makes an assumption, which you may or may not challenge. For me, it has worked extremely well—better than any model I have seen. It conceives of the system we call the health care system not as a service system but as a knowledge system, one of the products of which is various kinds of care offered to the public

and to the individual patient. In this, perhaps, it resembles the communication system, which is a knowledge system that produces means of communication called telephones, satellites, telegraphs, or something of that sort. But this system, to me, is a very interesting knowledge system that produces a socially and individually useful service that we call health care.

Now, in that system there are four very clear parts. I say this, and I want you to remember it, because if you read the standard literature and listen to the usual conversation, you find that people deal with the health care system in tri-part imagery. We too frequently have thought of medicine in terms of a three-legged stool called research, education, and patient care, and every dean bragged that he had a three-legged stool on which the legs were all of equal length and therefore it was stable and was to be greatly admired. But for me, this system is not one of three legs or three parts, sometimes related, sometimes not related. Rather, it is a remarkably integrated, rational system if one looks at it not as a service or research system or educational system or discipline, but as a knowledge system in which all these are elements. It's a four-part system—a clear, logical, and fortunately, rational system of four parts.

The first of these four parts is knowledge acquisition. This is familiar—research, if you will. It's the acquisition of knowledge. I use the word "acquisition" because it covers at least two different concepts: the initial discovery of knowledge and the simple identification of knowledge in a field that one never before looked at and that one suddenly finds relevant. For example, much of the knowledge that is now in the discipline called biophysics has been a part of physics knowledge for quite a long time. Only recently did we discover that that knowledge was relevant to biology and, therefore, to the biomedical art. This is also true in other disciplines, such as sociology, psychology, economics, philosophy and ethics, communication theory, organizational management, and so forth. So, acquisition has two parts: it may be the original discoveries that one thinks of as pure research—at the bench, for example, when one finds a new enzyme or decodes RNA or DNA. There also is the identification—the recognition—of knowledge that suddenly has become relevant, although it did not seem so in the past.

What struck me immediately about pharmacy was that it draws

its knowledge from the entire spectrum more than any other field in the health science system. Our tendency in thinking about pharmacy is to focus on the product. But drugs alone are essentially powerless. What we're trying to get is drugs and the knowledge that is germane to using them effectively. Pharmacy needs knowledge about behavior, communication, and economics. The hurdle that has tripped many people is not realizing that the pharmacist must excel in all of these disciplines. Pharmacists are on the firing point when it comes to knowledge utilization.

Secondly, there is the process of knowledge translation. Some people call that clinical research. It is the step by which one turns knowledge into a skill—surgical, for instance, or diagnostic, or therapeutic. Or one may turn a part of the knowledge into a product, such as a drug or a device like a pacemaker or an artificial kidney. It's the step in which this knowledge, either discovered through research or borrowed from some existing discipline, is then translated into skill, technology, and product. There is a translation in the art, skill, technique, technology, product, or device. The important point here is that in this process only a part of the knowledge acquired is turned into a product or skill. There is a very substantial and oft-neglected remainder of knowledge that is not encapsulated in a surgical procedure or a drug or a device. There is knowledge about that drug, its activities, its kinetics, its adverse reactions, and its interactions. So we come now from knowledge to the translation of some parts of that knowledge into skills, technologies, techniques, or products.

The third step is knowledge transmission, the step in which we transmit the knowledge, the skills, the technology, the product, into new forms. We academicians are very prone to think this is our bailiwick and that we do the whole thing, that we take all of this knowledge—our knowledge about these devices and these skills and technological developments (the second step, translation)—and transmit it by the education of a physician or a pharmacist, a nurse or a clinical psychologist. But there are a lot of other parts to transmission. There is the formal education of a professional, but there is also communication through the mass media; through the formal educational process, such as health courses in grade schools; through learned journals and popular journals; through TV; and

through radio. In this step there is also the distribution of all these products and devices. In pharmacy, this is very important because it is the distribution as well as the manufacture of the products. Professional education is only one part of this transmission. There are many other parts.

Finally, there is knowledge utilization—clinical, if you wish to use that word. This is the point where this knowledge and these devices, these skills, and these technologies are used by professionals called physicians, pharmacists, nurses, etc. They are also used by the people called patients and by organized society in the form of government. That would be the fields of public health and environmental health, where society gets organized via its institutions to use that knowledge at this particular stage. This is the point where the service occurs. This is the point at which the service becomes a visible product.

But there are other parts. There is the recognition of the relevance of already-known knowledge, which is equally important in the acquisition process. All of a sudden, the medics found knowledge that has been around for a long time in my field of physics that was relevant to the process of understanding disease and learned something about it. Pharmacy has discovered knowledge in the field of management sciences, communication, and in the behavioral sciences of psychology and anthropology, and so forth, that is relevant to pharmacy. You didn't have to go back to the bench, so to speak, and get those *de novo*. I use acquisition, therefore, for the more familiar term of research, which is the discovery of heretofore unknown data, ideas, and theories, as well as the identification of already discovered knowledge that suddenly becomes relevant.

That's the system. It has the asset, it seems to me, that it is logical. It's one of the most beautifully organized, most rational systems I know of in our society. But it is not rational when looked upon as a service system. It is rational only when looked upon as a knowledge system. It has some very serious limitations. One of the most obvious characteristics is that the natural—I shall call it gravitational—flow from the input point to the output point is down. By the nature of the process, the direction is always downward. Knowledge goes from acquisition through translation through transmission to utilization. It's almost a one-way system. It is not a

system in which what one has learned at the utilization point comes back into the translation point. There are no natural, inherent, automatic mechanisms in this system for feedback. It is almost a unilateral system. The question is, how do we get what we learn at the utilization—the clinical—stage to affect what it is we look for in our knowledge acquisition or translation systems so that we modify the educational enterprise or other parts of the transmission system to make the system more effective in terms of the actual patient and societal outcome?

Remembering that there are a number of parallel systems called medicine, pharmacy, dentistry, and so forth, the other fault that one could attribute to this system is that there is no automatic system by which the knowledge that comes out of pharmacy gets translated into the medical system and vice versa. Very little comes out of nursing that anybody pays attention to in the medical world, and this is another problem. Essentially, what we must do for society as a whole and as individual patients is to try to give this system an agency that will provide feedback from the utilization point back into the acquisition point, the translation point, or the transmission point.

Thirdly, the most obvious, the most serious, flaw in the system is this lack of a main feedback or a number of feedback systems. It was this conclusion that led the Study Commission on Pharmacy to ask itself, "If we recognize this and if it is an important matter in terms of pharmacy, what suggestions do we have to induce at least one, if not several, feedback mechanisms in this system to improve it as a whole, to make the facts that can be learned at the utilization stage begin to affect the acquisition step, the translation step, and the transmission step?" Our conclusion was that one has to do it with people. We could not conceive of any protocol or sophisticated computer that would suffice: it required people. Think of the kind of person who would be described as polyvalent, having several powers, competencies, capacities. This person could participate actively and competently at the utilization stage. This person could be a clinician who could talk to other clinicians. He would have the language, the experience, the status, the investment of stature, the appropriate position, and he could, at the same time, be useful and contributory at the acquisition stage as a scholar. We call him a

clinical scientist. We were tempted to use "artist-scientist" or "scientist-artist" or something because we were dealing with the world of knowing—science—and the world of doing—art. This is a clinical practitioner and scientist.

We were afraid people would take that word "scientist" to mean a man studying mathematics, physics, biochemistry, and subjects of this sort—the hard sciences. We're using the word "scientist" in its generic context, which is simply a knower, a person who deals with knowledge, its discovery and utilization, and its interpretation and organization. That's the meaning of scientist. And "clinical," again, is a slippery word. It comes from the Greek word "klinikos," to lie down. Obviously, a first clinical instruction of medical students was on horizontal patients, and therefore it was a clinical experience. We have now used it in such a way as to change its meaning. It does mean "doing," and, therefore, it's a knowledgeable doer, a doing scholar, a clinical scholar. This is the concept: a person who would be able to know, communicate, participate, be active, contribute as a knower and a doer. The clinical scholar.

Well, what can we do about it? I've been trying to answer the question "why?" Now the question is, "Where do we try to go?" We have had, historically, individuals working in the system who lived and worked in at least two of these steps. For many years we have had the clinical professor who takes care of patients and also teaches medical students. We have the clinical instructor in dentistry, the clinical instructor in nursing, the clinical instructor in pharmacy. So, we are familiar with people who work in both the utilization and the transmission phases. We've also been familiar with people who have worked both at the research bench and on the faculty of a medical school or school of pharmacy, or something of this sort, who have combined the acquisition of knowledge with the transmission of knowledge in the education of professional students. Although this has provided a feedback mechanism between two adjacent steps, it has not provided feedback between the first step and the last step, or, for that matter, between the second and the last steps. The only attempt to do this was the Markle Scholar Program, which attempted to produce the clinical scientist in medicine, the practicing physician who could hold his own in physiological research, biochemistry, or pharmacology, etc. We have some

of those people in the system, and I think that they've had a tremendous impact on medical education in the last two, perhaps the last three, decades.

Immediately, everybody says, "all right, clinical scholar." The image comes right back to what we have seen in medicine, where one takes an internist or a pediatrician and gives that person the opportunity to work in a laboratory of physiology or neurobiology or something of that sort, and he becomes at least a competent bench scientist at the same time he is having actual contact with real, perplexing patients with problems. The natural thought is that, following that model, one would try to take a competent practitioner of pharmacy and put him into a department of pharmacology, physiology, biophysics, immunology, or endocrinology and let him become a bench scientist there to hold his own with the Ph.D.s of those fields or with those few M.D.s/Ph.D.s.

What is happening here is not what one would call the instinctive idea of the "doer-knower" — that is, the clinical scientist. By "clinical," I mean "doing." And science in the way I use "scientist" is the generic word meaning "all of knowledge." Rather than having only the opportunity of the basic biomedical sciences, it is the opportunity of coupling the practice of pharmacy with scholarship in the behavioral, economic, and social sciences. This is the recognition of two ideas. One is the recognition of the need for an individual who will be the feedback mechanism to make this system better. Knowledge gained here (at the utilization point) comes back and is recycled to the system through the ever-increasingly important effectiveness, economy, and efficiency of the system in terms of what it actually does for people individually and collectively. The other is recognition of the fact that an awful lot of knowledge already existing or being discovered now, out here in this part of the spectrum that we call behavioral, social, organizational, and administrative sciences, is relevant to this whole process of serving mankind. So much for the concept of the clinical scholar — the knower and doer. We get too much tied up in the words scientist and clinical. It's the knower and the doer.

We see the individual I've described serving as a catalyst within this system, actually learning from his practice, being able to make judgments, to find new understanding and insight that will be useful

at the acquisition stage, the translation stage, and the transmission stage. How is he to make these contributions? Well, obviously, in our universities there are all kinds of people. They observe the physician who is running the hospitals, observe the inadequacies in the knowledge, the skill, the technology, and then they go back to the technology in genetics or pharmacology. There are people who are called clinical pharmacologists who do pretty good work at the bench in the department of pharmacology and remarkably good work at the bedside treating patients. I have used the word polyvalent for this concept, but there are limitations on that word. There is a polyvalent assumption: that the clinical scientist can be infinitely poly. This is not true. As a clinician, he will have to confine himself to one particular area. I think one has to look at the spectrum of disciplines that are reasonably relevant to the health science system concerned. The best a clinical scientist could do would be to take hunks out of that system and become polyvalent in a chosen area. What we are talking about is multidisciplinary. Let's stop talking about "interdisciplinary," which means falling between the cracks. This is the only base upon which you could create the polyvalent scientist. By poly, I mean bipoly or tripoly—I don't mean polyvalent. A clinician has a limited area of expertise. He can't have too broad a disciplinary base without becoming a dilettante. We're not going to have a man practicing internal medicine, pediatrics, pharmacy, and radiology.

I would also comment on the process of creating clinical scientists. This is a very important consideration. The process by which people become able to do something is the process which we normally call training. The process by which one becomes a scholar is education. We frequently use these two words interchangeably, saying "education and training" or "education or training." This seems to indicate that they are quite the same thing. They are really fundamentally very different. One of the processes is to know; the other is to do, through knowing of course, but the outcome is doing, doing well and reliably. So there's a process that has to be used to produce the clinical scientist that we're talking about, which comes about through both education and training. When I have said this to other people, they have said to me, "Well, what's the difference?" One of my teachers, Albert A. Michelson, said that training was the

process by which the master would raise the apprentice to his level of skill and capacity, but education was the process by which the teacher lifted the scholar to his shoulders so he might stand thereon and go beyond. For me, there is a very real, meaningful difference between those two processes.

Other people through the years have had problems when they were faced with the necessity of both educating and training. I think graduate medical education is our very best example. It is difficult in those years of the residency to continue the process of learning as knowing and the process of being able to do when applying the skills of doing. It was for this reason that the Commission on Medical Education strongly recommended that the university take much more responsibility for graduate medical education than it has in the past to produce individuals who are both trained and educated. This is relevant to the kind of situation you have here. This program is a partnership of the university and a number of excellent clinical institutions drawing a fine line between scholarship and services. And they are two different environments. They have two different scopes or purposes; they have two different modes of operation. You have to provide that symbiosis in which the partnership of these two agencies is such that the individuals who are responsible for the clinical scientists' futures will have the opportunity both to teach in the scholarly sense and to train in terms of clinical expertise, competence, and reliability, and this may give you some problems every now and then. But you will not be able to pull apart and separate these parts in terms of your understanding and commitment to this single challenge.

One way I expect clinical scientists to have an impact on the profession is by becoming faculty members at schools of pharmacy. Hopefully, a clinical scientist would not be too much of a gadfly to wear out his welcome soon. There are some models for this, in fact. The Markle Scholars have had an influence on the medical schools of this country. I can see the clinical scientists having a substantial effect in key positions in the health care system. Perhaps it is too much to hope that they might have some cataclysmic effect by going to DHEW or other organizations of that nature, but one can hope. They might have quite an impact in HMOs. I can think of a number of different environments where a catalyst is needed and

could be effective. I don't know whether a clinical scientist could have much effect in a pharmaceutical association, such as the Association of Pharmaceutical Manufacturers.

You've got to understand that this is, in a very real sense, a venture of faith. We aren't quite sure where the clinical scientists are going or that when they get there they're going to have done anything very important. On the other hand, you do have a conviction, I hope, that this is a very important undertaking, and nobody can give you an assurance of success. I use the expression "divine discontent." In my observation, the one thing that makes a university go is that it has a few people who are divinely discontented with the status quo: "We can turn out better doctors than we have been, . . . engineers . . . you name it, and let's do it." In a sense, you're trying to manipulate that quality of divine discontent. I'm not talking about the people who say, "*They* ought to make a better so-and-so" but about the people who say, "*We* can do this better" and then go and do it. What I'm urging here, and what I think I feel in some of you, is a certain amount of divine discontent. I use the words "venture" and "faith" because there is no certainty about this, but there's hope and there's faith that it is worth doing and that it can be done well. I use the words "divine discontent" to indicate something that is rather unusual in the human personality, but it is a very powerful force.

In response to the argument that the world doesn't need anyone as highly trained as the clinical scientist, I would say that the human race could probably last several more millennia without any more creative thought, but I don't think the Lord wants it that way. We have minds to use. We have very few people who think both theoretically and practically. There is a great gap in pharmacy between the bench scientist and those who have to deal with medication. Mankind has not been very astute in seeing the need for a person to bridge this gap. We must recognize that we're not training a cadre of people for a specific job. We are trying to get a few people into the system with the ability to see and observe in the hope that we get a few who can improvise, improve, and expand, who can point out better ways to do things.

Now this is the image, pure and simple, of the clinical scholar in pharmacy that the Study Commission has proposed and that has

found fertile ground in this institution. It might be possible to take an adequately educated, trained, and experienced pharmacist who has been on the firing line in the practice of pharmacy and to so deepen and widen his knowledge, his horizons, and his interests that he would be one of the feedback groups in this system, taking what we observe and learn in the utilization phase back into the level of acquisition or translation.

My concept is that we could provide the necessary feedback into the system if we could train a relatively limited number of individuals to be polyvalent—knowers and doers of these businesses that lead to a command of the language and education and understanding. If you could do this, you might be able to affect the system in a very important and useful way, to make it much more reflexive and much more efficient, and to improve the cost-benefit ratio that is important to the people of the United States who pay the bills.

In recruiting candidates, look for excitement about and commitment to pharmacy, a well-organized and disciplined mind, a capacity for work, and an evangelical spirit; look for formulators and communicators. You cannot describe a clinical scientist in terms of a job. You have to describe the individual, but you must recognize potential problems as well.

What I have been trying to tell you is where I think you ought to be trying to go and, more importantly, why. This is novel not only in terms of the concept of the clinical scientist, but also in the field of pharmacy. It's not new in the field of medicine, but it is new in the area of knowledge that you're trying to look at in order to improve the utilization of pharmacy knowledge for the benefit of the patients as individuals and for society as a whole.

So I get excited about this project. I'm trying to infect you with the same kind of excitement. You're on a double frontier. You're in three-dimensional space. I think you're moving out in the two-dimensional space of industry, but you're also moving out in the three-dimensional space of the totality of health care in the several systems.