(d) Finally, NIH has, in the past, supported and/or participated in the extensive type of field trial which firmly establishes the net benefit to be derived from a given compound under well-defined clinical conditions, and will no doubt do so in the future.

The first three of these types of studies can be expected to yield patentable discoveries and consequently the rate of evolution to an effective therapeutic agent generally available to the public will be determined by the terms and conditions which facilitate the interplay of the resources of the Federal Government, the university scientists, and the pharmaceutical industry.

Although NIH support of an investigator may stop at an early stage of development or cover only a part of the complicated sequence of drug development, our departmental patent policy requires that his invention be reported to the Surgeon General for his disposition, that is, the Surgeon General's disposition, since the invention in most instances is complete within the definition of the U.S. Patent Office. The Surgeon General's disposition generally results in title to the Government in accordance with the provisions of the Department's regulations, the title provisions of the President's memorandum and the Executive order governing disposition of employee inventions.

The uncertainties involved in after-the-fact determinations have created barriers for collaboration by the drug industry with NIH-supported scientists in bringing potential therapeutic agents to the point of practical application. The industrial firms want some guarantee of exclusive patent rights as compensation for and protection of their possible investment, which may be considerable before FDA clearance can be obtained. Because, as I understand it, there is some question as to whether we can or should extend such a guarantee, it is often difficult to motivate industry to undertake the perfection and marketing of the NIH-supported inventions, and by an NIH-supported invention I have in mind those which were made under circumstances wherein a part or all of the support was derived from the National Institutes of Health.

We, of course, support the basic policy that title to health and welfare inventions generated primarily with Federal support should reside in the Government. It does seem to us as persons responsible for the largest Federal medical research program that there does need to be clarification of the situation with regard to the issuance of licenses to inventions held by the Government. One possible solution might be the granting of short periods of exclusivity in such situations as I have discussed—that is, where it is found to be necessary to develop an invention to the point of practical application and there is no other way to obtain the needed industrial cooperation. Compounds which show some promise in early stages of investigation may be of no benefit to the public and may not serve the public interest unless clinical testing is undertaken and the resulting drug is cleared by the FDA and indeed marketed. We also believe that is seems sensible to be able to involve industry in the testing and marketing phases of drug development since these firms already possess capabilities in these areas that would have to be duplicated elsewhere to accomplish these necessary purposes.

The Department is in the process of reviewing its entire patent policy and practices that relate to this matter.

Passing on now to the second area on which you wished my comments, I would note that one of the common characteristics of scientific research activities performed in universities is receipt of joint and simultaneous support from Government and nonprofit organizations, and not infrequently from industry. In the biomedical sciences, the Government support is most frequently provided in the form of a grant from the NIH. Funds from these different sources of support are often commingled with the result that a given research project may be financed and dependent upon several different sources of income at the same time. Where the private sources of support impose no conditions upon their grant relating to inventions, the HEW regulations requirement that the NIH grantees report all their inventions to the Surgeon General for his disposition poses no technical problem. However, where, as in the case of the American Cancer Society and the American Heart Association, cosponsors maintain patent policies requiring their grantees to agree to assign all invention rights to them, the grantee who accepts support for the same research activity from both the NIH and such other sponsors has undertaken conflicting obligations he cannot fulfill. It is difficult to solve problems of conflict after the fact on the basis of priority as between the cosponsors. Neither is it a satisfactory solution to suggest that the grantee be limited to acceptance of support from only a single source which imposes such an obligaiton.

I believe it is in the public interest to encourage support of research from the private sector of our economy and to discourage exclusive reliance upon Government-financed support. In order to further this objective, it may be necessary to relieve universities and their research workers from the dilemma created by conflicting obligations to assign patent rights.

At the present time, it is my understanding that the patent regulations of our Departmen do not take into consideration the equities of cosponsors in making disposition of inventions arising from research financed by multiple sources, and the Surgeon General must make his determination solely on the basis of our support. As I have mentioned, I do understand that these regulations have been under review for some time with this matter being given consideration by the Department.

Thank you very much for this opportunity to appear before you. I would like to emphasize that I am obviously not a patent expert, but I would be glad to answer any questions from my perspective as the director of a large Federal research activity.

Senator McCLELLAN. I haven't had an opportunity to read your statement. I have tried to follow you, so I may not be able to interrogate you about it closely. But I note you say on page 2:

> In most instances the NIH or its grantees do not participate in the full development of therapeutic agents up to the point where it is made available commercially.

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. Why don't you? You participate in it up to the point where it becomes evident that it is patentable; is that right?

Dr. SHANNON. Yes, sir.

Well, a patent may issue on information developed quite early in the total development.

Senator McCLELLAN. Yes, but you do not participate in the final testing and processing, developing, and getting it ready for marketing.

Dr. SHANNON. This is correct, sir, except in the special instances of psychopharmacology and cancer chemotherapy where we feel that we have an additional responsibility.

Senator McCLELLAN. Let me ask you this: At the point where your assistance ceases, suppose nothing is ever done beyond that in some of these instances, maybe not in all, but in those that you are referring to here. If nothing is done beyond that, would the public ever get any benefit from it?

Dr. SHANNON. No, sir.

Senator McCLELLAN. Then whose responsibility is it? I will ask you first, is there an investment involved, an expenditure and a risk involved in the further processing of it to bring it to a marketable testing and approved stage to where it is marketable and beneficial to the public?

Dr. SHANNON. Senator McClellan, the answer to both those questions is "Yes." There is an additional expenditure, and there is indeed a very broad risk involved.

Senator McCLELLAN. I have no interest on earth in this issue, except to find out what is best for the public, and also to preserve those principles of patent rights to those who make a discovery, and to give them an opportunity for development.

Now, what is going to happen if the Government goes to the point where it is patentable, but it is not going any farther with its aid and assistance, and that the Government is going to take the patent? Who then is going to process it on their own if the Government is going to keep all rights to it? Who is going to make that investment and who is going to take the risk?

Dr. SHANNON. Senator McClellan, unless terms and conditions are such that it will permit industry to accept the risk within the context of anticipated profit, it is not likely to bring these advances to the public.

Senator McCLELLAN. I am talking about those cases where it is not known, though you have made the discovery, and that is the point when that discovery is made, let's say Government takes title to it.

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. Because it contributed to making the discovery. It helped to finance the research that brought about the discovery. You make the discovery. It is patentable. The Government takes the patent rights, and it stops there. Yet there has to be an investment made. There has to be further testing. There has to be revision. There has to be experimentation. It may take a good deal of money. It may take investment. Certainly it takes talent. It takes trained people. It takes equipment to do it.

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. Now, if the Government owns the patent, who in private industry is going to make the investment and take the

risk, if its competitor can immediately step in and enjoy or share all of the benefits without making any contribution?

Dr. SHANNON. Senator McClellan, I think very few people.

Senator MCCLELLAN. Well, what is the best, what policy is in the best interest of the American people and of the public generally with respect to it? That is what we are trying to find out.

Dr. SHANNON. Well, my opinion would be that limited exclusively in terms of a license to a commercial enterprise with march-in rights in order to monitor the price and distribution structure would indeed permit negotiations between the Government agency on the one hand and the industrial firm on the other, to undertake the development work that could lead to rapid and effective marketing of an essential discovery.

Senator MCCLELLAN. I can appreciate that abuse might occur and might very well occur if there wasn't some control beyond if you say, well, we will just assign all patent rights to you if you are going to develop it. Now, I don't go along with that.

Dr. SHANNON. No, sir.

Senator MCCLELLAN. I think that may be going too far. There should be, if the Government owns the patent, some way that the Government can offer some incentive to somebody to go out there and take this risk and spend that money to further develop it and process it to the point where it becomes marketable and beneficial to the public.

Dr. SHANNON. I agree completely.

Senator MCCLELLAN. There must be some incentive for that.

Dr. SHANNON. Yes, sir.

Senator MCCLELLAN. Unless the Government is going to take over the whole thing.

Dr. SHANNON. Which it cannot.

Senator MCCLELLAN. And you are not equipped to do that.

Dr. SHANNON. No, sir.

Senator MCCLELLAN. You are not equipped to do it. Then there ought to be another restraint when the Government has permitted or when we have permitted that development, we should not permit that interest to exploit it to the extent of profiteering off of it, so to speak, at the expense of the public, and that it should be made available on some basis for some competition.

Now, there may be given an exclusive right for a period of time to develop it and get it marketed and so forth. But then there ought to be some way, some provision, it seems to me, of licensing the use of it, licensing the practice under that patent to others who might be competitors.

Dr. SHANNON. I agree, sir.

Senator MCCLELLAN. Now, how to define, how to develop a statute of such regulations and such procedures as will protect the Government and as will insure those who take the risk and make the investment in processing and developing it to a marketable state, how to insure them some protection that immediately after they have done that their competitor just can't walk in and reap all the benefits of their investment and their risk, it is a very difficult area, and that is the area in which I am concerned about how to find an equitable solution.

Dr. SHANNON. Well, Senator McClellan, I am a technician rather than a patent lawyer, but, if I can define my position this way, there is a very substantial risk in the development of a new drug.

Senator MCCLELLAN. By that you mean the fellow who takes that risk from the time of patent on to development may spend his money and come out and find out it is no good?

Dr. SHANNON. We can put a dollar figure on it, sir. It costs between $200,000 and $400,000 from the initial discovery of an activity to the point where knowledge has been brought to a degree of acceptability by the Food and Drug Administration.

Senator MCCLELLAN. $200,000?

Dr. SHANNON. $200,000 to $400,000.

Senator MCCLELLAN. $200,000 to $400,000?

Dr. SHANNON. Yes, sir.

Senator MCCLELLAN. That has been your experience?

Dr. SHANNON. This is our crude calculation; yes, sir?

Senator MCCLELLAN. Sir?

Dr. SHANNON. Yes, sir, this is our crude calculation.

Senator MCCLELLAN. Well, now, is there the likelihood that chemical companies and drug companies and so forth would just pick up a patent and go spend that much money on it, take that risk, if when they perfected it, so to speak, and got it marketable, that their competitor could just step in and compete with them?

Dr. SHANNON. Senator McClellan, were I in industry I would not take that risk.

Senator MCCLELLAN. Let me ask you this then. From your experience or observation, what percent of them turn out to be useful and develop into a marketable product of benefit?

Dr. SHANNON. I can't give you a percentage, Senator McClellan, but I would say I can give you an order of magnitude from the standpoint of the initial discovery of activity to a marketable product. It is substantially less than 1 out of 10.

Senator MCCLELLAN. One out of 10?

Dr. SHANNON. Yes, sir.

Senator MCCLELLAN. In other words, 1 out of 10 becomes useful and beneficial and profitable from a commercial marketing standpoint?

Dr. SHANNON. I would say substantially less than 1 out of 10.

Senator MCCLELLAN. Less than 1 out of 10?

Dr. SHANNON. Yes, sir.

Senator MCCLELLAN. What happens to the other nine?

Dr. SHANNON. Well, the others drop along the way, and my figure of the $200,000 to $400,000 is the price tag that would provide for full development of the one that was successful. It does not cover the costs of those that are dropped along the way.

Senator MCCLELLAN. I understand, but they are dropped because upon further examination the industry says, well, it is not worth the risk.

Dr. SHANNON. They have less activity than other agents that are already available or they have more toxicity and they do not warrant full development.

Senator McCLELLAN. That is what the inventor or the industry conceives after further examination that they are not worth the risk?

Dr. SHANNON. This is with the development——

Senator McCLELLAN. But on those where they take the risk, where they actually undertake the development, how many of them fail?

Dr. SHANNON. Senator McClellan, that is very difficult to say, because it depends upon the point in the developmental process that you take off from.

Senator McCLELLAN. Do some of them fail?

Dr. SHANNON. Oh, yes.

Senator McCLELLAN. Where they do take the $200,000 to $400,000 investment, some of them fail?

Dr. SHANNON. A substantial number; yes, sir.

Senator McCLELLAN. A substantial number of them fail. So then we come to this point. Where the Government makes an investment in joint operation with private contributors, with a university, and the patent discovery is made which is patentable. Then from there on even where they undertake to develop it into a marketable beneficial product, a substantial number of them fail.

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. One out of 10 or less than 1 out of 10.

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. So there is a continuing risk involved.

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. Now, would you recommend that the Government take that risk?

Dr. SHANNON. No, sir.

Senator McCLELLAN. And that the Government undertake to do it?

Dr. SHANNON. Well, to be very frank, sir, were the Government to do it, it would have to develop in a very substantial fashion precisely the same type of developmental plant that is already is existence in industry.

Senator McCLELLAN. Would not the Government have to go out and contract with some plant?

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. With some private industry to try to develop it?

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. I am just trying to find the equity in the thing and how to approach this thing to get equity out of it.

Dr. SHANNON. Could I draw a parallel, Senator McClellan?

Senator McCLELLAN. Yes. We have taken longer than 15 minutes. I am the one violating the rule here, myself.

Dr. SHANNON. At the present time in research and development, the pharmaceutical industry expends roughly in the order of magnitude of $300–$400 million a year. It is estimated that our total expenditure for medical research in this Nation is about $1.9 billion as of today, as a rate. And the $300–$400 million is 1964 figures.

Current figures would be approximately $400–$500 million. So, roughly, industry contributes approximately 25 percent of all research and development to the biomedical field.

Now, in the development of weaponry, where the sole customer, if you will, is the Government, or in the space program where the

Government is the sole customer, you do not have developed a vigorous private industry that can thrive in the absence of Federal help. In other words, in our DOD activities and NASA we pay the total cost of all developments.

Now, this has never been the case in the chemical industry or the pharmaceutical industry, and in a society that is based upon the profit motive traditionally, it has been possible to develop a very vigorous enterprise within the private sector that has shown great capability of producing good things in the health field.

Now, I do not hold that with the Federal entrance into biomedical research such as has taken place in the last 20 years in a very large way, that all advances that are made through the use of Federal funds should be turned over to this industrial enterprise simply because it has the capability of developing them.

On the other hand, I do believe that terms and conditions for the covering or the protection of patentable entities should be such as to permit normal interplay between those forces of science that exist within the Government and those which exist within the university and those which exist within industry, because in the final analysis, our purpose here is to use all elements of society in the most rapid conquest of disease that is possible.

So that the terms and conditions that relate the expenditure of Federal dollars in relation to an industrial operation such as this should always have this as one of it major objectives. How can we most rapidly develop a compound into a marketable drug, and yet at the same time protect the Government's equity in this? And the Government's equity here is primarily the making available of the medicinal in the broadest possible way, in the shortest possible time, and at the lowest possible price. This is the primary Government equity here, in that we stand to protect the purchaser of the drug.

Senator McCLELLAN. But, Doctor, here is one of the objectives. The Government makes the investment. It helps to develop the process that becomes patentable.

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. And it is patented. The Government, that is taxpayers' money that goes into it.

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. Now, you have discovered the thing, but yet there is private investment in it, too.

Dr. SHANNON. Yes, sir.

Senator McCLELLAN. Well, now, if the private investor is permitted to take the discovery and exploit it into an enormous profit, even though the public ultimately gets the benefit of the healing qualities or the medical qualities of the drug, is not that particular investor, that particular contributor to the research and so forth that helped develop it from the private enterprise sector, is he not greatly benefited out of taxpayers' funds by reason of the fact that the taxpayers contributed to the original development?

Dr. SHANNON. Yes, sir. I did not suggest that this discovery be given to a private firm for the full uncontrolled exploitation.

Senator McCLELLAN. But you would recommend such an arrangement as a license or something that would present to him a proper incentive?

Dr. SHANNON. Yes, sir; this I would.

Senator MCCLELLAN. To make the investment?

Dr. SHANNON. Yes, sir.

Senator MCCLELLAN. To further development and to get it on the market?

Dr. SHANNON. Yes, sir.

Senator MCCLELLAN. I am trying to find a middle ground somewhere that is right between everybody.

One other question and I am through, the question of whether you are permitted to testify freely. Are you down here carrying out some administration's theme or department's theme or are you down here talking to us from your own knowledge and exercising your own free judgment, and so forth?

Dr. SHANNON. Senator McClellan, when I cannot answer a question frankly and honestly, I will leave my position in Government.

Senator MCCLELLAN. Well, the charge is made that you folks in Government now are under the command or the direction of the administration and you have got to carry out a singsong theme down here and testify. Is that in any way true in connection with you?

Dr. SHANNON. No, sir.

Senator MCCLELLAN. You have spoken freely your own judgments?

Dr. SHANNON. Yes, sir.

Senator MCCLELLAN. And your own thoughts?

Dr. SHANNON. Yes, sir.

Senator MCCLELLAN. Without any attempt at being restrained or under any inhibition not to talk freely?

Dr. SHANNON. This is correct, sir.

Senator MCCLELLAN. Thank you.

Senator SCOTT. You are under no obligation toward a consensus then?

Dr. SHANNON. Pardon?

Senator SCOTT. You are under no obligation toward consensus?

Dr. SHANNON. Toward consensus?

Senator SCOTT. Consensus, a famous word.

Senator MCCLELLAN. There is one in the administration who hasn't heard of it.

Senator SCOTT. I am glad.

That is all.

Senator MCCLELLAN. Senator Burdick?

Senator BURDICK. Mr. Chairman, I didn't hear the doctor's opening statement, but I will read is carefully.

Senator MCCLELLAN. Senator Fong?

Senator FONG. Yes, Mr. Chairman.

Dr. Shannon, this question has been very confusing to me, and the matter has been brought up on the floor of the Senate, just from the standpoint of the Government taking the patents. Now, judging from your testimony, you reveal some phases of this subject which are very interesting to me. We have two problems here, as I see it. One, when is the patent completed, up to the time the patent is completed and then from the time the patent is completed to the time that the drug is placed upon the market? As I understand it, the HEW says that if we do have funds in the research, and a patent is completed, the HEW, the Government, takes the patent. Is that correct?

Dr. SHANNON. This is generally correct, sir.

Senator FONG. But the problem is not as easy as that, is it, because here we have the commingling of funds as you have noted in some of these cases where private industry and the Government commingle their funds, and then something is discovered and that is patentable.

Dr. SHANNON. Yes, sir.

Senator FONG. Now, at that stage who takes the patent? Who should take the patent?

Dr. SHANNON. If the invention is made by a PHS investigator at an institution having 1 of our 18 institutional agreements, title is left to the institution for its disposition. But this occurs in only a small number of cases.

Senator FONG. Before we get to that, let's get to the point where we have discovered something.

Dr. SHANNON. Yes, sir.

Senator FONG. The thing is patentable. Who gets the patent?

Dr. SHANNON. Generally speaking, if NIH funds have supported the activity, the discovery is reported to the Surgeon General, and if he considers this a significant advance at his discretion he may——

Senator FONG. Take it over?

Dr. SHANNON. He may insist on assignment of that patent to the Government.

Senator FONG. Now, in your opinion, is that equitable?

Dr. SHANNON. It frequently is not, sir.

Senator FONG. Shouldn't there be a plane of equity here?

Dr. SHANNON. Because, as I pointed out, you may have equal support of the scientist, from the American Cancer Society, and from the National Institutes of Health you have identical patent policies, each saying that you must assign the patent to us. And I think that this puts the scientist in a position where he cannot discharge his obligation.

Senator FONG. You say that the balancing of equities here would be preferable?

Dr. SHANNON. I think there should be some way of balancing equity here, a joint decision.

Senator FONG. Yes.

Dr. SHANNON. As to how the patent shall be exploited?

Senator FONG. Roughly speaking, if the Government puts in 75 percent and private industry puts in 25 percent, there should be a balancing of, say, three-quarters to one-quarter, roughly speaking?

Dr. SHANNON. There should be some way of arriving at a realistic assessment of equity; yes, sir.

Senator FONG. In the discussion on the floor of the Senate as to who owns the patent——

Dr. SHANNON. Yes, sir.

Senator FONG. This is the problem which confronts the Senate. But now we go beyond that. Once we have the patent, then to exploit the patent you say that it requires from $200,000 to $400,000 to really put a product on the market?

Dr. SHANNON. Yes, sir.

Senator FONG. And less than 1 out of 10 do succeed.

Dr. SHANNON. Yes, sir.

Senator FONG. Is that correct?

Dr. SHANNON. Yes, sir.

Senator FONG. So, therefore, if you gave everything to one company actually to put a patentable drug on the market, it would cost about $2 to $4 million?

Dr. SHANNON. No, sir. Let me retrace these figures.

Senator FONG. Yes.

Dr. SHANNON. I said that from the time of the development of a patentable entity, that if one used what success one can have there, one will have success in less than 1 out of 10 cases. That was one statement.

I would say that that one successful case that one develops from the time of discovery to marketing, this will cost $200,000 to $400,000. The others may drop along the way and cost substantially less.

Senator FONG. So it may cost probably $500,000 to $1 million?

Dr. SHANNON. I would think that is reasonable; yes, sir.

Senator FONG. Now, here we have another problem, how to exploit it. If the Government hangs onto it and says it belongs to everyone, nobody will get anything; is that correct?

Dr. SHANNON. This is correct, Senator.

Senator FONG. Usually we find that if everybody owns the thing nobody takes care of it.

Dr. SHANNON. Yes.

Senator FONG. You have got to give it to one person and give him——

Dr. SHANNON. Some incentive.

Senator FONG. Some incentive for doing it.

Dr. SHANNON. Yes, sir.

Senator FONG. And now the question is, how many years do we give him?

Dr. SHANNON. On this, sir, I am not in a position to make a specific recommendation.

Senator FONG. So you just can't attack the problem just from the standpoint of who owns the patent?

Dr. SHANNON. No, sir.

Senator FONG. You have to go beyond that?

Dr. SHANNON. And I don't think you can say any given period of years will satisfy all needs, because in certain cases there may be an extraordinarily expensive development that will take an extraordinary period of time, and I think that any rules or regulations that emerge from legislation, Senator Long, from this committee, should provide for some degree of executive discretion, and I think that the basic legislation should deal with principles of action rather than details of action.

Senator FONG. Yes. I want to thank you very much for your fine testimony. I have been educated this morning. I have been the only Republican voting against the industry, and I want to understand the problem very thoroughly. Thank you very much.

Dr. SHANNON. Thank you, sir.

Senator MCCLELLAN. I just want to make this observation. I don't believe it is possible to write a statute that can do equity in all cases except that a discretion, a major discretion be left to those who administer it.

Dr. SHANNON. I would agree, sir.

Senator McClellan. I don't believe you can write a statute that can foresee and contemplate every circumstance attending a patent and the development of it. I think there must be somewhere some discretion left. As you said in some instances maybe you give them 5 years, in another 2 years, in another something else. I don't know all of the factors that will have to be taken into account and I wouldn't attempt to say, but I don't believe we can write a statute so rigid that it would apply to everything and do justice and equity.

Senator Fong. I agree with you there, Mr. Chairman.

Senator McClellan. Thank you.

Senator Burdick. Mr. Chairman, in view of the colloquy you had with my colleague, you say that when everyone has the right to a patent that no one will do anything. Would you elaborate on that?

Dr. Shannon. Well, first I will start by qualifying my comment to Senator Fong.

There are certain things that have such an extraordinary utility in the field of medicine that although everybody has access to it, every pharmaceutical house will attempt to do work on it, and I will mention some examples of these. They are primarily in the antibiotic field. In the case of penicillin, streptomycin, and chlorletracycline, these were wholly new advances where the primary profit to an individual corporate body was to be derived from the extent to which he could refine his processes and make the material more quickly than his competitor. But where the broad use had already been established by the initial observations, we have an example of where everybody had access to the discovery and the licensure, and all of the major pharmaceutical concerns put very substantial dollars into its development. In this case the bulk of those dollars went into process research, and I know this very well because I was in industry at the time. At that time E. R. Squibb & Son—I was director of the Squibb Institute for Medical Research—was the largest producer of penicillin in the country. They were large and had an adequate profit margin because they have very excellent process research. But, at the same time, there were a number of other pharmaceutical houses in it that made this highly competitive.

Now, on the other hand, take a drug that has more limited use at the time it is discovered. Perhaps such a discovery might be made as a result of a series of organic synthesis in a university laboratory, and this is a drug which is shown to have the capability of lowering blood pressure. Well, there already are in existence today a large number of blood pressure lowering agents. No one of these are perfect, but they are good enough to have reduced the mortality rate as a result of high blood pressure roughly 50 percent in the past 5 or 6 years.

On the other hand, many or most of them have fairly serious side effects. Some affect vision, others affect distribution of blood in the body, causing an unstable circulation, and none really gets at the heart of the issue from the standpoint of correcting the fundamental cause of hypertension and truly restores the individual to normal.

Now, from the time that this drug first emerges in the laboratory as a drug that will lower blood pressure to the time that it can

stand up in competition and really be compared effectively with the drugs that are already on the market, this is a period probably of some 3 years' development. And at the initial stage of development one cannot tell whether indeed it will effectively compete with drugs that are already available. In the case of a drug of that sort, for the director of research or the director of development of a given pharmaceutical house to take the gamble and to undertake the development process and undertake the clinical testing and its ultimate establishment as a superior therapeutic agent, an expenditure which in this case would be closer to $400,000 than $200,000, he must be able to show to his board of directors that there is some return in sight.

Now, if this happened to be a relatively simple chemical agent that can be synthesized by any one of a number of pharmaceutical houses, once the use has been demonstrated to be effective, and this becomes known quite generally during the initial stages of a broad clinical exploration, any pharmaceutical house can march in, synthesize the drug and market it in competition with the man who has expended the $400,000 or $500,000 to develop it.

So that unless you can give this man some equity, the chances of him placing his resources at the disposal of this development are very small.

Senator BURDICK. What you are saying, then, Doctor, is that in this field of drugs the American competitive system doesn't work.

Dr. SHANNON. Pardon?

Senator BURDICK. The American competitive system doesn't work as well.

Dr. SHANNON. No, sir; I am not saying that at all.

Senator BURDICK. Well, I mean if discovery X is open to anybody who wants to exploit it, you say it won't be exploited unless one manufacturer or one processor has a special right?

Dr. SHANNON. Sir, I would say that the heart of the American system is the patent system of the United States, and when you administer the patent system so that the innovator, or the man who puts capital at risk can have no assurance of benefit accruing especially to him, you change the financial structure of this industry, so that I do not say that the competitive system doesn't work, but I say that the competitive system has as one of the important elements of it the concept of the possibility of profit as the result of the taking of risk.

Senator BURDICK. What you are saying is that if this discovery is owned by the Government it is available to all?

Dr. SHANNON. Yes.

Senator BURDICK. It won't be developed as well as if some one developer had a special interest in it?

Dr. SHANNON. This is correct, Senator.

Senator BURDICK. Then that does rule out the competitive factor, doesn't it?

Dr. SHANNON. I don't believe so, sir; no.

Senator BURDICK. That is all.

Senator MCCLELLAN. Very well, thank you very much.

Dr. SHANNON. Thank you very much, Senator.

Senator McCLELLAN. In order to accommodate a member of the committee who needs to be at another committee meeting, we are going to skip down and call Dr. John H. Moyer, Department of Medicine, Hahnemann Medical College and Hospital of Philadelphia. We are calling you out of turn in order to accommodate Senator Scott, who needs to be at another meeting as soon as he can get there.

Senator SCOTT. I appreciate it, Mr. Chairman.

Senator McCLELLAN. Sit down, Doctor.

The Chair makes this observation. Apparently our 15-minute rule just simply will not work. I recognize it as quickly as any of you. But we will still undertake to expedite as much as we can, because we do want to hear everybody. As is indicated here at the moment, we are rearranging the calling of witnesses so as to accommodate a Senator who needs to be at another committee, and this afternoon I have to be at another committee so we will do the best we can.

Very well, you may proceed, Dr. Moyer.

STATEMENT OF JOHN H. MOYER III, M.D., PROFESSOR AND CHAIRMAN OF THE DEPARTMENT OF MEDICINE, HAHNEMANN MEDICAL COLLEGE OF PHILADELPHIA

Dr. MOYER. Good morning.

Senator McCLELLAN. You have a prepared statement. Do you want to submit it for the record and highlight it?

Dr. MOYER. Yes; I submitted a prepared statement.

Senator McCLELLAN. Proceed, Doctor.

Dr. MOYER. I am John H. Moyer III, physician, professor, and chairman of the Department of Medicine of the Hahnemann Medical College of Philadelphia. I am a graduate of the University of Pennsylvania School of Medicine, and I am certified for the practice of medicine in Pennsylvania, Massachusetts, and Texas.

Formerly I was professor of pharmacology and medicine at Baylor University School of Medicine in Texas. As evidence of my qualifications supporting my appearance before you, I am certified by the American Board of Internal Medicine, and I am currently president of the American Therapeutic Society; past chairman of the Medical Advisory Board Council for High Blood Pressure Research of the American Heart Association, and president of the American College of Clinical Pharmacology and Chemotherapy. Additional qualifications are available in my curriculum vitae.

Senator McCLELLAN. You have quite a background.

May I ask you do you own any medical patents?

Dr. MOYER. No, sir.

Senator McCLELLAN. Do you have any interest in any pharmaceutical enterprise?

Dr. MOYER. Yes, sir. I own some pharmaceutical stocks, as many other private citizens do.

Senator McCLELLAN. Very well, let's put that in as background too, because somebody may say you have a personal interest in it.

Dr. MOYER. Right.

Senator McCLELLAN. I have nothing to conceal. Let's get it all out in the open and see if we can't find the correct answer.

Proceed.

Dr. MOYER. Being oriented both by training and experience in the field of clinical pharmacology, which embraces the study of new drugs, I should like to make a number of points as to how the proposed changes in Government patent procedures might alter these activities in medical schools such as the Hahnemann Medical College.

I should like to point out at this point that in my presentation I don't mean to get into the legal technicalities of this consideration whatsoever but merely to present my points of view as an academician which I believe gets me out of the patent problem in so far as my own personal interests are concerned.

First I should like to emphasize that the study of new drugs in man is referred to as the science of clinical pharmacology, an emerging scientific field of ever-increasing importance. This involves the administration of chemicals, i.e., new drugs for the first time to patients which requires considerable knowledge and experience on the part of the physician who does this. Of necessity such clinical studies are usually done in academic institutions, that is, the administration of drugs to patients for the first time, where multiple skills are available in the various subspecialties of medicine and which are needed to assure maximum safety to the patient when drugs are used for the first time in man.

I might indicate that, for example, in our department we have subspecialties of endocrinology, clinical pharmacology, vascular diseases, cardiology, and the like. There are some 14 subspecialties represented by separate subsections of our department of medicine.

This collaborative effort in research on new drugs includes investigators who are proficient in basic biochemical information as well as the clinical subspecialties, that is, those who have a comprehensive knowledge of clinical medicine. This resource of trained personnel is an absolute requirement for the development of new drugs, since availability of biochemical agents on the shelves of the pharmaceutical companies is valuless unless the use for such agents can be found for the treatment of specific human illnesses, pointing out the fact here, of course, that biosynthesis is an initial phase of the development of a new drug but certainly is a long shot making the drug available for use in patients.

Senator McCLELLAN. What is that?

Dr. MOYER. The availability of chemical agents is far from the use of such agents in patients for the treatment of illnesses.

Senator McCLELLAN. I follow you.

Dr. MOYER. I think that it is important to emphasize these points because of the great advances in the development of new drugs over the past 10 years which have thrown a strain on the facilities, personnel, and equipment of academic institutions. Although the Federal Government has seen fit to support some of these activities, it has by no means supported the major share of the clinical evaluation of new drugs to date. It is essential that a cooperative program exist between the source of these drugs, that is, industry, and the academic institutions as well as the Government.

I might add at this point that of the drugs being used today, the majority of these were not available in 1950 except for some 12 or 15, perhaps basic drugs. Most of the drugs that were available when I first became interested in research along this line have now been altered in such a way as to be either more effective or entirely new agents for the treatment of disese have been developed.

To attempt an effective program of drug research and development in any other way than this cooperative venture in my opinion disturbs a relationship that has been so important in the medical advances of the past 30 years, and would be to the serious detriment of medical development in the area of patient care and the treatment of human ills.

I take now an example as it involves our institution.

Our Department of Medicine at Hahnemann Medical College initiated more than 100 research projects during the 1964–65 fiscal year. Although the total number of research dollars received from the Federal Government was greater than that received from private sources, the number of individual projects supported by non-Federal sources exceeded those supported by the Federal Government, a large number of these coming from pharmaceutical industries. In fact, over the past 5 years, we have worked with over 30 different pharmaceutical firms, studying different, new drugs. The very fact that one department of a single, medium-sized medical school composed of only 37 salaried physicians has a multiplicity of grants from the Federal Government as well as from industry, indicates the desirability and in fact the necessity of many of our personnel participating in a variety of projects variously supported when new drugs are being evaluated.

In other words, many of our personnel may receive portions of their salary from different sources. Perhaps they are working on one project, as basic project supported by NIH, 10 percent of their time, and then 10 percent of their basic salary is received from the National Institutes of Health.

On the other hand, that same individual may spend a portion of his time working on a new drug which obviously may lead to new development, and, of course, you see immediately the overlap within one individual or one investigator as to source of support.

Furthermore, the flexibility of these funds received from private sources for support of research should be borne in mind, because frequently you can get small grants for a new idea, and this can be arranged for within a matter of weeks, at least no longer than a month in many cases. Whereas the machinery of government is such that the shortest period of time is in excess of a year for support of a new concept from application to funding, at least by the National Institutes of Health. It is obvious then that if a Government patent policy exists claiming rights for the Government from all projects touched by Government money, collaborative research could not exist, and it would probably be impossible for a department, such as ours, to continue in the evaluation of new drugs, because we are supported so heavily from Government that we obviously coudn't forgo Government support. This would then block our participation in the minor area of non-Federal support of our program. Although from an applied point of view our contributions toward the health of our citizens is greater in the latter than in the former.

Since the same individual participates in two research projects, one would obviously have to go if patent procedures militated against this individual participating in both programs.

The source of nearly all new drugs is from private industry, and if industry is not able to bring about this trial of their new discoveries in patients, the results are obvious, I think.

By what I have already stated, I do not wish to indicate that the current status of patent rights as they relate to the development of new drugs should not be carefully evaluated. However, in my opinion, a clear delineation should be made between support received by the academic institution from the Government as research grants-in-aid and moneys received in the form of contractual arrangements for the specific development of new uses or of new inventions, which would include new drugs. The financial structure of most of our academic institutions is such that if the Federal Government claims patent rights for new drugs developed in those institutions receiving grants-in-aid in any form—again I differentiate grants-in-aid versus the contractual arrangements with Government, that is noncontractual research support—then it would make it impossible for most such institutions to continue to excel in the clinical pharmacological area; i.e., the development and clinical trial of new drugs. On the other hand, when support is received from the Federal Government through specific contractual arrangements for support of a research project and patent rights are involved on these specific projects, then the details can be negotiated and drawn up beforehand so that they are well understood by all, and an equitable arrangement can be arranged. This allows the institution to select and delineate and thus avoid conflicts of interests. To achieve these objectives, the right to negotiate must exist and flexibility in such negotiations is required.

The third point that I should like to emphasize, but that actually revolves around points 1 and 2 above, is the great desirability of cooperative venture among industry, the academic institution, the Government, and I think that this is very important. I have a very personal feeling about this, and the cooperative venture between the various personnel involved, the last of which is a commodity which cannot be purchased at any price. For example, it is not uncommon for our academic people who receive part of their support from the Government, part from the institution, and part from private industry, to sit down at the conference table, as representatives of the three parties, not only different representatives but many times the same individual may represent more than one party, to discuss common problems in therapeutic research. This leads to maximum originality and the development of cooperative ideas.

I think we should recognize that to date most developments are cooperative ventures involving many scientific minds. Very few of them result from individual endeavors; it is a team approach rather than an individual any more. Therefore, it would be a blot on our scientific endeavor should it become impossible to continue this cooperative venture, purely because of inept patent rights considerations.

I would emphasize here that monetary considerations which might accrue to the Government or be secured by individual citizens through nonexclusive patent rights would be relatively unimportant as com-

pared to the havoc that would be done through the destruction of the cooperative relationship of highly trained and experienced personnel among academic institutions, private industry, and Government, which presently exists.

Next I might paraphrase here Shakespeare, as to, "Is it not better to allow above-average compensation for an outstanding discovery than not to have discovered at all?"

I should now like to touch on the problem of inventions versus application. The two are not the same as it relates to us. In fact, a medical school's involvements in research, particularly in the field of clinical pharmacology, is primarily related to development and evaluation, and not to discovery and invention.

Nearly all of the pharmaceutical agents which we have evaluated have been developed by private industry as biochemical agents, coming out of major screening programs which would not be feasible in an academic institution. This is when 50 technicians, shall we say, can be set up for a technique of studying a drug which perhaps blocks the contraction of the smooth muscle in the intestine. A thousand drugs are then run through such a screen searching for an effective compound. An academic institution rarely would take on such a proposition. This, of necessity, comes from industry.

Then after the drugs are screened and developed, it becomes our responsibility in the medical schools around the country, based on our knowledge of drugs and their effects on patients, to evaluate their potential properties as therapeutic agents before they are ever given to large numbers of patients. If in this evaluation the drug does have a potential usefulness without undue toxicity, it is then evaluated as to its pharmacodynamics and its effectiveness in the treatment of human ills. That is, it is administered to increasingly large numbers of patients. It should be obivous that confidence must exist between the academic institution and the source of the drug as to the integrity and correctness of information.

Finally, I would like to comment that this whole problem, and I am sure this is not an original statement, is not simple. In fact it is rather complex as viewed from our point of view as a private institution such as ours faces its research problems, especially those related to multiple sources of financial support.

The orientation on patent policy, it seems to me, is now based as far as I can tell, upon equitable interests, and should be continued. I must say even the current NIH policy I think does in a minor way perhaps discourage the development of some new concepts that would be patentable.

For example, when the Government contracts and pay for a specific project, the Government should have the patent right to inventions leading from that project, in my opinion. But where there has been cooperative investment, the rights of each cooperative party should vary according to his contribution. If industry supports 50 percent, or shall we say 33⅓ percent, the institution 33⅓ percent, and the Government an equivalent amount, I should think that the equitable interest would be equivalent to all three parties.

Unfortunately, we cannot express a predetermined formula which spells out the equities of each project. We believe that equitable in-

terests of the contributing parties can only be protected by a flexible policy.

Senator McCLELLAN. Very well, Dr. Moyer, thank you, sir.

Senator Scott, do you have any questions?

Senator SCOTT. Dr. Moyer, I would like to have you give me an answer to this. How can we best achieve the objective of preserving the team effort of the Government and private sectors in developing drugs and medicine? And I mention the alternative, by granting discretion to the Secretary of HEW to acquire or waive patent rights on a case-by-case basis, or by limiting the discretion in favor of granting exclusive rights to the private contractors, or by some other alternative.

What is your conclusion as to what you believe would be the fairest solution?

Dr. MOYER. If I understand you, Senator Scott, you gave me two alternatives. One of them——

Senator SCOTT. One is based on one bill before us and the other is based on the other bill; that is correct.

Dr. MOYER. I do not mean to get into the technicalities of the bills, although I have read them very carefully—in my opinion, the law should be set up so that equitable rights of the participating parties can be honored, and I would see no reason, as of the moment, why the pharmaceutical firm in the development of new drugs would be any different than any other development—shall we say the development of hardware for computerization of research. On that basis, then, I would think that if the Government supported completely, for example, the research of a new drug for the treatment of hypertension, then they should own exclusive patent rights and handle them appropriately.

On the other hand, if the Government supported a research area in part for basic research, and these people finally also participated in the development of a new use or a new agent but that work was entirely supported by industry, then industry supporting that project should have those exclusive patent rights.

I don't know if that is——

Senator SCOTT. It is a difficult question to answer, in any event.

I am trying to recall the testimony of Dr. Shannon as to the advisability of granting a period of exclusivity.

Dr. MOYER. You mean insofar as the length of the patent right?

Senator SCOTT. Yes, I will read it.

Dr. Shannon said:

> One possible solution might be the granting of short periods of exclusivity in such situations—

As he was discussing—

> that is where it is found to be necessary to develop an invention to the point of practical application and there is no other way to obtain the needed industry cooperation.

Would you comment on that?

Dr. MOYER. Well, I would think that this would be appropriate. For example, if the Government did support a new development, a new use, or a new agent, then I would think that they should have the patent rights and they should handle the situation as they can

best develop the new drug. If this is an agent which does not have significant monetary return, then I should think that the Surgeon General, or an agent of the Government responsible for this, should set up exclusive patent rights for a company so that the company in question could get adequate return on their money for the development of this drug.

The development of this drug may require a much greater financial outlay, according to our current Food and Drug Administration requirements, than they did in the past. For example, we may have a chemical agent which we could predict, having used in animals, that it has a certain use for the treatment of multiple sclerosis. If there was such a drug, it would have a limited application. We know that beforehand. So that we couldn't expect to sell this drug for use on millions and millions of patients as we could a drug for the treatment of heart failure. This would have to be recognized, and this would require, I think, some exclusive patent rights or licensing to an individual or company, if the manufacture of the drug were to be feasible. This feasibility, I think, could be financially calculated on the basis of, first, the use of the agent; second, its effectiveness; and third, how much more be required from the toxicity point of view to make this available for the treatment of patients with multiple sclerosis.

With that information, then, you could calculate roughly what would be required, as far as exclusive patent rights are concerned, to let that drug go as an exclusive patent to a company for a limited period of time, say 3 to 5 years.

Senator SCOTT. I gather you feel that unless there is an incentive to industry as contemplated by the patent system generally, it would be most difficult to persuade industry to cooperate in carrying out further development of new discoveries or improvements upon old discoveries?

Dr. MOYER. I speak much as a layman here, Senator, but I can say one thing. If you don't have incentive, either to a group of individuals or to an individual himself, they aren't likely to do very much; is this not correct?

Senator SCOTT. Well, I think it speaks for itself.

Dr. MOYER. So that I think we have to recognize in our system that industry is set up to make money. The board of directors of a company, when they make investments as representatives of the stockholders, and they are obligated either directly or indirectly to take such steps as are needed to make money.

Now, in a particular drug, for example, this drug may not itself reap a large financial return. But the company may have other objectives such as the broad spectrum of available drugs for a certain group of diseases which that company wants to become known for. If given some guarantee that they won't lose money, the company may take on the chore of developing a new drug even though the company knows it won't make much, either. I speak now of drugs with limited sales. Such a drug could be a life saving commodity, even though needed infrequently.

Senator SCOTT. We lawyers have a phrase, where the property of a number of people has been mixed so that it can no longer be identified, we refer, for example, to wheat in the grain bin which belongs to a

number of owners and you cannot tell which owner really has which grains of wheat, and that is known as fungible funds.

Now, here the money contributions to research have in a sense become fungible. You can't really tell which contribution is from private industry, which by the Goverment, is being applied in exact proportion to fundamental research in the fundamental cause and cure of disease, let's say. It seems to me that is one of the most difficult problems to work out in legislation, and I belive you have expressed your views on it, and that is what concerns me just about as much as anything in the bill.

Dr. MOYER. I am in complete agreement with what you said. I think there are two points that I might emphasize. One of them has to do with the current method of NIH support. They do require a breakdown of each basic research project, in which salaries are involved, and require an estimate of that portion of the salary being supported by the Government based on the percentage of time the individual spends on the project. So, if you participate in a research project 10 percent of your time, this is identifiable according to current support as 10 percent of the investigator's salary. Thus any individual receiving part of his salary for the conduction of a Government-supported research project does, in effect, become Government supported. Such an individual working part time for a drug house on a new drug would jeopardize the patent right for that company. As you can see, this would preclude any investigator who receives partial salary support from his Government research project from doing investigation on new drugs for private industry.

Another point I would make is that there is no great difficulty, when you are supporting a specific research project, in identifying the priority of patent rights. But frequently from parent research projects come a number of throwoffs which are merely ideas, and I don't think you can ever corner the market on these. Just like I can't control your ideas and what you think about what I might present to you, so I don't think that you could ever confine by legislation the ideas and concepts of an investigator, irrespective of his support.

Senator SCOTT. That is all.

Thank you, Mr. Chairman.

Senator MCCLELLAN. Senator Burdick?

Senator BURDICK. Just one comment to make concerning your colloquy with Senator Scott.

You say that the incentives of a group and the incentive of the individual himself is very important.

Dr. MOYER. Yes, sir.

Senator BURDICK. I noticed you have on your staff 37 salaried physicians, according to your statement on page 3. You must have a considerable number of scientists on your staff also.

Dr. MOYER. I hope they are all scientists.

Senator BURDICK. I mean you have some that are categorized as physicians that are probably Ph. D.'s in some field of science, too.

Dr. MOYER. In that group I think there are only four or five Ph. D.'s. The others are M.D.'s, and I would say that all but two of these fellows participate in research projects. The reason those other two do not is their primary responsibilities are organizing our medical school teaching programs.

Senator BURDICK. This statement intrigues me. Here you have a group of men who spend a large part of their lives in training their minds in this field. We talk about commingling Government money. We talk about commingling industry money. But we forget entirely about the human element here, the idea that comes out of that human mind.

Dr. MOYER. Right.

Senator BURDICK. Does your institution ever give any patent rights to that scientist who himself finds the discovery?

Dr. MOYER. We have an arrangement with Research Corp. I can't give you the exact details, but it goes somewhat as follows: If the investigator gets an idea, and we have had three such cases occurring in my department in the last 4 years, if an investigator get a new idea which he thinks can be patentable, then he comes to me. Of course, not being knowledgeable in the details of these things, I send him up to President Cameron, who is responsible for this sort of thing, as far as our institution is concerned. The institution then has this reviewed by Research Corp., and, if it is decided by this more knowledgeable group that this indeed should be followed up, then an arrangement is made with Research Corp. in which they get a monetary return on the net proceeds; i.e., the royalties. The institution receives an amount, and they in turn can arrange with the individual investigator so that he receive some of the royalties. In fact, this happens to be President Cameron's policy. When an individual would, in fact, become responsible for the development of a new agent or a new use would come to fruition, then the individual would benefit in part from that development.

Senator BURDICK. Have any of your doctors or professors benefited so far from your research contracts?

Dr. MOYER. No, sir. There is one pending that could potentially develop.

Senator BURDICK. But your opinion is that, if the project is identified as a Federal project totally, then the patent right should go to the Federal Government?

Dr. MOYER. Yes, sir. I am removing the individual investigator, as referred to above, from consideration.

Senator BURDICK. It is only in this case where the interests and efforts are mixed where you think there should be some equitable solution?

Dr. MOYER. Yes, sir.

Senator BURDICK. Thank you.

Dr. MOYER. And I might add that I am particularly interested in our basic support. I mean I am particularly concerned that finances coming in for basic research, in which this comes into the same institution or same unit in the institution, the same department or even to the same individual who might also be working on developmental type research, that the fact that he receives support from the Government for his basic research does not prohibit his also participating in applied research; that is, the bringings of new drugs to fruition and use in the treatment of patients.

Here I think is the real potential harm, because, while the Government itself is trying to develop clinical pharmacology units, I can see

a barrier being set up in which, unless the whole industry was socialized, would block industry from having their drugs studied in any institution receiving this type of Government support.

Senator BURDICK. Thank you.

Senator MCCLELLAN. Thank you very much, Doctor.

Dr. Sprowls and Dr. Bliven, will you come around, please?

Gentlemen, will you identify yourselves and proceed?

I believe you have a statement. Is it a joint prepared statement?

STATEMENT OF JOSEPH B. SPROWLS, CHAIRMAN, EXECUTIVE COMMITTEE OF THE AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY; ACCOMPANIED BY DR. CHARLES W. BLIVEN, EXECUTIVE SECRETARY

Dr. SPROWLS. Sir, I have a statement which I am presenting for the Executive Committee of the American Association of Colleges of Pharmacy.

Senator MCCLELLAN. Very well, you may each identify yourselves for the record, and then proceed.

Dr. SPROWLS. I am Joseph B. Sprowls. I am professor of pharmacy and dean of the Temple University School of Pharmacy, and a registered pharmacist in Pennsylvania, Colorado, and New York.

I have been a teacher of pharmacy for nearly 30 years and have held full-time faculty status in three universities: the Universities of Colorado, Buffalo, and Temple University. I appear here as the chairman of the executive committee of the American Association of Colleges of Pharmacy. This is an elective position.

I have with me Dr. Charles W. Bliven, executive secretary for the association and formerly dean of the School of Pharmacy at George Washington University.

Senator MCCLELLAN. That identifies both of you sufficiently.

You may proceed.

Dr. SPROWLS. All of our 74 member colleges are engaged in scientific research, much of which derives some support from Federal granting agencies and some of which derives support from private sources, including industrial laboratories. Our interest in patent legislation derives from the research efforts of our member institutions.

We commend the Congress for its interest in new patent legislation, because certain clarifications are needed both for the protection of the proper interest of the public and for the clarification of the rights of inventors when public funds may have been involved in some phase of the development process.

We believe that the protections afforded by the present patent system to the inventor or the primary developer of a new and useful concept are quite important both because they help to stimulate the investment of private capital which provides major and essential support for the research and development efforts in our country, and because they provide the incentive for the initial production and distribution, without which the benefits of invention can never reach the ultimate consumer. We submit that these incentives are important in furthering the development, testing, and production of pharmaceuticals as well as all other useful products. We feel, therefore, that the best

interests of the public will be served by legislation which is neither discriminatory nor confiscatory and which permits an equitable arrangement for patent ownership with institutions which have made major contributions to patentable discoveries.

We believe that preemption of rights to inventions by the Federal Government should take place only in unusual instances where national security, public safety, or the health of the public demand, or when Federal funds have contributed in a major way to the development of the invention.

While research in academic institutions is not ordinarily undertaken with patent motivation in mind, it is, nevertheless, true that one of the benefits which occasionally derives from such investigation is an invention which has widespread utility or applicability. When such inventions do arise, it is usually necessary to secure a patent in order to obtain the interest of organizations which are equipped to produce and distribute products and to thereby make the benefits of the invention available to the public.

We would point out that many educational institutions have adopted policies which are designed to prevent abuses of the patent system and which provide for an equitable distribution of benefits between inventor and parent institution. In many instances provision is made for a considerable portion or all of the royalties collected on a patentable invention to be utilized in the support of further research. In general, these policies are designed to preserve the unselfish approach of the investigator as well as the public-spirited philosophy of the university.

We believe that some of the legislative proposals now under consideration do not provide proper recognition for the contribution which the institution and the investigator may have made in a particular instance. One proposal suggests that if any portion of the support has come from Federal sources, patent rights may be assumed by the Federal agency. Yet the particular research project may be the culmination of many investigations carried on by a scientist or his department. Furthermore, concepts do not usually emerge from a single research project but may represent the product of many investigations and a great deal of study and preparation on the part of the investigator. We believe that it is in the best interest of the public to make certain that contributions of institution and researcher are recognized in the assignment of patent rights.

The colleges of pharmacy have a particular interest in research which is related to public health, in particular that phase of research which is directed toward the development of new therapeutic agents. This research is often supported by, and/or coordinated with, research conducted by pharmaceutical manufacturers. For example, an investigator may synthesize a new drug, but he is usually in no position to carry it through the development and production procedures which are necessary before it can become available for public use. In fact, the university investigator is and should be more interested in the basic phase of the research, not in its application. Many departments have solved this problem by making arrangements with a pharmaceutical manufacturer for the conduct of the testing and development procedures. The preliminary screening of drugs is normally done

without charge by such companies in order to assist investigations in which they have a particular interest or capability. Passage of legislation such as section 4(a)(2) of S. 1809 would greatly lessen the probability of such cooperative arrangements. In fact, member colleges have already encountered difficulty in making arrangements for the testing of drugs when Federal funds have been involved in the research leading to their discovery. Unless a more equitable policy can be formulated, we foresee the development of a barrier between industry-university research which we believe is undesirable and not in the interest of the health of the public.

Approximately 75 percent of the financial support for research in member colleges now comes from Government sources; thus, we can conclude that more than half of all projects have been supported to some extent by Federal funds. It is unlikely that industrial laboratories will be interested in cooperating with such projects if it will be impossible for them to recover investment or to insure continued funding of operations through the marketing of a patent-protected invention. We believe that it is in the interest of progress to encourage cooperation between industry and university with the understanding that the university is primarily concerned with basic research, the industry primarily with its application.

Such considerations lead to the conclusion that section 4(a)(2) of S. 1809 should be modified in such a way that inventions in the health field may be treated in the same manner as inventions in all other fields. In this way the incentive to bring promising inventions from the research laboratory to the public as completely tested and fully developed dosage forms will be accomplished in an expeditious and efficient manner. Thus will the best interests of the health of the public be served.

Dr. Bliven and I appreciate the privilege of being heard on behalf of the American Association of Colleges of Pharmacy and we will be pleased to answer questions.

Senator McCLELLAN. Is that the only objection you have to S. 1809?

Dr. SPROWLS. Sir, we feel that 4(a)(2) is somewhat ambiguous.

Senator McCLELLAN. Which one?

Dr. SPROWLS. 4(a)(1) is somewhat ambiguous, also, but we were primarily concerned with the matters relating to public health and the possible interpretation of this in terms of pharmaceuticals.

Senator McCLELLAN. What would you suggest in lieu of subsection 4?

Dr. SPROWLS. I would suggest something along the line——

Senator McCLELLAN. Have you got any language you would suggest?

Dr. SPROWLS. I might say, Senator, I am not a lawyer. I, too, am a technician. I can only speak in——

Senator McCLELLAN. I am not trying to argue with you.

Dr. SPROWLS. No, I understand. I was just going to say that I couldn't possibly give you the proper language. I can only give you a philosophy. I believe that 4(a)(2) could be interpreted to mean that all drugs, or the patent to all drugs, must pass into the hands of a funding agency, of a Government agency, if there was any Federal funding involved, and if this is what it means we believe that it should

be modified so that an equitable distribution of the patent rights could be made.

I am not prepared to give you exact language, but I am prepared to state my philosophy about it.

Senator McCLELLAN. Have you any comment as to the other bills before the committee?

Dr. SPROWLS. I think, sir, that the language as contained in S. 2326 in this section is somewhat better.

Senator McCLELLAN. This is a bill that has just been introduced?

Dr. SPROWLS. Yes.

Senator McCLELLAN. I haven't had an opportunity to study it. You would suggest the language in——

Dr. SPROWLS. I think the language in S. 2326 is——

Senator McCLELLAN. You mean on page 5?

Dr. SPROWLS. Yes.

Senator McCLELLAN. Section 4?

Dr. SPROWLS. Yes. I think it is more explanatory.

Senator McCLELLAN. You think that language is better and preferable to the same section, section 4 of S. 1809?

Dr. SPROWLS. I think that in general it is somewhat more understandable.

Senator McCLELLAN. You may be correct in that. I wouldn't argue that.

I would like to get any specific suggestions that you folks have, because we might very well overlook something which you technicians would immediately recognize as being defective or not actually accomplishing what the author would like to accomplish or what the committee might like to accomplish.

Dr. SPROWLS. Much of what I would like to say was said by Dr. Shannon and by Dr. Moyer to the effect that we must have an equitable arrangement of some kind to recognize that many contributions have been made in the average invention. The institution has made a contribution. The inventor has made a contribution. The Federal funds represent only a part of the contribution, and if the patent is to become exclusive property of the Government I foresee all of the difficulties which were mentioned by Dr. Shannon with respect to bringing that invention to the ultimate users.

Senator McCLELLAN. Thank you very much.

Senator Scott, any questions?

Senator SCOTT. No, I have no questions.

Senator McCLELLAN. Senator Burdick?

Senator BURDICK. I am quite amazed at your statement. You say based upon—what do you call it, philosophy?——

Dr. SPROWLS. Yes.

Senator BURDICK (continuing). That you don't feel that public money spent for public-health discoveries made thereunder should belong to the public.

Dr. SPROWLS. I don't believe that I said that, sir.

Senator BURDICK. Well, that is what 4(a)(2) refers to, directly concerned with public health.

Dr. SPROWLS. Well, I hope I haven't said that we should give no consideration to the funds spent by the Government.

Senator BURDICK. I said should have exclusive rights for the expenditure of Government funds on public health. You say no.

Dr. SPROWLS. I say we must have an equitable arrangement which recognizes the contribution made by an institution or by an individual or even by a second funding agency.

Senator BURDICK. Even when it affects public health?

Dr. SPROWLS. Yes; certainly.

Senator BURDICK. That is all.

Dr. SPROWLS. I believe that we serve the best interests of the public health by making certain that these inventions come to the public.

Senator SCOTT. Mr. Chairman, may I make one comment here with all due respect to my colleague?

I might point out an illustration where the Government spends a good deal of public money where the benefit of the money is not controlled by the Government, where the Government has very little to say in the final analysis as to how it is spent, and that is in the present poverty program.

Senator MCCLELLAN. Very well. Thank you.

Mr. McKie?

Mr. McKie, please identify yourself and then you may proceed.

STATEMENT OF EDWARD F. McKIE, JR., ON BEHALF OF THE AMERICAN BAR ASSOCIATION

Mr. MCKIE. I am Edward F. McKie, Jr., an attorney in private practice in this city. I am here on behalf of the American Bar Association of which I am the vice chairman of its section on patent, trademark, and copyrights.

I do not appear here on behalf of any client, but rather only for the association in support of the beliefs which I hold in common with the association as to what is in the best interest of the public in this area.

I do have a printed statement, Senator, which I think you have a copy of. I would ask that it be printed in the record, but I do not intend to read it. I would prefer rather to highlight it.

Senator MCCLELLAN. Very well, your statement may be printed in the record in full at this point, and you may highlight it and make such other comments as you wish.

(The prepared statement referred to follows:)

STATEMENT OF EDWARD F. MCKIE, JR., ON BEHALF OF THE AMERICAN BAR ASSOCIATION, WITH RESPECT TO S. 2326 BY SENATOR DIRKSEN, RELATING TO GOVERNMENT PATENT POLICY

I am Edward F. McKie, Jr., in the private practice of law in Washington, D.C., specializing in the field of intellectual property. I am the vice chairman of the Section on Patent, Trademark, and Copyright Law of the American Bar Association and the chairman of the committee on legislation of that section. I appear here on behalf of the American Bar Association to supplement the testimony of Tom Arnold, now past-chairman of that section, delivered to this subcommittee on June 2, 1965, in respect of several bills dealing with Government patent policy. At that time Mr. Arnold explained the reasons of the American Bar Association for opposition to the various bills then pending. Since that time Senator Dirksen has introduced S. 2326 which is consistent with the beliefs of the American Bar Association as to an equitable and effective Government patent policy in the public interest. We, therefore, asked for an opportunity to appear again before

this subcommittee to supplement the testimony given by Mr. Arnold on June 2, in order that we might express our positive approval of the principles embodied in S. 2326.

To supplement only, because Mr. Arnolds' testimony is as well applied in favor of the distinguishing characteristics of S. 2326 as it is against certain features of the other bills now being considered by this subcommittee. The principal features of distinction between S. 1809 (McClellan) and S. 2326, as emphasized by Senator Dirksen in introducing the bill, are the following:

(1) Under S. 2326, no citizen of the United States could be deprived of a royalty-free license in any patent owned or controlled by the United States; and

(2) Under S. 2326, the Government can require an interest greater than a royalty-free license only in certain limited situations where the public interest justifies it.

Referring first to the second feature of distinction, it should be recognized that nearly all governmental research and development contracts may involve in some way the public health, welfare or safety. S. 1809, in its requirement for acquisition by the Government of the exclusive rights in any invention made in "exploration into fields which directly concern the public health, welfare, or safety" therefore raises the strong possibility that ownership by the Government of the right to exclude the public from the use of most inventions made in Government-sponsored research would result. Particularly when it is appreciated that many inventions are made as byproducts of the research being undertaken, and not as the object of that research, the result of Government ownership in such a high proportion of cases is believed inequitable.

The most important distinction of the Dirksen bill, however, resides in the limitation which it provides on use by the Government of the right to exclude granted by patents. This limitation is founded on the belief that the Government should never be permitted to take the exclusive right to an invention for the purpose of excluding its citizens from the practice of that invention. Rather, in the event it takes that right, it should be only for the purpose of preventing exercise of the exclusionary right to impede the free use of the invention by any citizen of the United States.

The consequences of the Government acquiring and enforcing against its citizens the right to exclude have been well brought out by Mr. Arnold and need not be repeated. However, his point that the patent right is not the right to use an invention bears repetition for it is so seldom appreciated. It must be realized that, no matter who takes title to the patent rights on inventions arising from Government-sponsored research, the Government will have the right to use those inventions. The patent right cannot control that use, though it can control use of the invention by nongovernmental entities. Its acquisition by the Government can give rise to Government control over private industry to an extent now impossible unless the implementation of that right to exclude is foreclosed by the Government.

The American Bar Association believes that S. 2326 is in accord with principles which it believes are in the best interest of the public. It therefore recommends enactment of that bill, or at least amendment of S. 1809, in the respects by which the Dirksen bill differs therefrom.

Mr. McKie. Thank you, sir. Of course, the American Bar Association has already appeared in these hearings on June 2 in the person of Tom Arnold, who at that time was chairman of our patent section. The reason for requesting to reappear is that at that time Mr. Arnold testified in the negative, essentially, with respect to certain of the bills that were then pending. That is, he criticized some aspects of these bills.

In the interim a bill has been introduced by Senator Dirksen, S. 2326, which is the other side of that coin. It is the positive approach, which is based on the principles which Mr. Arnold expressed. For that reason we asked to come back and explain our reasons for being in favor of the Dirksen bill.

There are two prime differences between the Dirksen bill and S. 1809, upon which of course it was primarily based. Those two dif-

ferences are in respect of Government ownership in the area that was just pointed out by the last witness, that is with respect to section 4(a)2 of S. 1809, that is the field of public health, welfare, or safety, and the second aspect is in respect of what the Government shall do with whatever patent right it has.

We feel that 4(a)2 is so broad that much if not most of the Government research money could be said to be spent in furtherance of the objectives of public health, welfare, or safety, and that as a result much of the patent rights on inventions developed by Government research and development money may go to Government.

Remembering that the patent right is the right to exclude and not the right to use at all, we are concerned about the use of this right to exclude by the Government to foreclose its citizens from the use of inventions developed with public money. So that these two principles are intertwined.

We think that section 4(a)2 is somewhat too broad in this respect, and prefer the approach expressed in the comparable section of the Dirksen bill in that area. Also we think that the Government should not attempt to exclude its citizens from the use of inventions made under the support of public money.

Senator McClellan. What do you mean exclude them from it? We are trying to find a way to get the inventions out to the users, the consumer, for the benefit of the public.

Mr. McKie. Right. The patent right is the right to exclude, however. We think that the Government has no need to have that right to exclude.

Senator McClellan. In other words, the Government shouldn't take the patent?

Mr. McKie. That is right.

Senator McClellan. That is what you are trying to say.

Mr. McKie. In general that is right. In general I think that is true, Senator. There are some areas in which the Government may feel that it should have the right to exclude, and these are also comprehended by the Dirksen bill.

Senator McClellan. Let me ask you this question. You name the disease. Suppose that you haven't found a cure for it yet, and the Government goes to some institution or pharmaceutical research center and says, "We want you to concentrate on this. We will give you a contract. Here is the money. We will finance it. Spend what you need until you find a drug that will be beneficial in the treatment of this particular disease. It will be a cure for it."

And that institution or that pharmaceutical house does that. The Government puts all the money in there. Do you not think the Government then should own the patent?

Mr. McKie. No; except in limited circumstances.

Senator McClellan. Do you think the private sector should own it?

Mr. McKie. Yes; that is right, Senator. I think for the reasons——

Senator McClellan. Even though the Government's money paid for all of it?

Mr. McKie. That is right, Senator. I would again emphasize that this is the right to exclude. It is not the right to use the invention that we are talking about. The public is going to have whatever benefit is derived out of the discovery of this invention.

Senator McClellan. I don't know. There is some testimony here to the contrary. You discover an invention and then unless someone processes it, and unless somebody refines it and tests it and experiments with it to bring it to that stage of human use and human benefit, there is no benefit.

Mr. McKie. That is another aspect of the same thing I think, Senator.

Senator McClellan. It is part of the same thing, I know.

Mr. McKie. Yes.

Senator McClellan. All right.

Mr. McKie. I think we are talking about a number of different things intermixed here. One, and I would like to emphasize this, the patent right is not a panacea. This is not the thing that causes all inventions to come to use by the public. It is one aspect only.

Senator Long, in some remarks on the Senate floor, has referred to a number of inventions that were brought to use by the public without any patent rights whatsoever. There are such inventions. This was indicated today also by other witnesses.

However, there are some inventions, we think a number, in which the patent right, the right to exclude, is important to give an initial period of protection. Now in such case we think that the person who should get that is the person who discovered the invention, or his assignee.

Senator McClellan. I think I agree with you on this. Where the Government under the conditions I have illustrated, a discovery is made and it is patented, at that stage I would think that the Government should own that patent, if all of the investment that went into it was taxpayers' money. I may change my mind about this, but as of now I am under that impression.

Now the thing is patented, that is the idea is patented, so to speak. But from there on there has to be risk capital or investment as has been testified to here, of from $200,000 to $400,000, and even may be much more, before it can be developed and tested and refined and put into a process for marketing.

Now to get that done, the Government is not in a position, it doesn't have the facilities, then why shouldn't it make a contract with someone who is in a position to do that, to take the risk and give it some incentive in the way of a license for a given number of years, an exclusive license for a given number of years or a requirement to license to competitors at a fixed price or some fixed consideration, to make certain that the benefit actually flows to the public.

Mr. McKie. Let me answer that this way if I may. That I think necessitates the willingness of the Government to sue its citizens for infringement of its patents, because you cannot force people to take a royalty-bearing license unless you are willing to sue infringers.

Senator McClellan. I think the licensee would be the one probably to bring the suit.

Mr. McKie. Well, he would have to bring the suit with the use of the name at least of the patentee under our present law.

Senator McClellan. It would be the infringement of a license granted by the Government as well as a patent granted by the Government.

Mr. McKie. Technically no, Senator. You would infringe a patent but you would not be infringing upon a license. If, however, an exclusive period should be granted, it seems to us that it is preferable that it be granted to the person who has an interest in the invention initially.

Senator McClellan. I would agree with that. I agree that the choice preference should go to him who developed the invention.

Mr. McKie. Then I think we are going around the barn to come back to the other side.

Senator McClellan. It may be.

Mr. McKie. If you leave the right originally with the person who made the invention, he has the most interest in that invention of anybody in the world at that particular time, he is more likely to bring the invention to the public and exploit it.

Senator McClellan. I agree with that. There is, and I can't get away from this, an equity on the part of the public where the Federal Government takes tax money and supports in this instance as I illustrated, provides the full financial investment necessary to bring about the invention. Now I think the public has some right in it.

This firm was paid to do a job. It did the job. It got paid for it. Now I agree with you that possibly it should have some preference in the arrangements made then for the further refinement and processing of the idea.

Mr. McKie. I agree with your statement, Senator, but let me point out that the public money is being spent not to develop the patent, but to develop the invention itself.

Senator McClellan. That is right.

Mr. McKie. Now if there is a need for the use of the patent to encourage the development, then it seems best that the patent ought to be in the person who made the development itself and not go to the Government and come back.

Senator McClellan. We come back to this point. Here is the Government that places one firm or one research institute or one private enterprise in a position to greatly profit at the expense of the taxpayers for a part of it that was developed primarily for the benefit of the public at the taxpayers' expense.

Mr. McKie. Well now, there must be a profit involved or else the product won't be produced, of course.

Senator McClellan. That is right, but that profit, should it go exclusively to one, or that opportunity for profit be made available to others in the same enterprise?

Mr. McKie. If it is, I think it should be available equally to all. That is if the Government owns the patent right, the right should be used in such fashion that everybody has a chance to use it.

Senator McClellan. Perhaps that would be true except for this. Again we come back to this. You are not sure it is going to work. You have got the patent. But you are not sure that it is going to work. Somebody has got to take the risk of an investment of $400,000 or $500,000 we will say, in order to determine that it will work, and after that expenditure, it may develop that it is not practical and not useful, and therefore all of the money invested has gone down the drain.

You say it ought to be equal, should the Government get the patent, and you say to everyone, "Here is the development, go ahead and develop it." Would anybody develop it?

Mr. McKie. In some cases yes, in other cases no, without exclusivity by reason of the patents.

Senator McClellan. Would the public interest suffer by reason of nobody doing it?

Mr. McKie. It is quite possible that it would; yes. In some cases, of course, certain products are on the market that shouldn't be there at all.

Senator McClellan. I come back to this. Anybody who says this whole thing is simple——

Mr. McKie. You are right, you are very right, Senator McClellan. But there was one other point.

Senator McClellan. I am not sure what is simple when you say this is simple.

Mr. McKie. There is one other point I would like to bring out. There are many inventions that are made under support of Government money which are not the objects of the contracts themselves. They are incidental to the contract. They may be due primarily to the background of the contractor, for instance, whether or not it is in the public health and safety field. Those inventions I think should be treated differently than others, and I am speaking only for myself in this area.

Senator McClellan. I think there are areas where that is true, and that is why it is so difficult to write a statute here that would give equity.

Mr. McKie. I think you can make a distinction in respect of the object of the invention. If you take your illustration, in which the Government is granting a great deal of money to someone to come up with a cure for a disease, now that invention of the drug that cures that disease might be in one category. However, all inventions made incidental to that contract, such as a new process for synthesizing a a new drug or a new component that must be used to arrive at that drug, I think that could well be in an entirely different category.

Senator McClellan. Very well, go ahead. I did not mean to interrupt you too much.

Mr. McKie. Let me point out further that with respect to the possible——

Senator Burdick. Mr. Chairman.

Senator McClellan. Senator Burdick.

Senator Burdick. Before we leave this field of inquiry, I would like to ask a question. My question would be very similar to the chairman's, to be perfectly frank. But I want to add another facet to this argument.

If we were to follow your suggestion, and give patent rights to an individual firm where all money has been expended by the Federal Government in making a discovery, what would happen if that firm sat on its patent and did nothing? What recourse would the Government have, or any other individual have, to process it? Suppose they did nothing, and that is not unusual, to do nothing.

Mr. McKie. Under S. 2326, the Dirksen bill, there would be a right to apply for compulsory license after a limited period of exclusivity. That is, nobody could suppress an invention within the provisions of this bill.

Senator Burdick. What is the period under that bill?

Mr. McKie. Three years; 3 years after the invention is made.

Senator Burdick. But they could sit on it for 3 years at least.

Mr. McKie. That is possible. It is very unlikely that such would occur.

Senator Burdick. If the Government had it and there wasn't any action, they could give a license to someone else.

Mr. McKie. That is right, but I think S. 1809 provides for the same period of exclusivity, if I am not mistaken.

Senator Burdick. That is all.

Mr. McKie. Thank you, Senator. I was about to refer to the profiteering aspects of this, and this is in the same area actually as you have just brought out.

Under S. 2326, it would be impossible for a contractor who had a patent right by reason of Government research and development money to profiteer to an unconscionable extent in this area, because of the compulsory licensing aspects of the bill. It would be possible then for a competitor to come in and ask for a license, and if he could prove that he was capable of satisfying the need, then he could get a license within the provisions of S. 2326.

Senator McClellan. Anything further? Thank you very much.

Mr. McKie. Thank you very much, Senator.

Senator McClellan. Dr. Barr, will you come around, please? Will you identify yourself, please, sir? You have a prepared statement.

STATEMENT OF JOHN A. BARR, DEAN, SCHOOL OF BUSINESS, NORTHWESTERN UNIVERSITY, ILLINOIS

Mr. Barr. I have a prepared statement. I will read it, and I can do it well within the 15 minutes, Senator. I might say I am not a doctor.

Senator McClellan. I beg your pardon. I see you are a dean. I apologize. Some lawyers are doctors.

Mr. Barr. My name is John A. Barr. I live at 790 Sunset Road, Winnetka, Ill. I am dean of the School of Business at Northwestern University, Evanston, Ill.

I have held this position only since June 1 of this year. For approximately 30 years prior to June 1, I was associated with Montgomery Ward & Co., and was chairman of the board of directors of Montgomery Ward for the last 10 years of that period.

I was a trustee of Northwestern University for 8 years prior to June 1, and served as a member of the trustees' patent committee for 5 of those years. I was chairman of the patent committee for 4 years.

As chairman of the trustees' patent committee, which is responsible for the university's patent policy, I had occasion to consider various problems involving patent rights in relation to research at the university. I also had occasion, from time to time, to consider the

Government's patent policy, particularly as it related to work at the university.

In my present position as dean I have a direct interest in the resources available to support the research and teaching activities of the university, and I retain a direct interest in the patent field as a member of the patent committee of the faculty.

In my testimony today I will limit my remarks and observations to the experiences and interests of Northwestern University. I believe, however, that the interests, experiences, and concern of Northwestern in this field are fairly representative of the interests, experiences, and concern of many other institutions of higher learning.

The direct objectives of the university are effectively to teach the students who come to us, and to advance the frontiers of knowledge.

The university is interested in research because research is important to the fulfillment of both these objectives. Research as a general rule, is the source of new knowledge, and research contributes to the vitality of the faculty and to the effectiveness and fullness of their teaching.

The Government also is interested in research because the development of new knowledge and the stimulation generated by research are important to the growth of the economy, to the public health and welfare, and to maintaining a competitive position with, and hopefully a competitive advantage over, the nations on the other side of the curtain.

There appear to be many similarities between the interests of the Government and the interests of the university in the field of research and the related field of patent rights. The interests of both would be harmed by any curtailment of research activity; the interests of both are basically noncommercial; and the facilities and resources of neither should be dedicated to advancing the private interests or competitive position of any particular entrepreneur.

Because of this, I thought it might be of interest and helpful to you in your deliberations of how best to protect and advance the public interest, so far as the patent policy of the Government is concerned, if I told you something about our experiences with patent policy and patent rights at the university.

To satisfy its need for research activity the university relies on research grants from both the Government and from private industry. This necessarily raises the question of how patent rights should be treated as between the university on the one hand and the grantor of funds on the other.

Our patent policy at Northwestern for many years provided that the title to any patent of discoveries resulting from research performed at the university must rest with the university and that exclusive licenses would not be granted to any sponsor. There was no way for any commercial firm to secure patent or exclusive rights arising from research at the university, regardless of the nature or extent of their sponsorship. The university was motivated by a desire to avoid any possibilty of its facilities or resources being used to advance the competitive interests of any individual company.

Two cases which the faculty presented to the trustees' patent committee last year illustrate the type of problem which arose under this policy and which led to a liberalization of the policy.

In the first case, company A asked a faculty member to undertake a research project in the field of engineering. The company offered to pay the full cost of the project in return for any patent rights which might arise from the research involved. The university rejected the offer because of the policy provision that all patent rights arising from research at the university must accrue to the university. The university offered only to grant a nonexclusive license to the sponsor to use any discovery which might result from the research. The company stood pat on its original offer. Understandably, it did not feel justified in investing several thousand dollars in the project if any resulting discovery would be equally available to its competitors.

The faculty was unhappy with this result because they felt the proposed project to be worthy basic research which might produce new knowledge and which, in any event, would be of scholarly value to the faculty members and graduate students involved.

The second case arose in the chemistry department where basic research results in the development of dozens of new chemical compounds each year. These compounds are synthesized in the course of basic research studies with no thought of possible commercial exploitation. The university does not know, and has no facilities or resources for ascertaining, whether any of these compounds have practical value. Some of these compounds might have great value, such as a drug to be used in the treatment of disease, or as a pesticide or fungicide or weed killer for use in agriculture. There is no way to determine whether any of these compounds are of practical value except by extensive testing at substantial cost.

In this setting, company B approached the university and offered to test a number of these new compounds to determine whether they were of practical value. Company B was prepared to spend a substantial sum of money for this purpose if the university, in turn, would grant to it an exclusive license to produce any of the compounds found to have commercial value. The university was forced to reject the offer because of its policy against granting exclusive rights to any one company. The practical result of this position was prevention of any determination of whether any of the compounds would be useful or beneficial to society, and precluded any commercial development which would have made any such benefits available to society. While the university's position was, in itself, quite proper from the standpoint of intellectual independence and freedom from commercial exploitation, the result was not in the public interest. No one could say that one of these new compounds sitting on the shelf was not a valuable lifesaving drug.

As a result of these and similar experiences, the university's trustees amended the university's patent policy last year to permit the granting of exclusive licenses or the assignment of patent rights to commercial sponsors of research, and to others, in specific cases approved by the patent committee.

I relate these university experiences to you because I believe they are relevant to your consideration of what the Government's patent policy should be.

Consider, for a moment, the last case which I related. Suppose that the research which resulted in the development of these new

chemical compounds had been partially financed by a Government research grant, and suppose the Government's policy was to require that all patent rights arising from research involving use of any Government funds must be vested in the Government. Would not the practical result be the same as it was under the university's old restrictive policy? The compounds would gather dust on the shelf, and the public would never have an opportunity to enjoy the benefits they might hold. The university does not have the facilities or resources to test the compounds to determine their value to society. And the commercial companies who do have the facilities and competence to test, develop, and market the compounds would, as a practical matter, be precluded from doing the job by a Government policy which denied them rights of exclusivity which are properly necessary to justify their risk of investing funds in testing compounds of unknown value.

I believe that this experience with company B, which is representative of other similar experiences, demonstrates the fact that in any determination of Government patent policy, provision must be made for granting adequate privileges of exclusivity to a commercial firm which assumes the risk of testing and developing discoveries of unknown value, even though the research which produced the discoveries was partially financed by the use of Government funds. Otherwise, many such discoveries would never be tested and their benefits never be made available to the public.

Senator McCLELLAN. May I interrupt to inquire if this policy would apply in fields other than drugs or chemicals?

Mr. BARR. I think it would apply in any field.

Senator McCLELLAN. In any field?

Mr. BARR. In any field.

Senator McCLELLAN. The same principle?

Mr. BARR. Yes.

Senator McCLELLAN. In other words, you might very well deprive the public of the use of many instruments of great value and convenience if the Federal Government just simply took the patent and said it is available to anybody?

Mr. BARR. Anything which is worthy of patent is of some benefit to society, to the public. Otherwise it wouldn't be worth patenting. This is true of medicine and that is true in other fields too.

Senator McCLELLAN. But what you have been saying here, in its raw state the patent may not be any good until it is proven.

Mr. BARR. It may not be.

Senator McCLELLAN. And the cost of proving is what would keep it on the shelf.

Mr. BARR. That is right.

Senator McCLELLAN. If everybody had an equal access to it.

Mr. BARR. That is right.

Senator McCLELLAN. If nobody is going to get any benefit from making the risk investment, if there is no prospect of them getting any advantage or any return on that investment, they wouldn't make it.

Mr. BARR. I think that would be true in the field of electronics, engineering, or medicine. I don't see any distinction.

Senator McCLELLAN. You don't see any distinction?

Mr. BARR. No, sir.

Senator McCLELLAN. That is why I wanted to emphasize it at this point. All right, proceed.

Mr. BARR. The first case which I related—the instance where company A refused to award a research grant to the university unless its investment was protected by a grant of exclusive rights to any discovery which might result—also illustrates a point which is relevant to the Government's policy.

As I mentioned before, the university is dependent on both public funds and private funds to finance its research activity. Frequently, funds from both sources become involved in different phases of a research study. If the Government were to adopt a restrictive policy requiring that all patent rights arising from research involving any Government funds must vest in the Government, the result could well be a refusal by private companies to support any research project which might be related to or to some extent dependent on another research study involving Government funds—just as company A refused to support the project in the actual experience which I related, where, for another reason, the company was denied exclusive rights. The harm of this would be the availability of less private funds to finance research at our universities, and, consequently, a curtailment of research activity.

Senator McCLELLAN. May I ask you if you think what you have just related here, that private industry wouldn't join in and make a contribution to a joint project, so to speak, do you think that is a reasonable assumption?

Mr. BARR. I think it is.

Senator McCLELLAN. That they wouldn't do it?

Mr. BARR. I think the incentive for private industry to invest risk capital in research activity rests on the strength of the profit motive, and so far as research and development areas are concerned, it is the protection of exclusivity which flows from our system of patents which holds forth that opportunity to make a profit.

Senator McCLELLAN. Do you think such a policy then would simply dry up a great deal of the source of private research capital?

Mr. BARR. I think its tendency would be to dry up the source of private research funds, and that is the reason we are concerned with it.

Senator McCLELLAN. That certainly wouldn't be in the public interest.

Mr. BARR. It would not.

Senator McCLELLAN. Very well.

Mr. BARR. Based upon my experiences as a businessman and as a university trustee and officer, and based also upon my interest in furthering the cause and quality of higher education and in strengthening the American system of free enterprise, both of which I believe to be in the public interest, I respectfully submit that these principles should be recognized and implemented by the committee in its determination of the Government's patent policy:

1. The great progress which has been achieved in America in science and technology and medicine is largely due to the enterprise and activity of private entrepreneurs, motivated by a desire and an opportunity to make a profit. Patent protection has been an important factor in attracting risk capital to research and to

the discovery, development, and marketing of new products. Any patent policy adopted by the Government should recognize the constructive force of the profit motive in our society. The Government should avoid any policy provision which would weaken or curtail the force of this motive.

2. The public interest requires that the benefits of useful discoveries be made available to society, and no policy should be adopted which would operate to deny or curtail the availability of such benefits. The testing of new discoveries for usefulness and value, and the development and marketing of useful discoveries is a commercial process. Even though Government funds have contributed to a discovery, provision must be made which will permit private entrepreneurs to test discoveries of unknown value with a right to develop and market those which prove to be useful with a commensurate degree of exclusivity.

3. Research is important both to our institutions of higher learning and to the public. Any policy which would have the effect of curtailing research, either research supported by public funds or research supported by private funds, would be harmful to our universities and contrary to the public interest. In cases where both Government and private funds have contributed to a research study which produces a useful discovery, provision must be made which will give the private sponsor an opportunity to develop and market the discovery on a basis which recognizes his investment of risk capital in the project, and affords him a commensurate degree of market exclusivity.

4. As a general rule, in those instances where Government research funds are granted to a properly recognized or accredited university or college, any patent rights arising from such research should be vested in the grantee university or college, to be administered in accordance with a Government-approved patent policy of the grantee institution. The university, like the Government, is dedicated to the public interest, and is not engaged in commercial manufacturing or marketing. The vesting of proprietary rights to any such discoveries in the university would strengthen the motivation of university personnel to use the Government funds most effectively and efficiently, and would broaden the opportunity for scholarly contact and interchange between the scholars and scientists of the university and their counterparts in the commercial organizations with whom the university would work in securing the necessary testing, development, and marketing of useful discoveries.

All in all, my suggestions are aimed toward a policy which will maximize the amount of research done in America, regardless of whether it is financed with public or private funds; which will strengthen the position of institutions of higher learning to make fuller use of their vast resources of scholars to advance the frontiers of knowledge; and which will give the greatest assurance that the benefits of new discoveries will flow through to the public through recognition and support of the strong constructive force of the profit motive in private enterprise. Thank you.

Senator McClellan. Thank you very much, Dean Barr. I know others may disagree with what you have presented, but certainly you have presented a very able statement here.

Mr. Barr. Thank you, sir.

Senator McCLELLAN. That deserves the closest attention and consideration of this committee.

Mr. BARR. Thank you, sir.

Senator McCLELLAN. And of our Government, in trying to arrive at a patent policy in the public interest. Thank you very much.

Dr. Suter and Dr. Maurice Seevers, if you would both come around, please, I think maybe we can hear both of you before we recess, and that will conclude the witnesses we have scheduled for today. Is Dr. Seevers here?

All right, then we will proceed with you, Dr. Suter.

STATEMENT OF DR. C. M. SUTER, DIRECTOR, STERLING-WINTHROP RESEARCH INSTITUTE

Dr. SUTER. Mr. Chairman and members of the committee, this statement will be very brief.

Senator McCLELLAN. Very well, you may read it.

Dr. SUTER. I am pleased at the opportunity to appear here today to comment on issues raised by S. 1809, the chairman's bill on Government patent policy. I am speaking on behalf of Sterling-Winthrop Research Institute, the pharmaceutical research division of Sterling Drug, Inc., a diversified drug company with over 40,000 stockholders and 13,000 employees here and abroad.

My name is Chester M. Suter. My graduate scientific education was in organic chemistry with an M.S. and Ph. D. from the University of Kansas followed by a postdoctorate fellowship at Yale University. Following this I was on the faculty of Northwestern University, Evanston, Ill., for 14 years, where my time was divided about equally between teaching of premedical and advanced chemistry students and doing research mostly in areas of medicinal interest.

When I left Northwestern I was chairman of the department of chemistry. I resigned to go to Winthrop in Rensselaer, N.Y., to organize a drug research facility on behalf of Winthrop and for Sterling Drug as a whole. Starting from scratch we now have a total staff, scientists and supporting personnel, of about 600. My publication and editorial experience includes numerous research papers, patents, and books. In recent years my work has been as much administrative as scientific. More information on qualifications would probably bore you, but are available in "American Men of Science."

As a director of medicinal research I am concerned about section 4, subsection (a)2, page 4, of S. 1809. This subsection has already been put into effect by NIH in its grants to universities and other nonprofit research groups. This policy has largely blocked collaboration between scientists of these groups and the pharmacologists in industrial laboratories. These biologists could determine whether the compounds made under NIH grants have the potential for practical value. The industrial people cannot logically invest in this effort because all results which might lead to a useful product are subject to confiscation by the NIH without recompense.

I might add at this point that we are continually deluged with other important problems, so it isn't a question of doing a project here or

not doing anything at all. But it is a question of doing something else which may appear to be almost equally important.

Senator McCLELLAN. Tell me how this policy now is detrimental to the public interest, the policy now in effect which you said I believe S. 1809 involves.

Dr. SUTER. As will appear later on here——

Senator McCLELLAN. All right.

Dr. SUTER. All right, I will go ahead, Sentor.

It is not always realized that the cost of biological testing and development of a new product is much more expensive than the original invention. An actual experience may emphasize this. This happened to come across my desk just at the time I was getting ready to come down here. Recently we obtained an exclusive license to an invention for a new product which may represent an advance in a certain area. The preliminary work on the invention by the outside party represented only a modest monetary expense. I think it would be very comparable to a grant such as NIH might give to a university. For us to get a suitable formulation ready for its first clinical study has cost us $281,000 during a 3-year period. Our expenses furthermore has just begun because at this point we would turn the product over to Dr. Moyer, for example, in accord with his earlier statement, for his work in clinical pharmacology. This represents the expense up to that point, because ahead of us are extensive clinical studies and further more detailed animal studies prior to submission of a new drug application. Without an exclusive right to market the product we could not afford to be interested in it. A similar invention, therefore, made under an NIH grant would go undeveloped. This, I urge, is not good national policy. The taxpayers may not get full benefit from $1 billion spent in grants in research aid under these circumstances.

When the NIH policy first went into effect I received a long letter from a university scientist asking about our testing NIH grant compounds. I had to turn him down as I could not run the risk of losing stockholders' money when other attractive work was at hand. In effect the NIH was trying to take over $100 worth of results after spending $10 or less. No private firm can take part in such a program, so testing of NIH-financed compounds has largely stopped. Contamination of a research program with a minor amount of Government money crowds the title to the rights on new products under present circumstances.

Senator McCLELLAN. You make a statement here which I would like to emphasize:

> No private firm can take part in such a program, so testing of NIH-financed compounds has largely stopped.

Dr. SUTER. That is certainly true in our place.

Senator McCLELLAN. You are talking about——

Dr. SUTER. That is our reaction to it, and I think it is never 100 percent true because there are always unusual circumstances, but I do have the——

Senator McCLELLAN. You say since the incentive has been cut off your institution is not interested?

Dr. SUTER. For the pharmaceutical industry as a whole, the R. & D. tab of $310 million, 96 percent is company money now, so that this indicates to me a break between the collaboration that might occur, you see, between the NIH and the pharmaceutical industry.

Senator MCCLELLAN. All right.

Dr. SUTER. I might elaborate on that point. This does not mean that we never take small NIH grants. There are occasionally projects which are not likely to lead to inventions, which are done purely on a package basis, and now and then as a matter of accommodation, so to speak, we have taken small grants in that area, although we do not have one at the present time.

This situation can be remedied by suitable modification of section 4, subsection (a) 2, so that medicinal inventions are accorded the same treatment as other inventions now receive and would receive under the proposed S. 1809. Until this is done an industrial research laboratory will rarely be interested in becoming involved in a Government-subsidized program where inventions are likely to occur. This applies to participating in the programs of others at company expense or seeking direct grants from Government agencies. I would regret seeing the present NIH policy continued and extended as a permanent program. A good analysis of the problem and a suggested alternative solution has been developed by the American Patent Law Association. This is published in the June 1965 bulletin of this association, pages 327–333, and, I believe, has already been given by W. Brown Morton as testimony before this subcommittee. He was scheduled, I know, on July 7. A more concise statement of the changes in S. 1809 that seem to us to be desirable are given in appendix A of the testimony by Dr. Austin Smith before this subcommittee on June 1, 1965, on behalf of the PMA. The point of view expressed by the American Council of Education in their excellent statement of July 20, 1965, is reasonable and covers a section of the area under discussion.

And I might add that I am very much pleased, and enthused, by the statement made this morning by Dean Barr, who gave his testimony just before I came up here. It is just a coincidence that we both happen to be from Northwestern. I have never seen him before. But we feel that his approach to this situation, whereby the university as a nonprofit institution acts on behalf of the public, is a very good approach to the matter of handling Government grants.

It might be pointed out that the Federal Government and the people of this country both share under any circumstances in any success that a company may have in developing a new medicinal product, spending some scientific work in a university. Physicians have at their disposal a superior new product prescribed for their patient, and the Government gets about half of the profits, if any.

If royalties on any such invention could go to universities, medical schools, or other nonprofit institutions, to strengthen their facilities, this would be a suitable and desirable consequence of the original grant I think from the Government to the university. That concludes my statement.

Senator MCCLELLAN. Thank you very much. The letters to which you refer are attached?

Dr. SUTER. Yes.

Senator McCLELLAN. They will be published in the record at the conclusion of your statement.

(The letters referred to follow:)

STANFORD UNIVERSITY,
DEPARTMENT OF CHEMISTRY,
Stanford, Calif., August 9, 1962.

Dr. C. M. SUTER,
Director, Sterling-Winthrop Research Institutes,
Rensselaer, N.Y.

DEAR DR. SUTER: I am writing this letter to you at the suggestion of Prof. W. S. Johnson, chairman of our chemistry department. Recently we submitted to the National Institutes of Health a research proposal entitled "Amino Sugars of Potential Pharmacological Utility." The main portion of this proposal involved specific reactions in the aminosugar series, with emphasis on neighboring group participation, direct replacement reactions and reactions of aminosugar derivatives with organometallic compounds. In view of the pharmacological importance of the aminosugars, we also suggested that the substances prepared in connection with the above studies might be subjected to screening tests for pharmacological activity at any one of several companies who perform such tests. Since such compounds are indeed apt to have pharmacological characteristics of interest, it seems quite to the point to mention this possibility in connection with our proposed studies.

In the past, both the Abbott Laboratories and Merck, Sharp & Dohme have conducted routine screening tests in connection with compounds which we have prepared in some of our studies. Accordingly, we approached these companies before seeking collaboration elsewhere. In view of the agreements required by the NIH, however both of these companies regretfully expressed a lack of interest in screening the compounds to be produced from our researches in this area.

Accordingly, at the suggestion of Professor Johnson, I am writing to you to ask if your laboratories would be interested in collaboration with regard to routine screening of compounds in this class. In order that you know the requirements which the NIH would impose upon such collaboration, I am including herewith a copy of the NIH patent agreement recently forwarded to me by Dr. Helen Jeffrey, of the NIH.

I would be most interested to hear from you at your early convenience regarding the possibilities of conducting such screening tests in your laboratories, and in particular as to whether the details of the patent agreement, etc., required by the NIH are agreeable to your company in connection with the conducting of such tests.

Hoping to hear from you at your early convenience in regard to the above matters, I am

Yours very sincerely,

WILLIAM A. BONNER,
Professor of Chemistry.

STERLING-WINTHROP RESEARCH INSTITUTE,
Rensselaer, N.Y., August 31, 1965.

Prof. WILLIAM A. BONNER,
Department of Chemistry,
Stanford University.

DEAR DR. BONNER: Your recent letter regarding the possibility of our testing certain amino sugars for pharmacological action has now been considered by several of us here. Although we recognize that there might be some interest in screening these compounds in several tests we think this is outweighed by the complications which would arise if a useful action were found.

We are already involved with so many complicated Government regulations and restrictions that we are unwilling to take on a project of this sort.

I am personally sorry to react in this way, but we feel there is not much alternative under the circumstances.

Sincerely yours,

C. M. SUTER, *Director.*

Dr. SUTER. As you may gather, I called the professor at Stanford regarding this letter, and he said he would be glad to have this included and attached to my statement.

Senator MCCLELLAN. Very well. I regret that the other witness is not here. He had a right to anticipate that he wouldn't be called until this afternoon.

Dr. SUTER. Thank you, Senator.

Senator MCCLELLAN. Thank you very much. The testimony this morning has been very helpful I think. From it the committee will get some better understanding maybe than it has had heretofore of what can happen if we legislate a bad policy of Government in this field.

Certainly, if the Government makes an investment that results in an invention, that invention is taken by the Government to patent, and it is just put on the shelf and it is never developed, no one benefits from it, and the indications here are that in some instances inventions that could prove very beneficial to the public might never be developed and put on the market.

So this subcommittee has a very difficult task of trying to unravel this problem and get some legislation that will be in the national interest.

I regret the other witness is not here, but he had a right to expect to testify this afternoon. Since we will not be able to hold hearings this afternoon, we will try to hear Dr. Seevers Thursday morning. Tomorrow the subcommittee will hold hearings on copyright legislation. We had it scheduled that way. And Thursday morning at 9:30 the committee will resume hearings on the patent bills.

Senator Morse is scheduled to testify on Thursday morning, at 9:30 and immediately after that we will try to hear Dr. Seevers. We are beginning early Thursday morning so as to accommodate Senator Morse.

The committee will stand in recess until Thursday morning on the patent hearings, and until tomorrow morning at 10 o'clock for copyright hearings.

(Whereupon, at 12:35 o'clock p.m., the subcommittee recessed, to reconvene at 9:30 o'clock a.m., Thursday, August 19, 1965.)

GOVERNMENT PATENT POLICY

THURSDAY, AUGUST 19, 1965

U.S. SENATE,
SUBCOMMITTEE ON PATENTS,
TRADEMARKS, AND COPYRIGHTS OF THE
COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The subcommittee met, pursuant to notice, at 9:30 a.m., in room 3302, New Senate Office Building, Senator John L. McClellan (chairman of the subcommittee) presiding.

Present: Senators McClellan and Burdick.

Also present: Thomas C. Brennan, chief counsel; Edd N. Williams, Jr., assistant counsel; Stephen Haaser, chief clerk, Subcommittee on Patents, Trademarks, and Copyrights; Horace L. Flurry, representing Senator Hart; and Clyde M. DuPont, representing Senator Fong.

Senator MCCLELLAN. The committee will come to order.

Our first witness today is Senator Morse, of Oregon. Senator Morse has introduced S. 2160 to amend the patent provisions of the Space Act of 1958. Since Senator Morse's bill relates only to the patent policies of NASA, it was referred to the Committee on Aeronautics and Space Sciences.

I shall direct that the text of this bill be printed in the record immediately following Senator Morse's testimony.

Very well, Senator. We are very glad to welcome you here this morning.

STATEMENT OF HON. WAYNE MORSE, A U.S. SENATOR FROM THE STATE OF OREGON; ACCOMPANIED BY HERBERT L. SPIRA, COUNSEL, SENATE SMALL BUSINESS COMMITTEE

Senator MORSE. Mr. Chairman, I appreciate your hearing my testimony this morning. I ask two things: first, that there be inserted in the record the full statement of some length that I have prepared. I will not take the time to read that.

I would also like to have inserted in the record a summary of that statement, from which I shall make my testimony this morning.

Senator MCCLELLAN. Is this what you want inserted in the record [indicating]?

Senator MORSE. Yes. That is the full statement.

Senator MCCLELLAN. The full statement, then, may be printed in the record at this point.

Senator MORSE. Then I would like to have my summary statement inserted in the record, preceding it, I think, Mr. Chairman, because I am not going to be able to read all of that, and I would like to have it included in the record in its entirety.

Senator MCCLELLAN. All right, the summary statement presented by the witness will be inserted immediately preceding the full statement which I have just ordered be inserted in the record.

(The summary statement and the full statement referred to follow:)

SUMMARY OF PATENT STATEMENT

Since 1947, the American taxpayer has spent $85 billion on Government-financed research and development. In the next 6 or 7 years $85 billion more will be contributed by the taxpayer and appropriated by the Congress for these purposes. The commitment of public funds on this scale to scientific research and development is surely one of the most significant economic events of modern history.

This subcommittee has the task of formulating national policies for disposition of the rights to the commercial exploitation of patent property created as a result of these public expenditures.

The chairman's letter of invitation to Members of the Senate is one more indication of thorough and conscientious approach which the subcommittee has taken to this extraordinary and complex task. I feel that the Nation is fortunate in having such consideration by the chairman and the diligent participation by the members of the subcommittee which is being brought to bear on these problems.

My formal statement is rather lengthy, since there is a good deal of statistical and historical material which I would like to have available to the subcommittee. I would like to proceed with about a 20-minute summary of the highlights of the statement. If there is time remaining, I would be glad to go into a particular area which the subcommittee believes might be helpful.

I am aware that the subcommittee is very much concerned with the commercial utilization and exploitation phase and I will place my emphasis there.

In accordance with the chairman's wishes, I have included in my statement an outline of my activities in the patent and public property areas, including the history of the Morse formula, my participation in the atomic energy legislation, and the legislation which I have introduced on NASA patent policy during the 88th and 89th Congresses. My position, as embodied in S. 2160 on NASA patent policy, is that taking of title by the Government in behalf of all of the people should be coupled with a flexible system of licensing, such as was discussed with Dr. Shannon on Tuesday morning (August 17). Under procedures which I envision, this system will provide equal protection and even greater incentives than waiver of patent rights for contractors developing and marketing inventions.

A precondition for such a flexible policy is, of course, the assertion of title by the Government agency concerned in the first instance. Once patent rights are waived to an individual contractor for 17 years, flexibility is lost forever.

At the opening session of the hearings, the President's Science Adviser gave great emphasis to this issue of utilization. My experience makes me sensitive to additional considerations of great importance. An excellent summary of these factors is found in the findings and conclusions of the Attorney General's Report of 1947, which I would like to take a moment to read:

"IV. INVENTIONS MADE BY GOVERNMENT CONTRACTORS

"1. Where patentable inventions are made in the course of performing a Government-financed contract for research and development, the public interest requires that all rights to such inventions be assigned to the Government and not left to the private ownership of the contractor. Public control will assure free and equal availability of the inventions to American industry and science; will eliminate any competitive advantage to the contractor chosen to perform research work; will avoid undue concentration of economic power in the hands of a few large corporations; will tend to increase and diversify available research facilities within the United States to the advantage of the Government and of

the national economy; and will thus strengthen our American system of free enterprise."

This work entitled the "Investigation of Government Patent Practices and Policies," was begun at the request of President Franklin D. Roosevelt in 1943 and during its course, 14 Federal agencies and 10 national governments were consulted. It was ultimately published in 1947, and has formed the foundation for a position in favor of the public interest, which the Justice Department has adhered to from that day to this. I invite the subcommitee's attention to this document, as it is the most comprehensive and pursuasive study I have been able to find.

I believe that these considerations, together with the evidence gathered by Secretary of Agriculture Benson (cited at p. 7 of my statement) that Government title does not impede the commercial development of inventions, are convincing of the value of a basic title policy for Government-financed R. & D.

However, the subcommittee is quite correct in coupling its consideration of ownership provisions with the system of utilization. The two go hand in hand.

It is my feeling that contractors should feel that they are receiving completely fair treatment from the Government in this area, just as small businessmen, taxpayers, and individual inventors should feel that their interests are getting an even break.

In contrast to the bright successes of title policy, in the areas of agriculture, TVA, and atomic energy, let us examine the consequences of the license policy, as exemplified by the Department of Defense, and more recently of NASA. I have spent a considerable time analyzing the effects of our Government contract and patent policies on increasing concentration of wealth and assets among the Nation's largest companies. At this time, I am pleased to make these findings available to the subcommittee.

As the subcommittee is aware, the Council of Economic Advisers told the President in January that:

"* * * Within the important manufacturing sector, certain structural trends have emerged since World War II: (1) Through internal expansion and merger, large firms have grown more rapidly than the manufacturing section as a whole. * * *

I am informed that mergers hit an alltime high of 991 in the first 6 months of 1965.

Of course, the agency which has the greatest effect upon these figures and trends is the Department of Defense, which spent more than 70 percent of all Federal R. & D. money in 1961 and still spends more than half. It is also pertinent to note that NASA, which now spends close to 30 percent, has increasingly adopted the Department of Defense position.

To illustrate the seriousness of the concentration issue, particularly in the Department of Defense, may I quote the testimony of Dr. Robert F. Lanzillotti, chairman of the Economics Department of Michigan State University, before the Senate Small Business Committee in 1963, as follows:

"The Government R. & D. contracts appear to be highly concentrated among the very large firms. While small business averages around 16 to 17 percent of Department of Defense procurement, when it comes to research and development small business accounts for some 2 to 3.5 percent. In fiscal year 1961, 20 corporations accounted for nearly 75 percent (of total military R. & D.).

"* * * is it not inconsistent—not to say dangerous—for the Federal Government to nurture each concentration in the technologically most advanced fields which can be preempted by the particular firms selected by military officials?" ("Economic Aspects of Patent Policies," hearings, Mar. 8, 1963, p. 121).

The seriousness of this matter of selection is indicated by the fact that, in fiscal year 1962, 97 percent of DOD research awards were made on a nonprice, noncompetitive basis (hearings, "Testimony of Dr. R. J. Barber, Southern Methodist University Law School," p. 52).

It should be further noted that for the same year, 10 firms received 56 percent of DOD's total research money; and for NASA, the top 10 companies received 54 percent. Furthermore, five of these contractors are on both lists (hearings, loc. cit. Mar. 7, 1963, pp. 56–57).

Now, in the face of these tendencies, which (as I document in an appendix to my statement) the Justice Department has viewed with alarm under both Democratic and Republican administrations since 1947, what has been the impact of Federal research and development policy?

A most trenchant analysis of the dangers in these trends was made by a Republican Attorney General, Herbert Brownell. In 1956, he declared, in the following language, his concern: "with the future of competitive enterprise, and it is important that its share of this (research) activity be administered to promote competition * * *. [W]hat indications that are available warn that the Government expenditures may not run counter to the industrial trend toward concentration, but in some degree may actually enforce it. * * * The disproportionate share of total industrial research and development in the largest firms may foreshadow a greater concentration of economic power in the future. * * * (A) present concentration of such manpower and progress means that in the future an increasing share of anticipated improved technologies and new production lines will be introduced by the industrial giants."

These trends are relevant to the question of who should receive the benefits of a policy of granting exclusive commercial rights to contractors. At a minimum, Federal R. & D. policy in the administration of contracts, as well as in the allocation of patent rights, should attempt to counteract trends toward monopoly and concentration, rather than reinforce them as these policies, as they have been doing.

To return to the issue of utilization; my position has been private enterprise, as in S. 2160, should be given the sole task of developing and commercializing inventions arising out of Government-financed research.

However, there must certainly be appropriate safeguards for the economy, the taxpayer, the small businessman, and the consumer in the form of the terms and conditions on which this development is carried out. These terms and conditions now engage our attention.

Seventeen years is a long time in this era of breathtaking technological change. One company, General Electric, is fond of saying in its annual report that half of its sales are attributable to products which did not exist 10 years ago. A system where the Government takes title and provides for a liberal granting of exclusive and nonexclusive licenses, would allow a more realistic period of 3 to 5 years for a company to proceed with development and marketing phases with absolute incentives and absolute protection. At the end of such a period, the company could come back into the agency and make a showing of what it had done, as a basis for a possible renewal of this license for a renewal period.

Not only would this give a complete flexibility as to the number of years involved, but as to other terms and conditions of the grant. For instance, there could be consideration of States and municipalities which must provide services for all of the people, and of hospitals and universities, which are rendering services in the public interest. Such a system could provide for equitable access for small businesses which did not participate in the original contract for research or development. They could also provide for a determination of royalties, in certain cases, which would provide a return to the taxpayer of some of his $15 billion annual investment. An additional feature should be that the so-called "walking-in provisions" should require walking-in by the contractor, who desires to retain a preferred position. This would save the Government the administrative burdens and expense of monitoring and enforcement. A renewal proceeding would also provide an opportunity for other parties to present their views and claims on the basis of changing circumstances.

I now turn to the field of procedure. As the chairman knows from his long career in public life, the procedural section of any bill is just as important as the policy declaration, if not more so. My formal statement contains several recommendations as to procedural devices, and I would like to point up a few of these.

I have been especially concerned with the status of small business under patent legislation that may be enacted. May I say that my small business philosophy is not the protective variety. I believe that we must give small business of today an even break so that they can grow up to be the large substantial businesses of tomorrow. This keeps our economy dynamic. It is particularly important in new fields which are being opened up by Government-financed research and development. Firms like IBM, Texas Instruments, or Tektronix, from my own State of Oregon which will be testifying before you today, were all once small businesses.

The problem is how to provide access to the $15 billion products of Government R. & D., which is performed by relatively few firms, for all of the small business community. The subcommittee has a golden opportunity to do this.

I say particularly to my brother member of the Small Business Committee (Senator Scott) that Congress should take the time and trouble to devise the procedural features which will carry out this access. This would not be a Republican measure or a Democratic measure but a bipartisan effort to strengthen the foundations of our economy by giving the small man a fair shake. In S. 2160, my bill on NASA patent policy, which I have attached as an appendix to my statement, several of these procedures are set forth. I would like to advance them for the committee's considerations. Since there are few landmarks in this area, I would like to stress that these suggestions should not be regarded as definitive. These are efforts which I hope might contribute to the creation of a workable system.

These procedures have three features: Notice, hearing, and limited judicial review.

I am also concerned as is the subcommittee, with the interests of the taxpayer. The taxpayer would benefit, under the licensing system described above, from increased competitiveness and lower prices of the finished product. He could also benefit immeasurably from the institution of a general policy of sale or royalty of the patent rights in areas where this is a practicability. I have recommended in my statement that the committee secure the opinion of a fiscal expert on the amounts that might be realized through such a royalty system.

The cause of the individual inventor has also been mentioned. I believe that consideration of this legislation presents an outstanding opportunity to give greater standing and possible financial reward to the individual inventor. Any provision governing the relationship between the Government and the contractor on this point should probably be conditioned upon the relationship between the contractor and the individual employee.

To conclude, I shall attempt to sum up the directions I believe the committee should take. With respect to S. 789, I believe it is a fine example of a procedural trap. As stated by the Department of Health, Education, and Welfare, "the entire thrust of the bill is thus to impede the Government's taking and retaining of ownership in inventions derived from federally financed research, by making this a long, arduous, and exceedingly difficult, and in many cases, impossible task."

S. 1809 is, of course, the principal bill before the committee. I commented upon the provisions of this bill in considerable detail in my formal statement. I might repeat that I consider section 11, which repeals the public interest patent provisions of the last 30 years, to be unsound and undesirable. This legislation, rather than reject the past, should be built on its monumental successes.

With respect to the chief section, section 4, I believe the policy of favoring the waiver of patent rights to the contractor doing the work is undesirable for the reasons that I have discussed above. This policy goes even further than the 1963 patent statement in following the practices of the Defense Department which are getting the economy in so much trouble. The fine provision placing the presumption title in the public interest is applicable only to the area of health, welfare, and the public safety. The wisdom of this policy is demonstrated by the case of the test for PKU which has come in for a good deal of discussion on the Senate floor, in the committee, and in the press.

On August 12, 1965, two Senators introduced a bill (S. 2402) that would appropriate "such sums as may be necessary" to buy a test for every newborn baby in the country. A little arithmetic demonstrates that the sums necessary would be more than $2 million higher under a license policy than under a title policy. Since the original appropriations for developing the PKU test are estimated to be about $1 million, it can be seen that a failure to take title would result in the taxpayers being charged annually $2.5 million for something they had already bought for $1 million. This matter is detailed in an appendix to my statement.

However, if it makes sense to safeguard the taxpayers' investment in this area, where the taxpayer puts up an estimated 15 to 25 percent of the research money, does it not make even more sense in scientific instruments, where the taxpayer furnishes 57 percent; or electronics and communications equipment, where the taxpayers' share is 67 percent; or aircraft, where the share is 89 percent? (Federal Bar News, November 1963, p. 357.)

In the final appendix of my statement, I set forth data confirming the fact, which was discussed on Tuesday morning, that as we move toward fields where the Government needs "end items," the proportion of development paid for by the

Government approaches 100 percent. For instance, there is almost complete transference between items such as the KC–135 jet tanker and the Boeing 707; and the military synchronous satellite and the Early Bird commercial satellite. It is thus in the defense and space areas where the necessity of protecting the public interest by this type of policy is the greatest.

My statement also goes into detail on the reasons that S. 1809 does not give an even break to the small businessman, the taxpayer, the farmer, or the consumer. I also present evidence as to the undesirability of procedural standards such as "exceptional circumstances" and "special circumstances" which are important in S. 1809. Lastly, S. 1809 would seem to make no improvement in the unfortunate situation at the space agency, where congressional intention and policy is constantly being violated under the present NASA regulations. It is my impression that the bill will merely repeal the congressional mandate and leave matters to the same administrative discretion which has created this unfortunate situation.

Some suggestions are also advanced as to data which the committee should obtain and update relating to matters which have been the subject of subjective opinions but which no firm data has been advanced.

It is my belief that any patent legislation should be governed by the following six general principles:

(1) A clear policy statement that Federal research and development property is a "natural resource belonging to the people of the United States," and must, therefore, be safeguarded accordingly.

(2) Plain and certain penalties for the giveaway or unauthorized disposition of Federal R. & D. property.

(3) Provision for preserving the many congressional patent protections that have been ordered into law over the past three decades.

(4) Practical means for discouraging monopoly and concentration, and thus protecting the interests of small business and an "open economic system."

(5) Clear and unambiguous standards for separating private and public interests in the commercial development of the property.

(6) A system whereby Federal R. & D. property sought by private companies for commercial development could be sold or licensed to them for an amount equivalent to fair market value, and the same property sought by other public institutions for dedication to public purposes could be sold or licensed for half of the fair market value wherever practicable.

In S. 2160, I have suggested additional provisions for public licenses and royalties, and procedures which would result in written findings by the head of an agency as to both public versus private interests, and value of patent interests. These proposals might be helpful to the subcommittee in formulating the necessary standards, and I commend them to the subcommittee's consideration. If I can further assist the subcommittee during its deliberations, I would be glad to do so.

STATEMENT OF SENATOR WAYNE MORSE

Mr. Chairman, members of the subcommittee, I am most grateful for the subcommittee's courtesy in scheduling my appearance—for several reasons.

The patent bills presently before you raise what I consider to be the most important economic issues of this generation. They involve the economy of my State, the future welfare of the 90 percent of America's business population which is small business, and the public interest of the taxpayer in property which is accumulating at the rate of about $15 billion a year.

BACKGROUND

As the subcommittee is aware, I have been concerned with safeguarding the property in the public domain since I came to this body. The so-called Morse formula grew out of consideration by the Armed Services Committee, in 1947, of a policy for disposal of the mountains of surplus military property that was left over from World War II. We decided, rather than give this public property away, that it should be sold at fair market value to private companies, and for 50 percent of market value to States and municipalities for public use. Since then, I have sought to apply this formula to all transfers of real estate and tangible personal property coming before the Congress. If I may say so, the Library of Congress made a tabulation in 1962, indicating

that an area about two-thirds the size of Rhode Island had been made subject to this formula, and about $800 million had thus been saved and returned to the Treasury. I believe that the chairman is interested in such economy measures.

In addition, I have devoted myself to the preservation of the public's interest in their navigable streams and rivers, through multipurpose river valley development.

These concerns led me to take an active part in the debates on the atomic energy and space communications legislation of 1954 and 1962, where large amounts of intangible patent property and technology belonging to the U.S. taxpayer were at issue. They have also prompted me to introduce bills in the 88th and 89th Congresses to correct the continuing violations of congressional patent policy by the National Aeronautics and Space Administration. In addition, I have been able to participate in the consideration of the economic aspects of patent policies by the Select Committee on Small Business during the past 3 years.

As the chairman pointed out, on the first morning of the hearings, the issues are complicated, and it is difficult to gain an understanding of all of their facets.

It is a source of satisfaction that it is possible for me to participate in the "great debate" on patent policy. I shall try to assist the subcommittee by relating my experience and explaining my views on the bills before you and the broad questions which I feel they raise.

SIGNIFICANCE OF THE ISSUES

In my judgment, the sheer amount of public property the subcommittee is dealing with is enough to elevate the significance of a congressional decision to the level of those made in the Northwest ordinances, the homestead acts, and the land-grant college legislation. A little later, I shall show how all the public property disposed of under these great acts of Congress was worth less than $1 billion. Yet, we are talking here about property being paid for out of taxes at the rate of $15 billion a year.

Any congressional declaration of policy in this field will be looked upon as a watershed in the philosophy of this country. It will have far-ranging and unforeseen effects on the climate of opinion for decades to come. Senator Norris, in his autobiography, made the following statement:

"The early twenties brought the American people to their knees in worship at the shrine of private business and industry.

"It was said, and accepted without question by millions of Americans, that private enterprise could do no wrong.

"The next 12 years was to produce one of the great classic struggles of the legislative branch of the National Government, the battle of the Tennessee Valley Authority, better known as TVA." ("Fighting Liberal," by George W. Norris, ch. 2.)

After the breakthrough forged by Mr. Norris, and his colleagues in the legislative and executive branches during the 1930's, there was a good deal of forward-looking legislation in the interest of all of the people of this country, wherein patent rights were retained by the Government and made freely available to the public.

It seems to me, Mr. Chairman, that the exigencies of World War II and the cold war have made the wheel come full circle. We now hear considerable advocacy of the position that only the largest private corporations are fit custodians of property developed at public expense. I submit that we who have been in public life for some time, and have seen these cycles of publicity, and what passes for "public opinion," have a solemn obligation to protect the statute books of this country from the notion that private business can do no wrong.

There is, secondly, significance of a very material nature in the disposition of public property worth $15 billion a year. The way Congress distributes these valuable commercial rights will have a measureable impact on the structure of our economy, the balance between small, medium sized, and large businesses, the trends toward concentration and monoploy, and the relative power of the civilians and the military in controlling our Government.

Third, this legislation, by proposing to repeal the public interest patent sections of many benchmark acts of Congress threatens to undo the work which many of

us have fought for, and devoted our careers in Congress to, over the span of the last 30 years.

May I comment on these three points in reverse order.

EXISTING STATUTORY SAFEGUARDS OF THE PUBLIC INTEREST SHOULD BE PRESERVED

As you are aware, section 11 of S. 1809 would, under the label and in the guise of "technical amendments," sweep away patent provisions of 10 laws enacted by Congress since 1935. The patent sections in this legislation were not "technical matters" when they were considered by the various committees of this body and of the House of Representatives. They were not "technical matters" when they were debated on the floor of the Senate, in the press, and throughout the country. They were not "technical matters" when they were signed in the law of the land by our Chief Executive.

As was observed by the distinguished junior Senator from Alabama and the chairman of the Commitee on Small Business, Senator Sparkman, on the floor of the Senate on July 24, 1954:

"In other words, these private power and industrial companies want to determine who should be licensed to receive the benefits of discoveries and inventions financed primarily by the Federal Government and also what price they should pay to receive these benefits. This a tremendous amount of power which could be used to stifle competition by excluding small producers and distributors of electricity.

"In my mind this is the meat, the core, of the legislation which is now proposed to amend the 1946 Atomic Energy Act. * * * There are other issues, but we must not lose sight of the big show—the attempt of these industrial giants to obtain exclusive private patents." (Congressional Record, vol. 100, p. 11789.)

Mr. Chairman, patent rights to public property are still the "big show," and section 11 is an attempt by private business and its representatives to steal the show.

A little later in my testimony I will show how few companies—actually only about two or three dozen—stand to receive the lion's share of these public patent rights.

I have searched the Record for compelling reasons for undoing the 10 legislative provisions that section 11 proposes to extinguish. I have looked for studies; for empirical data. I have yet to find any reasons or data. The simple explanation, I suspect, is that they do not exist. On the contrary, the evidence I have found points uniformly toward the retention of these provisions on their merits.

TITLE POLICY HAS SHOWN ITS WORTH

Let us take a hard analytical look at the consequences of the "title" and "nontitle" patent policies, beginning with the oldest sections in point of time, those dealing with agriculture and forestry.

First, let me say to the subcommittee that I am familiar with the problems of a State in transition between an agricultural and industrial economy. The economy of the State of Oregon is quite similar to the economy of a State like Arkansas in many ways:

In its reliance on agriculture and forest products.

In the fostering of industrialization, based largely on byproducts and new developments in the technology of the agriculture and forestry fields.

In its recreation industry, stemming from location astride the Pacific flyway, as Arkansas lies along the Mississippi flyway.

The passages of the 1962 Industrial History of Arkansas regarding the State's efforts to plan for compatibility among these elements could just as well have been written about my State.

The patent policies of the Department of Agriculture, which were worked out laboriously over 80 years, and are embodied in the 1935 and 1938 acts, have a direct bearing on such economic activity. As is well known, this legislation carried forward the policy originally set forth upon the Department's establishment. In 1862, the Department was "required to acquire in diffuse of the people of the United States useful information on subjects connected with agriculture, in the most general and comprehensive sense of that word, and to further, to procure, promulgate and distribute among the people new and valuable seeds and plants." (Organic Act of 1862, 5 U.S.C. 411.)

The 1938 act established four regional utilization research laboratories, to search out new outlets and wider markets for farm products. In accordance with this philosophy, the patent policy of the Department of Agriculture has been to retain ownership in the Government, so that access can be given freely to any responsible person or business concern.

What have been the results of this policy? As President Johnson stated in his farm message in February:

"Thirty years ago, over 7 million American families lived on the farm. Today 3½ million families feed a population that has grown by 50 percent. Enough food is left over to fight hunger among free people all around the globe." (H. Doc. No. 73, 89th Cong., 1st sess.)

And as Vice President Humphrey noted in his remarks to the Farmers Union in March:

"The American consumer now is enjoying food at the lowest cost of any people in the world in terms of human effort expended.

"The miracle of American agricultural efficiency is leaving its imprint in every area of the world.

"We now are exporting at a $6-billion annual rate.

"Agriculture is our greatest dollar earner in foreign trade today.

"Food is power. Abundance—and the ability to produce abundance—is one of our most valuable assets of strength in the world today." (Speech of Vice President Hubert H. Humphrey at March 15, 1965, convention of the National Farmers Union, Chicago, Ill.)

My State has realized direct economic benefits from the inventions and processes which have arisen out of Government-financed research. They have enabled the forest product and agricultural industries to maintain and increase their competitiveness, in the face of substitute materials and processes. Let me mention a few instances:

1. The reversible circulation kiln, which in the words of this subcommittee "constituted a very significant contribution to the lumber producing and wood-using industries, and is now used by large and small companies to achieve "great improved moisture quality control * * * (for) about 40 percent of the total lumber produced in the United States."

2. The plywood processes called impreg and its compressed counterpart, compreg. Manufacture of these materials under Department license is now a multi-million-dollar industry.

3. Of great interest is the turpentine derivative patented by the Department, and which is now licensed to at least three companies and is produced commercially at the rate of over 2 million pounds per year with a market value of over $1 million. This substance accounts for virtually all synthetic rubber for automobile tire treads. (Source of this material: "Patent Practices of the Department of Agriculture," preliminary report of the Subcommittee on Patents, Trademarks and Copyrights, 87th Cong., 1st sess., pp. 37–39.)

As an appendix to my remarks, I will place in the record a description of other Agriculture Department inventions which have substantially benefited the lumber industry, one of which accounts for about 7 percent of all woodpulp production.

I am impressed also by the benefits which the Southern Utilization Research and Development Division has brought to the cotton industry by virtue of the 23 patents it has obtained. The cotton carding apparatus, which Time magazine declared to be "the first major improvement in cotton carding equipment in 60 years," has resulted in a savings of between 2 and 5 percent. This has eliminated 50 percent of the usual waste and saved more than $40 million annually for the U.S. cotton textile industry.

The Department has also registered outstanding successes with the development of wash and wear and wrinkle resistant finishes. These processes account for the use of about 800,000 bales of cotton, and according to a report to Secretary of Agriculture Ezra Taft Benson continued "to hold the greatest promise for expanding or retaining markets for cotton." (Utilization and Research, U.S. Department of Agriculture, October 14, 1960.)

Other patents cover the discovery of a process to make cotton flame resistent. During World War II alone, the military used more than 700 million yards of flame resistant fabric and the potentiality for this type use is unbounded.

TITLE POLICY DOES NOT IMPEDE COMMERCIAL DEVELOPMENT

In 1960, the patent policy underlying these advances was examined for the then Secretary of Agriculture, Ezra Taft Benson, by Roy C. Newton, retired vice president for research of Swift & Co., one of the largest food processing concerns in the world. Mr. Newton's remarks on the question of the relation of title policy to commercial utilization are very interesting, and I quote: "(the only complaint that) has to do with domestic patents arises from the fact that a company cannot get even a temporary exclusive license to compensate it for the expense of commercializing a product of the (Department of Agriculture). These people will say that it inhibits the very objective of the research which is to market new products of agriculture, because no one will put up the necessary capital for such a new venture without some exclusivity to protect it. A few leading questions, however, usually develop the fact that they will go into the venture if their competitors are making a success out of it and if the invention is good enough to be very promising to their competitor, they will try to beat him to it. It is doubtful, therefore, that this policy is a serious handicap to commercialization of new developments by utilization research." (Department of Agriculture Utilization of Research.)

This is how a spokesman of big business, in a position of governmental responsibility appraised the Agriculture title patent policy. The Department itself pointed out to this committee in 1961 that the policy of reserving title and granting free access by licenses best serves the public interest by making the benefits of its research "freely available to the farmers, food processor, consumer, farm product manufacturer, and all of the members of the general public." (Patent Practices Report, p. III.)

This story of the title policy of the Agriculture Department which has had an opportunity to mature during the 30-year period that our generation has been in the Senate, and has been an outstanding success in every sense of the world. Are we now at the point where we should turn our backs on what this wise policy has accomplished?

A glimpse at the future of agricultural products as raw materials for the chemical industry, provided in the Industry & Engineering Chemistry Magazine in May of 1962, convinces me that we are not. The magazine pointed out that industry has, in the past, done a good job in utilizing agriculture byproducts such as cotton linters, soy bean oil, and tall oil from pine trees under patents assigned by the Secretary of Agriculture. In fact, it estimates that the value to commercialized products and processes under these Government patents amount to about $2.5 billion as against the total cost of research plant and facilities and operations of about $170 million. This is a ratio of return upon invested capital of 14.7 to 1.

But we promised to look ahead. The article states: "From the chemical industry viewpoint, the future holds tremendous potential for using greater amounts of agricultural raw materials. Most segments of the industry believe that the ready availability, low average cost, and presence of chemical configurations obtainable in synthetics only a high cost (or not at all) will lead to increased chemical uses for certain agricultural uses.

"Opinion is virtually unanimous that all realization of the potential of agricultural raw materials hinges upon a continuing and vigorous program of research and development."

Mr. Chairman, these developments on the horizon promise to make our agriculture even more the wonder of the world, and they can make the wonder state a participant in this exciting story.

If the title policy of the last 30 years had not existed, the picture would not be so bright. If it is reversed now, it would be a great disservice to our States and their people.

A similar Government title policy with free access by licenses was adopted by the Tennessee Valley Authority. As a result, this Nation leads the world in technology of fertilizer production. I think it is interesting to note that there are half dozen plants in the State of Arkansas which are using one or more TVA licenses on fertilizer as the basis for their entire operation, and there are nine companies in Arkansas which receive quantities of TVA-produced fertilizer materials for direct distribution, or for upgrading of their own products. A list of these concerns will also be made available.

A similar story could be told, I suppose, in nearly every State of the southern region of this country, and I believe that this subcommittee holds the proxies of

their southern colleagues when it comes to changing the patent policy of the Tennessee Valley Authority. It occurs to me that many of these Senators will have something to say in their own right should this matter come to the Senate floor.

S. 1809 WOULD UNDERMINE ACCEPTED ATOMIC ENERGY POLICY

Now may I comment on the patent policy of the Atomic Energy Commission, which surely has international and national implications as well as regional and State ones. I recall on July 17, 1954, during my first speech on "The New Giveaway: Atomic Energy," when I asked the question: "Are we to make use of the lessons taught by those great liberals who have gone before us, who in their day, too, were attacked and abused as dangerous, creeping socialists, who were charged with an attempt to set up some type of state economy, when all they were trying to do was to write into the law checks which would protect the public interest of the people of the United States against a private utility monopolistic combine."

At that time I quoted a newspaper columnist by the name of Thomas Stokes who wrote in the Washington Star of July 16, 1954:

"It may sound somewhat melodramatic that Congress is on the eve of one of the great legislative decisions in its long history.

"But that hardly seems an exaggeration * * * unless the bill as it was presented to the Senate * * * is amended to protect the public against the monopoly that some experts believe is inherent in its patent and other provisions, then future generations may be in for a lot of headaches."

The fight that we made at that time was similar to the fight to withstand private attempts to take over the Grand Coulee site and the Muscle Shoals damsite. I said then, and I feel now, that: "We are fighting for expanded free enterprise economy which requires the efforts of the Nation to harness the waterpower and the atom to produce low-cost waterpower and the other blessings they bestow. We are fighting for the people's right in their streams and the technology developed with their taxes."

In 1954 we were successful: we followed in the great work of George Norris and Theodore Roosevelt, Gifford Pinchot, Charles McNary, and Dill and Couzens and Senator George of Georgia. The seeds of this policy are just beginning to bear fruit. I should like to place in the record as appendix II an article from the Wall Street Journal of July 20, describing the proposal for construction by a private company for the State of New York of a multipurpose surfside reactor on Long Island. This plant will not only generate power, but purify a million gallons of water a day, and produce isotopes for medical uses.

I stated in 1954 and would like to state again:

"I would like to know whether there has ever been a finer example of that kind of cooperation directed at full use of resources of a region and to build up a region and to build up our great country that is found in Tennessee Valley Authority or the Bonneville Administration * * *.

"These programs enjoy the real American concept of progress in which the Federal Government as a partner provides only its services which the local people could not perform well or could not perform at all themselves. Never had the people found any programs so well calculated to foster and simulate and support a healthy flowering of private enterprise throughout the country.

"Backward peoples throughout the world [have been] flocking to our shores to learn how to follow our pattern * * * [as] an important key to achieve a higher and better civilization." (Congressional Record, vol. 100, p. 12147.)

And I can add our atomic energy development, under a "title" policy to this list. Thirty years from now, when desalinized water, and abundant power for the developing nations of the world become increasingly critical, the wisdom of the Congress in the field of atomic energy will surely be cataloged as "one of the great legislative decisions of its long history."

Is this the kind of policy the Congress should reverse by a "technical amendment"?

I read with interest the statement by Dr. Hornig at page 33 of the transcript implying that this reversal would benefit the public interest, since the agency could compel contractors to insure licensees and there is a possibility of the AEC taking title to more patents on nonatomic byproduct patents.

Dr. Hornig does not mention, however, that the Atomic Energy Commission is strongly opposed to S. 1809, and feels that section 152 of the Atomic Energy

Act of 1954 "should not be repealed." (AEC letter to Hon. James O. Eastland, dated June 30, 1965, p. 4.)

The AEC cites, in support of its position, "a comprehensive study" based on "extensive hearings" by the Joint Congressional Committee on Atomic Energy resulted in the approval of the basic "title" policy of 1954 and certain amendments in 1960. In addition, the Joint Committee has reviewed the Presidential patent policy of 1963, and recommended no changes.

As far as I am aware, the proponents of reversing this policy have advanced no evidence or authority whatever.

SECTION 11 IS UNSOUND AND UNDESIRABLE

In addition to the agriculture, TVA and Atomic Energy title policies, which have proven their worth many times over, there are other "title" provisions of more recent vintage, which are still in their infancy, but are bright with similar promise. We have the Space Act, the National Science Foundation Act, the Coal Research and Development Act, the Saline Water Conversion Act, and the Arms Control and Disarmament Act. There is the Water Resources Research Act of 1964, where a title policy might enable us to cope more rapidly with the pollution that has contributed to reducing the duck breeding population to a record low. (Daily Congressional Record, Aug. 12, 1965, p. 19407.)

Through all of these congressional enactments runs the thread of the public interest. We have new fields of technological opportunity which are being opened up by investment of the taxpayers money, accompanied by a patent policy which makes available information and inventions to all—not just the one company which was paid a profit to do the original research job. These programs listed in section 11 have been and are now major building blocks in our strength, character, and fame as a nation.

Yet, they are all scheduled for the guillotine under S. 1809, without the benefit of trial or even indictment. For Congress to act in this manner is not sound in law, in economics, in policy, or in legislative procedure. Further, in my judgment, to allow this consistent line of successful public interest patent legislation to be put to death quietly and in the dark, under the heading of "technical amendments," is inequitous. Adoption of such a provision by this body would be a breach of faith with the past as well as the future.

On the contrary, the Congress should build its policy for the future on these monumental achievements of the past.

PROPERTY DISPOSITION STATUTES OF THE PAST HAVE SHAPED OUR NATIONAL CHARACTER

While I am on the subject of the wisdom of Congress in molding our national character, I would like to invite the attention of the subcommittee to the analogy between the disposition of public R. & D. property and the guidelines for disposition of real estate in the public domain.

In 1785 and 1787 the Northwest Ordinances established the pattern for ownership and use, as well as the political organization, of our western territories. It is recalled with pride that Thomas Jefferson, the principal author of these laws, provided that the new territories would affiliate with the United States not as colonies, but as free and equal States. Further, it was decided that ownership of 1 section out of each 36 in a township would remain in the Government for the support of common schools. This Government acreage was later raised to 2 in 1848 and to 4 during the 1890's.

In 1862 the Homestead Act established a policy in accordance with President Lincoln's devotion to democratic ideals, which allowed any person to obtain a homestead of 160 acres by living and working on it.

In 1862, also, the Morrill Land Grant College Act endowed each State with 30,000 acres for each Member of Congress for the support of agriculture and mechanical institutions of higher education.

I believe that this wisdom of these policies for the disposition of the public domain have brought independence of livelihood and of mind to our people and honor to our Nation. It is interesting, I believe, that the land disposed of to further common schools, including the land-grant colleges is about the size of the

States of New Mexico and Montana.[1] It is also interesting that the amount of public land granted to small holders under the Homestead Act and its successor legislation amounted, as of June 30, 1963, to an area equivalent to the area of the States of Arkansas, Michigan, North Dakota, and Texas combined.[2] Since these figures are 2 years old, we might even be able to squeeze in Hawaii by now. (See the "Public Lands, Studies in the History of the Public Domain" by Vernon Carstensen, University of Wisconsin Press, 1962.)

Now, Mr. Chairman, we know how much this land was worth in 1862, because it is set forth in the Homestead Act—between $1.25 and $2.50 per acre. Even using the $2.50 figure, the maximum worth of all of this land in 1962, the total value of the property disposed of by the 37th Congress amounts to less than a billion dollars. Look at the good that has been done by disposing of this $1 billion worth of public property in the interests of all the people. By 1954, total investment in atomic energy had reached a cumulative total of $12 billion. In 1964, our public investment in patent property reached about $15 billion a year.

In this discussion, I am assuming that the patent rights to this public property are worth its cost—what we are spending on it. The patient rights may be worth less, or they may be worth a great deal more. The record is, I believe, deficient in this respect. The Congress needs some expert testimony on what this property is worth, and I recommend the subcommittee obtain such testimony.

At any rate, between 1947 and 1963, the Congressional Record reflects that about $85 billion of the taxpayers money had been spent to create public R. & D. property. (Congressional Record, Mar. 9, 1965, p. 4420.)

In the next 6 or 7 years, the Congress will probably appropriate an additional $100 billion for this purpose—an amount equal to our entire national budget.

THE MAIN ISSUE: HOW WILL THE BENEFITS OF THIS PUBLIC PROPERTY BE DISTRIBUTED?

Distribution of this wealth of intangible property rights is the central issue in this controversy. The issue is not how fast inventions are developed, or how much profit is made on them. This is what the business interests, whose responsibility is to be concerned with such matters, would like to have us believe.

This is the argument that Dr. Hornig comes back to again and again in his testimony,[3] that companies must be granted exclusive patent rights as incentives for commercial development. From this emphasis, you might suppose that this was the only important issue, or, at least, the most important. It is put forward as the overriding reason for the Government's parting with title to $15 billion worth of property a year.

On the question of commercialization, I am aware of no evidence which would contravene the conclusions of the Agriculture Department that a title policy is not a barrier to commercial development. I might say that, in my opinion, a self-serving statement by a contractor in this regard is not entitled to the same weight as a study, where contractors have been cross-examined, and other facts adduced.

EXCLUSIVE LICENSE SYSTEM A GREATER INCENTIVE THAN PATENTS

However, even if the subcommittee remains in doubt on this point, and believes that additional incentives are needed, Mr. Chairman, I ask the subcommittee whether the writing of incentive provisions is not a simple matter? Isn't it possible for a bill to provide, with great ease, for furnishing contractors with incentives, and also protection, by means of exclusive licenses to identified patents? Could not these licenses extend for 3 or 5 years, subject to renewal if the contractor shows he is making an effort to develop the patent? I submit that formulating such a system would be child's play for this committee.

May I ask further—would not such an approach have the advantage of retaining our successful "title" provisions of the past, and the additional advantage of almost unlimited flexibility in the future, as to the terms and conditions of licenses to be granted?

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[1] 78,600,000 acres for common schools and 9,290,000 for land-grant colleges or 137,328.1 square miles compared to 121,666 square miles for New Mexico and 147,138 for Montana.
[2] 287,300,000 acres or 448,906.24 square miles.
[3] Transcript, pp. 11, 12, 13, 14, 16, 17, 20.

If the subcommittee is most concerned with incentives for rapid development of inventions, I submit that such an exclusive license system is an even more powerful incentive device than exclusive patent rights, because the contractor is obliged to come back to the Government and make an affirmative showing of progress in order to retain his preferred position. Another benefit is that the Government agency does not need to bear the expenses of monitoring or enforcing "walk-in" rights. I suggest we let the recipient of the benefit walk in periodically, rather than making the taxpayer bear the additional monetary burden of bringing him in. I urge that this alternative receive appropriate consideration.

CONSIDERATION OTHER THAN INCENTIVE

However, incentives are not all we are worried about. The Justice Department unmasked the current version of this mythology in its dissenting opinion to the annual report of the Patent Advisory Panel of 1964. The Justice Department stated:

"(3) the report assumes that any commercial development or any invention by anyone is per se a public benefit. The Department of Justice disagrees with such an assumption. When the inventions are used to extend and consolidate commercial monopolies which go far beyond the scope of inventions or any group of inventions, we regard the public interest as having been seriously injured." (Memorandum from the Department of Justice representative, Patent Advisory Panel, Federal Council for Science and Technology, Dec. 4, 1964.)

JUSTICE DEPARTMENT'S CONSISTENT ADVOCACY OF A TITLE POLICY

In this connection, I should like to invite the subcommittee's attention to the opinion of the Attorney General in the most comprehensive Government patent report that has come to my attention, the "Investigation of Government Patent Practices and Policies." This study was begun at the request of President Franklin D. Roosevelt in 1943 and during its course, data was collected from 14 Federal agencies and 10 national governments. That study, and its supporting documents, were ultimately published in 1947, and have formed the foundation for a position in favor of a "title" policy, which the Justice Department has adhered to from that day to this. I will submit as appendix III these consistent expressions of policy by Attorney Generals since 1956—Democrats and Republicans alike.

The relevant findings and conclusions of the 1947 study are an excellent summary of the public interest factors over and above rapid utilization. They read as follows:

"IV. INVENTIONS MADE BY GOVERNMENT CONTRACTORS

"1. Where patentable inventions are made in the course of performing a Government-financed contract for research and development, the public interest requires that all rights to such inventions be assigned to the Government and not left to the private ownership of the contractor. Public control will assure free and equal availability of the inventions to American industry and science; will eliminate any competitive advantage to the contractor chosen to perform research work; will avoid undue concentration of economic power in the hands of a few large corporations; will tend to increase and diversify available research facilities within the United States to the advantage of the Government and of the national economy; and will thus strengthen our American system of free enterprise."

THE REAL PARTIES IN INTEREST

The "big show," as I believe I have made clear, is how the benefits of this public property shall be distributed. The matter can be traced back to the division between the Jeffersonian Democratic Party and the Federalist Party of Alexander Hamilton. It is whether the powers of Government shall be exercised for the benefit of the many, or of the few.

I believe it is important to stress that any congressional patent bill is dealing only with Government property. It has nothing to say about private research

and development. We are dealing here only with property bought and paid for by the taxpayer.

On October 10, 1963, there was issued the President's statement on Government patent policy which gives us the following perspective:

"During the past 20 years there has been a great deal of discussion and controversy of what rights the Government should acquire to inventions resulting from Government-sponsored research and development. The importance of this question has been studied increasingly since World War II with the ever-increasing and now substantial contribution the Government is making to the research and development effort in practically every field of science and technology. The debate focuses on the public interest * * *."

If I were to characterize this debate, I would say that it has been the common law, the courts, the Justice Department, and the public interest on one side and the contractors and their representatives on the other.

Lately, the traditional business interests, who are responsible to their shareholders and whose job is to make money, have been joined by a new element. These are the scientists.

THE ROLE OF THE SCIENTISTS

We have seen a good deal of speculation on the possible effects on society of the ascendancy of scientists in our national life. I believe it is germane to point out that the patent statement of 1963 which is the work of this group, contains no memorandum or law supporting its policy. It contains no empirical study based on patent practices of the agencies whose policy it proposes to change. It contains no reference whatever to the definitive report of the Department of Justice in 1947. Needless to say, there is no discussion of the constitutional responsibilities of Congress as to patent policy or the constitutional obligations of Congress concerning the disposition of property belonging to the United States.

Mr. Chairman, I submit that the Congress has an obligation to protect the country against the presumption that the scientists can do no wrong. Many of our eminent scientists are employed from time to time by large corporations and universities, which are the recipients of large amounts of Federal R. & D. money. Many of them thus have a direct or indirect financial interest in advocating the retention of patent rights by contractors or other institutions.

In addition, their areas of responsibility are not defined in terms of political localities which contain agriculture as well as industry, small business as well as large, poor areas as well as wealthy ones. They are not subject to the same influences as a man who has gained his adult experience in the field of public service, and who is impressed with a public trust. They have not seen the ebb and flow of national policy over many decades. The scientists are wizards in creating valuable R. & D. property, but when it comes to disposition of this property, it is well that the Constitution places the ultimate responsibility with public men.

CONSTITUTION RESPONSIBILITY FOR PATENT PROPERTY IS WITH THE CONGRESS

The responsibility for dealing with property owned by the taxpayers is spelled out in article IV, section 3 of the Constitution, which provides:

"The Congress shall have the power to dispose of and make all needful Rules and Regulations respecting the Territory, or other Property belonging to the United States."

Article I, section 8, clause 8, of course, gives Congress the power:

"To promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writing and discoveries."

The chairman reaffirmed these principles earlier this year, and in opening these hearings, noting:

"In recent years the Congress has frequently considered the inclusion of patent provisions in legislation authorizing new Government research programs. It is clearly the intent of Congress that the basic guidelines of Government patent policy should be determined by the Congress."

Even so, vigilance is called for in order to remind executive agencies, private corporations, and the people of the United States of these responsibilities. It is up to the statesman in Congress to resist the powerful pressures of this hour and to reassert the interest of all the people in their patent property.

I confess to surprise in reading the portions of the Patent Advisory Panel progress report of June 1964 which purports to establish a uniform patent policy by executive action, and to review patent practices and policies of each Government agency—many of which have been established by congressional enactment—"to identify areas where, in the opinion of the subcommittee (on Regulations Review) the regulations are either in conflict with the policy statement or fail to carry out its full intent * * *" (progress report, June 1964, p. 7).

It was shocking to me that an executive department; namely, the National Aeronautics and Space Administration, would establish a patent policy by its own regulations which is not only contrary to the report, but is in direct contravention to the National Aeronautics and Space Act, enacted in 1958 by this body. I have spoken at length and in detail upon these departures from the law on a prior occasion (Congressional Record, June 17, 1965, p. 13581).

As the subcommittee is aware, NASA's current policy leaves the disposition of Federal research and development to the discretion of individual contracting officers, who can dispose of all Federal rights at the time of contracting, when the nature, extent, and value of patent property cannot possibly be known.

These kinds of trespasses on congressional intention and responsibility should not be allowed to persist. However, I have the impression that S. 1809 would merely ratify these abuses by repealing the "title" presumptions and procedures of the Space Act and leaving matters to the same administrative discretion which has created the present unfortunate situation.

THE CONSEQUENCES OF PAST POLICY

In order to legislate on this matter for the future, I think it is necessary to assess the effects of what we have done in the past, in terms of the distribution of benefits of taxpayer-financed research.

It is my view that Congress use its power to protect public R. & D. property for the benefit of the many—the taxpayer, the small businessman, the State and municipal governments which must provide services to the people, the hospitals, and other such institutions which do not participate directly in the allocation of the $15 billion annual R. & D. appropriation.

The subcommittee may have seen the article in the Washington Post of July 17, 1965, headlined "L.B.J. Prods Cabinet for Budget Economy." I have attached it to my statement as appendix IV.

The article notes that, for the second straight day, President Johnson spoke personally with Cabinet and other officials about economy in Government.

He said: "I want each of you to bear in mind that the great burden of Federal taxation is not on the rich of this country, not on the poor of this country, but on the average family * * *. It's the average family that's going to pay the bill. They are the ones that buy the missiles. They are the ones who pay for the chauffeured limousines * * *."

Similarly, it is the average family who paid for $15 billion worth of research and development last year, and $85 billion worth since World War II, and the average family should get some return from it.

As to the small businessman, it seems to me from the following information developed by the Council of Economic Advisers, the Bureau of the Census, and the National Science Foundation, that the overall effect of Federal patent policy during the post-World War II era has been to reinforce and accelerate trends toward concentration in our economy.

The Council of Economic Advisers had this to say about trends in industrial structure in its annual report to the President in January 1965:

"* * * Within the important manufacturing sector, certain structural trends have emerged since World War II: (1) Through internal expansion and merger, large firms have grown more rapidly than the manufacturing section as a whole * * *.

"The market share of the 100 largest U.S. manufacturing firms has grown rapidly * * * between 1947 and 1962, their share of value-added in manufacturing grew from 23 percent to 32 percent. And their share of all manufacturing assets increased from 39 to 45 percent between 1950 and 1962.

"(Since 1948, the FTC) has recorded more than 11,000 mergers * * *. Since 1950, the 200 largest industrial corporations have acquired more than 2,000 other concerns, and 257 of the largest 1,000 manufacturing corporations have disappeared through merger. (Economic Report of the President, released Jan. 28, 1965, pp. 132–133.)

As several members of this subcommittee are well aware, the Federal Trade Commission estimates that trends toward concentration are becoming even more pronounced. It has testified that the share of manufacturing assets held by the 100 largest manufacturing companies rose from 38.6 percent in 1950 to about 45 percent in 1962 and perhaps as high as 48 percent in 1964. The share of the 200 largest seems to be increasing even faster. (See "Economic Concentration," hearings before the Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary, U.S. Senate, July 2, 1964, p. 121.) The Commission says further that mergers for the first 6 months of 1965 are running at an alltime high rate of 991. (See, also, "Mergers and Superconcentration, Acquisitions of the 500 Largest Industrial and 50 Largest Merchandising Firms," staff report of the Select Committee on Small Business, House of Representatives, Nov. 8, 1962.)

Now, in the face of these tendencies, which the Justice Department has viewed with alarm under both Democratic and Republican administrations, what has been the impact of Federal research and development policy?

FEDERAL R. & D. POLICY HAS ENCOURAGED CONCENTRATION

For a beginning, we will take allocation of Federal R. & D. money to the top four companies of all industries and compare this with how industry itself allocated its R. & D. money. Between 1958 and 1962, concentration of research and development funds spent by the top four in industry declined 14 percent. Over the same period, the concentration of federally financed research and development increased 16 percent, a difference of 30 percent. For the leading eight companies the industry concentration ratio declined 4.76 percent, but Federal research and development concentration ratio increased 9.52 percent, a net difference of 14.82 percent. This is shown by the following chart, which is to be included in the National Science Foundation publication entitled "Funds for Basic Research, Applied Research and Development in Industry, 1962."

TABLE 1.—*Funds for R. & D. performance of selected groups of manufacturing companies with the largest R. & D. programs as percent of total for all manufacturing companies performing research and development, 1958–62*

Selected groups of companies ranked according to size of R. & D. programs (based on total funds for R. & D. performance) [1]	Percentage of total for all manufacturing companies																	
	Total funds for R. & D. performance					Changes in concentration	Federally financed R. & D. performance					Changes in concentration	R. & D. performance financed by company and other non-Federal sources					Changes in concentration
	1962	1961	1960	1959	1958		1962	1961	1960	1959	1958		1962	1961	1960	1959	1958	
						Percent						*Percent*						*Percent*
First 4 companies	22	22	22	22	20	+10.66	29	32	28	29	25	+16.00	12	9	13	13	14	−14.28
First 8 companies	35	34	34	33	33	+6.66	46	45	42	41	42	+9.62	20	20	23	22	21	−4.76
First 20 companies	55	54	54	54	54	+1.85	68	66	65	68	68		38	38	36	33	36	+5.55
First 40 companies	69	69	68	68	68	+1.47	84	84	83	86	84	0	49	50	48	43	46	+6.52
First 100 companies	80	81	81	81	81	−1.23	93	92	92	94	93	0	64	66	65	62	64	0
First 200 companies	87	88	88	88	87	0	96	96	96	98	96	0	76	78	76	73	75	+1.33
First 300 companies	91	91	92	91	90	−1.11	97	97	97	99	97	0	82	84	83	79	80	+2.50

[1] Companies were ranked individually for each of the years. Therefore, particular companies comprising the selected size groups may have changed from year to year.

This data is confirmed by reference to the data on an industry-by-industry basis. In areas where comparisons are available, the most recent (1962) figures indicate that, for the top 4 companies, the proportion of Federal money exceeds the proportion of private money in 10 cases, while one comparison is the same, and the other differs by 1 percentage point. For the top 8 companies the concentration of Federal research and development money exceeds industry concentration in 16 cases out of 19, and for the first 20 companies, the Federal concentration exceeds the industry by 14 to 4.

What is even more disturbing is that this concentration has become worse as the years have gone on and Federal research and development expenditures have risen sharply.

A comparison of the 1962 figures with the relative concentration figures of 1958 indicates the following:

"In industry, concentration of research and development funds has gotten worse in 7 cases, better in 42 cases, and has remained the same in 3.

"For Government research and development funds, where figures are available, there has been a worsening of concentration in 9 cases, an improvement in only 16, while 2 have remained at the same percentage levels."

This is illustrated by another chart comparing figures developed by the National Science Foundation for the years 1958 and 1962.

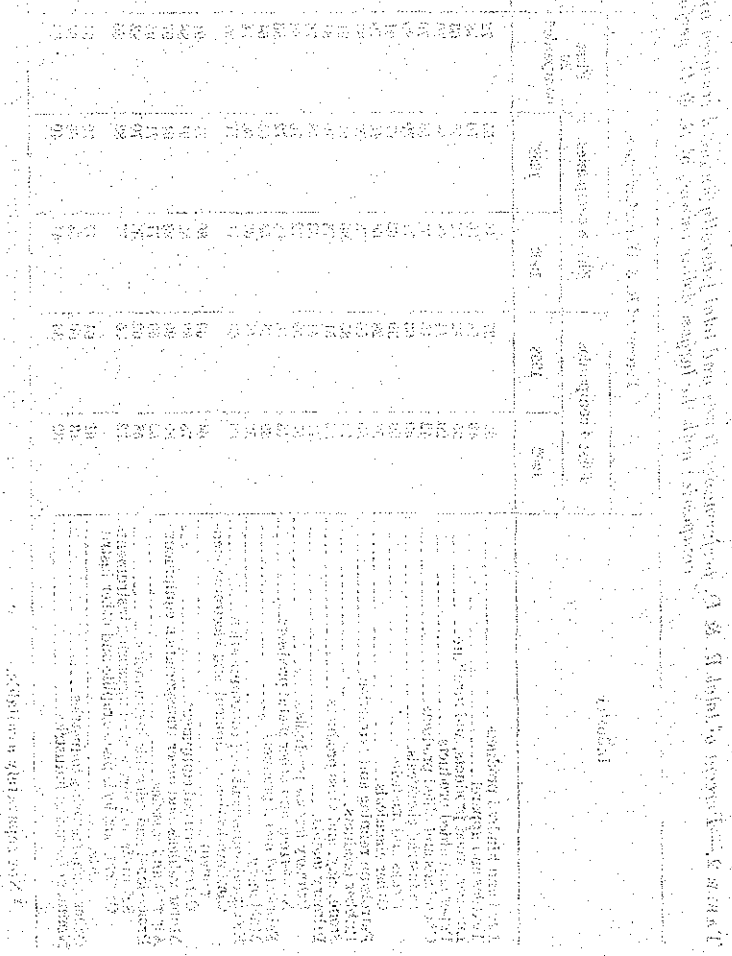

TABLE 2.—*Percent of total R. & D. performance funds and total federally financed research and development accounted for by the 4, 8, and 20 companies with the largest dollar volume of R. & D. performance by industry, 1962*

Industry	Percent of R. & D. performance					Percent of federally financed R. & D. performance				
	First 4 companies		First 8 companies		First 20 companies	First 4 companies		First 8 companies		First 20 companies
	1962	1958	1962	1958		1962	1958	1962	1958	
Food and kindred products	32	37	48	55	72	95		97		98
Textiles and apparel	40	58	56	70	78	(1)		(1)		(1)
Lumber, wood products, and furniture	35	42	52	55	63	(1)		(1)		(1)
Paper and allied products	29	44	48	58	70					
Chemicals and allied products	42	45	53	56	70	74	86	90	91	94
Industrial chemicals	59	63	74	79	89	65	87	91	92	96
Drugs and medicines	39	39	62	67	94	(1)		(1)		(1)
Other chemicals	58	28	66	45	79	(1)		(1)		(1)
Petroleum refining and extraction	50	50	73	73	93	86	62	100	66	100
Rubber products	79	85	86	91	91	(1)		(1)		(1)
Stone, clay, and glass products	52	51	73	70	88	(1)		(1)		(1)
Primary metals	41	44	53	58	76	51	47	51	73	66
Primary ferrous products	57	59	72	76	88	(1)		22		87
Nonferrous and other metal products	48	56	68	72	86	(1)		74		81
Fabricated metal products	39	48	53	65	84	(1)	62	80	89	84
Machinery	52	48	62	58	74	64	64	77	79	90
Electrical equipment and communication	60	63	74	77	84	61	64	79	81	91
Communication equipment and electronic components	64	60	80	77	91	63	63	81	80	94
Other electrical equipment	78	89	82	91	88	89	97	91	98	94
Motor vehicles and other transportation equipment	89	90	93	94	97	91	93	96	98	98
Aircraft and missiles	52	50	71	71	94	52	51	72	71	95
Professional and scientific instruments	58	62	68	70	83	69	71	79	81	88
Scientific and mechanical measuring instruments	72	75	77	83	86	(1)	92	89	95	95
Optical, surgical, photographic and other instruments	61	64	77	79	94	(1)	63	75	81	91
Other manufacturing industries	43	60	53	66	67	(1)	57	(1)	66	(1)
Nonmanufacturing industries	32	33	44	40	60	38	69	50	73	68

[1] Not separately available.

As those interest in this field know, there are enough forces in the economy militating against growth of small and medium-sized business without adding sledge-hammer blows from the disproportionate administration of Federal research and development funds in favor of the giants in each industry.

LOW PERCENTAGE OF FEDERAL R. & D. FUNDS AWARDED TO SMALL BUSINESS

Yet, we have the spectacle of about 85 percent of all Federal research and development funds being awarded, under the system of classification used by the National Science Foundation, to "large" companies of more than 5,000 employees. "Medium-sized" companies of from 1,000 to 5,000 employees receive about 9 percent, with "small businesses" having less than 1,000 employees receiving only about 6 percent of these enormous sums. (Most recent figures from National Science Foundation, 1962.)

Of course, the agency which has the greatest effect upon these figures and trends is the Department of Defense, which spent more than 70 perecnt of all Federal R. & D. money in 1961 and still spends more than half. It is also pertinent to note that NASA, which now spends close to 30 percent, has increasingly adopted the Department of Defense position.

CONCENTRATION RAISES ISSUE OF CIVIL-MILITARY BALANCE

To illustrate the seriousness of the concentration issue, particularly in the Defense Department, may I quote the testimony of Dr. Robert F. Lanzillotti, chairman of the Economics Department of Michigan State University, before the Senate Small Business Committee in 1963, as follows:

"The Government R. & D. contracts appear to be highly concentrated among the very large firms. While small business averages around 16 to 17 percent of Department of Defense procurement, when it comes to research and development small business accounts for some 2 to 3.5 percent. In fiscal year 1961, 20 corporations accounted for nearly 75 percent (of total military R. & D.).

"* * * is it not inconsistent—not to say dangerous—for the Federal Government to nurture such concentration in the technologically most advanced fields which can be preempted by the particular firms selected by military officials?" ("Economic Aspects of Patent Policies," hearings, Mar. 8, 1963, p. 121).

The seriousness of this matter of selection is indicated by the fact that in fiscal year 1962, 97 percent of DOD research awards were made on a nonprice noncompetitive basis. (Hearings, testimony of Dr. R. J. Barber, Southern Methodist University Law School, p. 52).

It should be further noted that for the same year, 10 firms received 56 percent of DOD's total research money; and for NASA, the top 10 companies received 54 percent. Furthermore, five of these contractors are on both lists. (Hearings, loc. cit., Mar. 7, 1963, p. 56–7.)

CONCENTRATION OF PATENT ACQUISITIONS

Specifically as to patent acquisitions, a Department of Justice study for the 5-year period ending in 1956 found that, among defense contractors, the top 15 companies accounted for 3,559 patents out of 6,788 assigned, for a total of 52 percent. (Hearings, loc, cit., p. 122). I would urge that the subcommittee obtain the updated figures, and make a judgment as to the degree of correlation between R. & D. contract administration and patent acquisition.

Mr. Chairman, I have recited these figures in considerable detail because they are relevant to the question of who would receive the benefits of a policy of granting exclusive commercial rights to contractors. At a minimum Federal R. & D. policy, in the administration of contracts, as well as in the allocation of patent rights, should attempt to counteract trends toward monopoly and concentration, rather than reinforce them as these policies appear to have been doing.

POSITION OF SMALL BUSINESSES SHOULD BE PROTECTED

With the formulation of a general patent bill, this committee has a golden opportunity to do something about it in a practical way. Yet, what do we find?

As you know, S. 1809 has no such small business provision. The President's Science Adviser admits at page 26 of the transcript that patent questions are "especially important" to small businesses. He admits at page 27 that the patent

right problems of subcontractors are unresolved. Mr. Chairman, in the name of the 90 percent of American firms which are small business, and the 300,000 manufacturers which are small business, we ought to give small business an even break in any patent bill.

I am not asking for preferential treatment for small business. But when, year after year, the two or three dozen largest companies in the country receive one-half or two-thirds of the research money, and take out a half or two-thirds of the patents, there is little question that this policy is preferential to big business.

In the name of all we value—independence of business enterprise, of finances, of mind, and of spirit—the Congress ought to take the time and trouble to provide equitably for small business in any patent legislation.

S. 1809, which is the principal bill before this subcommittee, is based very heavily upon the language and philosophy of the Patent Advisory Panel Progress Report of June 1964.

On page 3 of this report, we find the essence of this philosophy. You will recall the following language:

"* * * where a Government contractor is expected to build upon existing knowledge in a field of technology directly related to an area in which the contractor has an established technical competence and a nongovernmental commercial position, the policy statement stipulates that the principal or exclusive rights to resulting inventions should normally remain in the contractor * * * *this situation is perhaps best illustrated by the typical Department of Defense contract which is intended to build upon a contractor's established technical competence.* * * *" (Emphasis added.)

The statistical material above indicates what has been happening to the structure of our economy under a Government patent policy dominantly influenced by the Department of Defense. These trends threaten further concentration in the economy if this philosophy is projected into the future.

This would mean disadvantage for not only small business and medium-sized business, but all business in this country except the favored few corporate giants.

Enactment of such a policy by the Congress at this time of rapid technological change and scientific discovery would cast a pall on our system of free enterprise for generations to come.

It would assure that the top companies get bigger and more powerful, while smaller rivals would be under increasing pressure to merge, sell, or be driven out of business. It also means that many men of initiative would be denied the rights of going into business, or seeing their own businesses grow and flourish. The philosophy of this proposal thus strikes at the heart of our free enterprise system.

Accordingly, Mr. Chairman, I recommend that there be a mechanism by which small businesses can gain access to public research and development patents done by the giant corporations with public funds. Retention of title and a flexible system of licensing according to the equities involved seems to me an avenue that should be explored.

In S. 2160, a copy of which is attached as appendix VI, one system of this kind is available for the subcommittee's inspection.

DOES S. 1809 PROTECT THE POSITION OF THE TAXPAYER?

Now, at last, we come down to the individual taxpayer. How can we demonstrate how his monetary interests are affected?

In the course of the "great debate," the Senator from Louisiana (Mr. Long) has raised the case of a test developed to detect PKU, a cause of infant mental retardation. While title was in the Government, commercial manufacturers were producing this test for 1½ cents to 2 cents per baby, and making a profit. When a private firm claimed a patent on this test, it was priced at $0.52 per baby.

On August 12, 1965, two Senators introduced a bill (S. 2402) that would appropriate "such sums as may be necessary" to buy a test for every newborn baby in the country. A little arithmetic demonstrates that the sums necessary would be more than $2 million higher under a license policy than under a title policy. Since the original appropriations for developing the PKU test are estimated to be about $1 million, it can be seen that a failure to take title would result in the taxpayers being charged $2½ million every year for something they had already bought for $1 million.

The details of this story are more fully set forth in appendix VII, attached, as I believe they are especially pertinent in view of the members of the Judiciary Committee who have taken an interest in this particular matter.

I realize that S. 1809 contains a special exception for "fields which directly concern the public health, welfare, and safety." But this is a limited field, where less than 5 percent of R. & D. funds are spent.

If it makes sense to safeguard the taxpayers' investment in this area, where his Government puts up an estimated 15 percent of the research money, doesn't it make even more sense in scientific instruments, where the taxpayer furnishes 57 percent, or electronics and communications equipment, where the taxpayer's share is 67 percent, for aircraft, where the share is 89 percent. (See Federal Bar News, November 1963, p. 357.) What about education? What about housing?

How many tax cuts could be paid for by the sale or reservation of royalties on some of this extremely valuable patent property areas? Far from assisting the taxpayer in this respect, S. 1809 would prevent agencies now sharing royalties to continue to do so. (Letter to the chairman of the Judiciary Committee by Federal Aviation Agency, June 5, 1965, p. 2.)

From the foregoing, it does not appear that S. 1809 gives the taxpayer an even break. I, therefore, urge the subcommittee to seek testimony from qualified fiscal experts the effects of a general sale or royalty system.

CONTENT OF GENERAL PATENT LEGISLATION

Now, Mr. Chairman, let me comment further as to the specifics of the legislation now before the committee. I have noted that the Departments of Justice and Health, Education, and Welfare, have both expressed the opinion that further experience should be accumulated under the President's patent policy of 1963 before it is embedded permanently in the form of statutory law, and the Atomic Enery Commission opposes enactment of S. 1809. If the subcommittee does report a bill, I believe that these reservations and this lack of experience and empirical data should be recognized by making the legislation quite general and providing for collection of the needed information. I believe that a bill on the subject at this time should be governed by the following six principles:

1. A clear policy statement that Federal research and development property is a "natural resource belonging to the people of the United States," and must, therefore, be safeguarded accordingly.
2. Plain and certain penalties for the giveaway or unauthorized disposition of Federal R. & D. property.
3. Provision for preserving the many congressional patent protections that have been ordered into law over the past three decades.
4. Practical means for discouraging monopoly and concentration, and thus protecting the interests of small business and an "open economic system."
5. Clear and unambiguous standards separating and providing for private interests and the public interest in the commercial development of the property.
6. A system whereby Federal R. & D. property sought by private companies for commercial development could be sold or licensed to them for an amount equivalent to fair market value, and the same property sought by other public institutions for dedication to public purposes could be sold or licensed for half of the fair market value, wherever practicable.

The language of the policy declaration as you are aware is taken from the October 10, 1963, memorandum. In my judgment, it is consistent with settled law and sound public policy. A summary of the applicable law is attached as appendix V. The absence of such a declaration or the adoption by expression or implication of a contrary policy, would be, I believe, a historic failure by the Congress.

PROCEDURAL SECTIONS ARE AS IMPORTANT AS POLICY

Several of these provisions pertain to matters of procedure and standards. These are the vehicles by which any policy would be carried into effect, and are fully as important as the policy sections.

S. 789 is a fine example of a procedural trap. As stated by the Department of HEW, "the entire thrust of the bill is thus to impede the Government's taking and retaining of ownership in inventions derived from federally financed research, by making this a long arduous and exceedingly difficult and in many

cases impossible task." As Dr. Hornig stated: "In short, I think it leaves too few rights to the Government." [4]

As to an appropriate standard for waiver, I would recommend the one put forward by the 1947 Justice Department report, that there might be waiver under "emergency conditions" where the head of the agency certified this was so. I believe that this standard would cover the equities of all contractors adequately, but I would be willing to change my view in the face of enough concrete evidence that it would not.

There are several standards set forth in S. 1809, under which contractors would be able to acquire exclusive rights. The principal one of these is "exceptional circumstances."

The use of this phrase in connection with patent administration by a Federal agency has been specifically considered by a member of this body, the Senator from Connecticut (Senator Ribicoff), when he was Secretary of Health, Education, and Welfare. He warned of the dangerous ambiguities in the use of this standard in the following terms:

"The phrase in 'exceptional circumstances' is relatively vague and indefinite and in the absence of any indicated criteria in the policy itself would appear to leave considerable latitude to each agency head to determine what constitutes such circumstances. While this does have the advantage of flexibility, it does have the disadvantages of exposing agency heads to the pressures of those contractors who would urge that each circumstance of hardship, however slight, represents an exceptional circumstance calling for more generous allocation of invention rights."

The phrase "special circumstances" in section 4(c) of the bill is open to the same criticism which I consider to be wholly persuasive.

As a matter of fact, the report of the Patent Advisory Panel upon which S. 1809 and S. 789 are based, admits, and I quote:

"The working experience of the subcommittee has revealed that various agencies have placed different interpretations on certain key phrases found throughout the policy statement. It is believed that unless additional guidance is given, this problem of proper interpretation would only become exaggerated if left to the unguided judgment of the hundreds of contracting officers throughout the Government. The following are examples: * * * 3. The phrase 'exceptional circumstances.'"

Mr. Chairman, I believe this confession is the best evidence the subcommittee can have to establish two propositions: (1) That the disposition of these billions of dollars worth of patent properties should be placed by Congress, once and for all beyond the power and discretion of "hundreds of contracting officers throughout the Government"; and (2) that the phrase "exceptional circumstances" is not an appropriate standard to be used in this legislation.

It is my strong feeling that the power of disposition should be given into the ultimate responsibility of the head of any agency who is responsible to the President of the United States. Every effort should be made to preserve the actuality of responsibility for the disposition of Federal patent property, rather than perpetrating a misleading appearance of responsibility.

In S. 2160, I have suggested additional provisions for public licenses and royalties, and procedures which would result in written findings by the head of an agency as to both public versus private interests and value of patent interests. These proposals might be helpful to the subcommittee in formulating the necessary standards, and I commend them to the subcommittee's consideration.

If I can further assist the subcommittee during its deliberations, I would be glad to do so.

Appendix I

Inventions of the Department of Agriculture Commercialized for the Benefit of the Lumber Industry

1. The neutral sulfite semichemical pulping process for softened chipped wood in order to obtain pulp for good quality paper from woods once regarded as unsuitable for papermaking. It was reported in the press this month that application of this process has been extended to redwood chips. The process is used throughout the country, in more than three dozen mills and accounts for

[4] Transcript, p. 37.

about 7 percent of all pulp production, with a tangible value in excess of $200 million. One of the largest uses is making corrugated board for shipping containers which are superior to those made with any other materials. It also accounts for the use of more than 1½ million cords of hardwood, most of which are too low in quality for other purposes.

2. Another agriculture patent development is the fiber-glass electrical soil moisture meter for determining soil quality for both forest and range land. Again, in the words of this subcommittee: Its results have made businesses large savings in time or agriculture research workers and improved the reliability of soil by moisture determinations."

3. The electric wood moisture indicators which are widely used by lumber producers and wood-using industries.

4. Fiberneer is a new and useful packaging material. It combines the desirable attributes of paper overlaid wood veneer with corrugated fiberboard to produce a thin and lightweight material possessing substantial compressive strength under high moisture conditions.

These components have long been used separately in the packaging industry. Because of its strength, wood containers can support heavy superimposed stacking loads even when subjected to humid storage conditions. However, an all-wood container is heavy, bulky, noncollapsible, and somewhat difficult to fasten, store, and print. Corrugated fiberboard containers are lightweight, inexpensive, provide some degree of cushioning, permit labeling at time of manufacture, and are relatively strong when dry. Under high moisture storage conditions, however, an all fiberboard container loses its strength. Thus, failure to sustain substantial stacking loads places the load directly upon the contents of the container. To alleviate this problem, the height to which the containers are stacked is generally limited, resulting in inefficient use of storage space.

The object of this invention is to provide a packaging material which has the strength and resistance to moisture of wood and the light weight, low price, and printability of fiberboard. Containers fabricated from such a material, comprising a glued-up assembly of two paper-faced wood veneer sheets separated by a corrugated fiberboard medium, provides high stacking strength even when subjected to high humidity or high moisture conditions.

5. This invention relates to a machine that produces corrugated fiberboard capable of increasing the stacking strength of containers about one-third while reducing steam energy requirements to about 10 percent of conventional operations. Also, the floor area requirements are only a small fraction of present needs.

The machine produces corrugations in the machine direction of the corrugating medium, as contrasted with the conventional across machine direction. This contributes to the increased top-to-bottom compressive strength of containers fabricated from it and to the increased speed of the manufacturing operation. The speed can be increased because it is virtually a stress-free operation and the machine provides a continuous means for applying both top and bottom face liners simultaneously. Boxes can be fabricated from it on regular slotting, scoring, and printing equipment.

APPENDIX II

[From the Wall Street Journal, July 20, 1965]

NEW YORK STATE GIVES AMF GO-AHEAD TO BUILD ATOMIC DESALTING PLANT—NOTICE PORTENDS $2,750,000 ORDER FOR FACILITY TO CONVERT DAILY 1 MILLION GALLONS OF SEA WATER

(By a Wall Street Journal staff reporter)

NEW YORK.—American Machine & Foundry Corp. said it was authorized by the New York State Atomic and Space Development Authority to begin work on a $2,750,000 contract for a nuclear-powered desalination plant.

The facility will be located at Riverhead, N.Y., on Long Island Sound, and will convert salt water to fresh water at the rate of 1 million gallons a day. It will also have an electric generating capacity of 2,500 kilowatts and will produce high-energy radioactive isotopes for industrial and medical uses.

The authorization was in the form of a letter of intent providing for the execution within 3 months of a definitive contract under which AMF will provide all basic development, design, and equipment for the project. This includes the nuclear reactor, the desalting equipment, and the electric generator.

The project will involve an additional $1.5 million for other costs. Financing is being supplied in part by a $3.5 million appropriation authorized by the State legislature. The remaining funds are being requested from the Atomic Energy Commission and the Interior Department.

Construction is slated to begin early next year, pending approval by the AEC of an application for a construction permit. The permit is required to insure that the reactor isn't a hazard to the public. The plant is scheduled to be completed by 1968.

The project has been tilted with the acronym "Surfside," which stands for Small Unified Reactor Facility with Systems for Isotopes, Desalting, and Electricity.

Water output from Surfside will be purchased by Riverhead at prices ranging from 35 cents per 1,000 gallons in the 1st year to 45 cents in the 11th and succeeding years. Electricity output will be bought by Long Island Lighting Co. for 15 mills per kilowatt hour. The New York State atomic agency plans to operate the project and amortize its investment from revenue from the sale of water, electricity, and radioactive isotopes.

APPENDIX III

STATEMENTS OF THE ATTORNEYS GENERAL ON DANGERS OF CONCENTRATION INVOLVED IN PATENT POLICY

Among the factors decided in President Roosevelt's 1947 report, the theme of monopoly and concentration as a consequence of Government patent policy has recurred with regularity and increasing intensity as Federal involvement in research and development financing has mounted over the last 25 years.

A Republican Attorney General, Herbert Brownell, 1956, declared, in the following language, his concern:

"* * * with the future of competitive enterprise, and it is important that its share of this (research activity) be administered to promote competition. * * * (W) indications that run counter to the industrial trend toward concentration, but in some degree may actually enforce * * * the disproportionate share of total industrial research and development in the large firms may foreshadow a greater concentration of economic power and progress means that in the future an increasing share of anticipated improved technologies and new production lines will be introduced by the industrial giants."

In 1961, before Senate Subcommittee on Patents, Trademarks, and Copyrights, and in response to questioning by the chairman (Senator McClellan), Assistant Attorney General Lee Loevinger made the following summary of arguments as to the danger of concentration:

"Senator MCCLELLAN. * * * concisely, * * * if the Government gets all the benefits it wants from a license, what is the real objection to letting the inventor or discoverer, whether an individual or industry, take the patent rights for exploitation commercially * * *?

"Mr. LOEVINGER. One, this constitutes an outright subsidy to the contractor. He gets commercial rights that have been paid for generally on a cost-plus basis by the people of the United States, (and) exploits them exclusively for his own commercial benefit. They would be rights that he would otherwise have to pay for, and they are given to him out of tax moneys.

"Two, these subsidies are given not to the least able or the financially most needful, but to those that least need them, generally to the largest, most monopolistic corporations in the country.

"Three, because of this (there is a tendency toward) increasing concentration of economic power which in turn subverts the basis policy of antitrust law. * * *

"And, four, we believe that this is going to lead ultimately to a degree of concentration that will require the Government to step in with a kind of regulatory power over these great concentrated monopolies that is nothing more or less than a precursory to or a kind of socialism, if you like. I think that the surest road to socialism for this country is through the increasing monopolization of economic power.

"This alone won't do it, of course. But this is one of the ways by which this country is most likely to reach socialism [—] not by violent overthrow of the Government, but by concentration of economic power.

"Senator MCCLELLAN. You are saying in effect that monopoly leads to socialism?

"Mr. LOEVINGER. Yes, sir." (Government Patent Policy, hearings before the Subcommittee on Patents, Trademarks, and Copyrights of the Committee on the Judiciary, U.S. Senate, Apr. 21, 1961, p. 198.)

Successive Deputy Attorneys General of the Kennedy and Johnson administrations have expressed this concern in similar statements. Deputy Attorney General Byron R. White, before the Senate Small Business Committee on March 26, 1962, spoke as follows:

"Many of these contractors are already leaders in their respective commercial fields. They already possess highly developed facilities and mature capacity for research. The effect of allowing such firms additional patent rights as well, tends to consolidate their already dominant positions and make their preferred status in newly developed industries even more immune to competition than it is now.

"The license policy automatically grants patents to the contractor and consolidates dominance without regard for the consequences in terms of monopoly power. The experience of the Antitrust Division has demonstrated that litigation to break up unlawful aggregations of patents and know-how is a difficult and frequently ineffective remedy. It is usually available only after considerable injury has already been suffered by the economy.

"Where title generally vested in the Government, ready access of small business to know-how as well as patent rights, is more adequately safeguarded than would otherwise be the case."

The present Attorney General, the Honorable Nicholas DeB. Katzenbach, told the Senate Small Business Committee a year later:

"The Department of Justice has frequently stated that, when inventions are produced as a result of governmental expenditure it is generally undesirable to permit the developing contractors to exclude others from the use of inventions. This is partly true in cases where the research itself is aimed at developing commercial products to promote public health, public safety, or increased productivity but, beyond these obvious examples, we believe that the Government should generally retain title * * * and rarely, if ever, should the Government agency in advance of the time when the invention is known and produced for title to be given to the contractor * * * the great defect of a policy which routinely provides in advance of inventions that contractors retain title is simply that no one can know at the time (of contracting) what it is that the Government is giving up or the contractor is acquiring." (Economic Aspects of Government Patent Policies, hearings before the Monopoly Subcommittee of the Senate Small Business Committee, Mar. 7, 1963, p. 2.)

The present opinion of the Department of Justice, dated July 22, 1965, is also contained in the record.

APPENDIX IV

[From the Washington Post, July 17, 1965]

L.B.J. PRODS CABINET FOR BUDGET ECONOMY

(By Alvin Spivak, United Press International)

For the second straight day, President Johnson called in Government officials yesterday to tell them to cut costs by budget-making time.

The President, who has managed to keep the budget under $100 billion for each of the past 2 years through similar techniques, again took a personal hand in the Government's economy drive.

He has indicated there is a serious question whether the budget could remain under $100 billion next year in light of the increased cost of the Vietnamese war and his Great Society programs. For the current fiscal year, the budget is $99.7 billion, with a deficit of $5.3 billion.

At yesterday's session Mr. Johnson told a gathering of officials from various departments and agencies, "I want each of you to bear in mind that the great burden of Federal taxation is not on the rich of this country, not on the poor of this country, but on the average family."

He placed heavy stress on reduced Government costs to permit the United States to finance its world leadership in education, health, and other fields.

Interior Secretary Stewart L. Udall, Agriculture Secretary Orville L. Freeman and Poverty Program Director Sargent Shriver were among the officials who reported on their own money-saving achievements.

Mr. Johnson ended the session by urging subcabinet officials to come up with "a realistic bare bones budget" that their bosses can defend when he scrutinizes it line by line at the end of the year.

He urged each Cabinet member to make at least three suggestions that could be of use to other departments as well. Pointing to charts behind him on how the Defense Department had saved billions of dollars, Mr. Johnson said:

"You all don't work with missiles but you may find out how to save on a pencil bill, or an electric bill, or a food bill, or anything. * * *

"It's the average family that's going to pay this bill. They are the ones that buy the missiles. They are the ones that pay for the chauffeured limousines. They are the ones that pay to light the chandeliers * * *."

APPENDIX V

MEMORANDUM OF LAW APPLICABLE TO DISPOSITION OF PATENT RIGHTS ARISING OUT OF GOVERNMENT-FINANCED RESEARCH AND DEVELOPMENT

This constitutional provision is silent as to the methods of disposing of property belonging to the United States, and any appraisal of the scope of authority conferred thereby is to be obtained almost entirely from the judicial precedents wherein this provision has been construed. A thorough examination of the debates and journals of the Constitutional Conventions, the Federalist, and Story's Commentaries discloses merely that the framers of the Constitution, during their consideration of this provision, were preoccupied with the acquisition and disposition of public lands by the United States.

In *United States* v. *Gratiot* (14 Pet. 526, 531, 532–533, 537–538), wherein a litigant contended that the constitutional power to dispose of federally owned property embraced only the sale, but not the lease, thereof, the Supreme Court answered by holding that the power of disposition "is vested in Congress without limitation," and "the disposal must be left to the discretion of Congress." Again, in *Ashwander* v. *Valley Authority* (297 U.S. 289, 331–333, 338 (1936)), the Court reiterated that this—

"Consitutional provision is silent as to the method of disposing of property belonging to the United States. That method, of course, must be an appropriate means of disposition according to the nature of the property, it must be one adopted in the public interest as distinguished from private or personal ends, and we may assume that it must be consistent with the foundation principles of our dual system of government and must not be contrived to govern the concerns reserved to the States.

"The occasion for the grant (of this power) was the obvious necessity of making provision for the government of the vast territory acquired by the United States. The power * * * to dispose of that territory was deemed to be indispensable to the purpose of the cessions made by the United States. And yet it was a matter of grave concern because of the fear that 'the sale and disposal' might become a source of such immense revenue to the National Government, as to make it independent of and formidable to the people.' Story on the Constitution (pars. 1325, 1326). The grant was made in broad terms, and the power of regulation and disposition was not confined to territory, but extended to 'other property belonging to the United States,' so that the power may be applied, as Story says, 'to the due regulation *of all other personal and real property* belonging to the United States.' And so, he adds, '*it has been constantly understood and acted upon.*'" [Emphasis supplied.]

"It would seem to be clear that under the same power of disposition which enabled the Government to lease (its mineral lands) and obtain profit from sales by its lessees, it could * * * have provided for mining directly by its own agents * * * and obtain profit from its own sales."

In other decisions the Court repeatedly has acknowledged that "the Government has with respect to its own land the rights of an ordinary proprietor to maintain its possession and prosecute trespassers. It may deal with such lands precisely as an ordinary individual may deal with his farming property. It may sell or withold them from sale * * *. The United States can prohibit absolutely or fix the terms on which its property may be used. As it can withhold or reserve the land, it can do so indefinitely * * *. *The full scope of this paragraph* (art. IV, par. 3, cl. 2) *has never been definitely settled.* Primarily, at least, it is a grant of power to the United States of control over its property."

(*Light* v. *United States*, 220 U.S. 523, 536–537 (1911), citing and quoting *Camfield* v. *United States*, 167 U.S. 518, 524, (1897) and *Kansas* v. *Colorado*, 206 U.S. 46, 89 (1907)). To the same effect are *United States* v. *Midwest Oil Co.* (236 U.S. 459, 474 (1915)) and *Sinclair* v. *United States* (279 U.S. 263, 297 (1929)). [Emphasis supplied.]

According to the Statement on Government patent policy of October 10, 1963:

"The inventions in scientific and technological fields resulting in work performed under Government contracts constitute a *valuable national resource.*" [Emphasis supplied.]

This declaration appears to rest upon sound principles of both law and public policy.

According to settled law, a company hired to perform identified research and development is subject to turning over the patent properties arising out of this research to any employer including the Federal Government. (*Standard Parts Co.* v. *Peck*, 264 U.S. 52 (1923): *U.S.* v. *Dubilier Condensor Corporation*, 289 U.S. 178 (1933)). Since the substance of Government research and development work must be defined before contracts are granted, the Federal Government and thus the people of the United States are, under existing judicial precedents, entitled to the entire interest in the resulting property.[1] The taxpayers' interest extends not only to a license or right of use, but to the whole ownership of any invention, patent or process made in the course of a specific research assignment.

The companies performing these contracts fully recognize this principle in the universal practice of requiring their employees to sign over rights to any patent properties. This assertion of ownership applies to inventions these individuals discover or perfect in the course of not only of these same Government contracts, but the entire term of their employment and, with at least one company, beyond their employment.

APPENDIX VI

[S. 2160, 89th Cong., 1st sess.]

A BILL To amend section 305 of the National Aeronautics and Space Act of 1958 with respect to the disposition of proprietary rights in inventions made thereunder, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 305 of the National Aeronautics and Space Act of 1958 (42 U.S.C. 2457) is amended to read as follows:

"SEC. 305. (a) Whenever any invention is made in the performance of any scientific or technological research, development, or exploration activity under this Act every invention made as a result of such activity shall be the exclusive property of the United States, and if such invention is patentable a patent therefor shall be issued to the United States upon application made by the Administrator, unless the Administrator waives all or any part of the rights of the United States to such invention in conformity with the provisions of subsection (f) of this section and in compliance with the requirements of this section.

"(b)(1) Each contract and lease entered into by or on behalf of any officer or agency of the United States with any party, and each grant made by any such officer or agency to any party, under authority conferred by this Act, shall be entered into or made under conditions effective to insure that such party will furnish promptly to the Administrator a written report containing a full and complete description of, and full and complete technical information concerning, each invention, discovery, improvement, and innovation which may be made as a result of any activity undertaken or performed under that contract, lease, or grant.

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[1] "* * * Virtually all governmental research contracts mark out clearly the nature of the project; this is essential, for otherwise neither party would know what costs are pertinent to the grant and hence to be reimbursed by the Government. Since the work is thus well defined and one of the goals is to invent, the Government would, under existing judicial precedents, normally be entitled to the patents and other rights in any inventions made during the performance of the contract * * *" ("Economic and Legal Problems of Government Patent Policies," report of the Subcommittee on Monopoly of the Select Committee on Small Business, U.S. Senate, June 15, 1963, p. 13).

"(2) If any such party fails to transmit any such report to the Administrator within thirty days after the date on which any such invention, discovery, improvement, or innovation is made, such party shall be liable to the United States for the payment of a civil penalty in the amount of $100 for each additional day of delay in the transmission of such report to the Administrator. Action for the recovery of any such penalty shall be instituted by or under the direction of the Attorney General, and may be instituted in the district court of the United States for any judicial district in which the defendant resides, is found, or transacts business. Process of such court in any such acttion may be served in any other judicial district of the United States by the United States marshal thereof.

"(c) No patent may be issued to any applicant other than the Administrator for any invention which appears to the Commissioner of Patents to have significant utility in the conduct of aeronautical and space activities unless the applicant files with the Commissioner, with the application or within thirty days after request therefor by the Commissioner, a written statement executed under oath setting forth the full facts concerning the circumstances under which such invention was made and stating the relationship (if any) of such invention to the performance of any work under any contract, lease, or grant entered into or made under this Act. Copies of each such statement and the application to which it relates shall be transmitted forthwith by the Commissioner to the Administrator.

"(d) Upon any application as to which any such statement has been transmitted to the Administrator, the Commissioner may, if the invention is patentable, issue a patent to the applicant unless the Administrator, within ninety days after receipt of such application and statement, requests that such patent be issued to him on behalf of the United States. If, within such time, the Administrator files such a request with the Commissioner, the Commissioner shall transmit notice thereof to the applicant, and shall issue such patent to the Administrator unless the applicant within thirty days after receipt of such notice requests a hearing before a Board of Patent Interferences on the question whether the Administrator is entitled under this section to receive such patent. The Board may hear and determine, in accordance with rules and procedures established for interference cases, the question so presented, and its determination shall be subject to appeal by the applicant or by the Administrator to the Court of Customs and Patent Appeals in accordance with procedures governing appeals from decisions of the Board of Patent Interferences in other proceedings.

"(e) Whenever any patent has been issued to any applicant in conformity with subsection (d), and the Administrator thereafter has reason to believe that the statement filed by the applicant in connection therewith contained any false representation or omission of any material fact, the Administrator within five years after the date of issuance of such patent may file with the Commissioner a request for the transfer to the Administrator of title to such patent on the records of the Commissioner. Notice of any such request shall be transmitted by the Commissioner to the owner of record of such patent, and title to such patent shall be so transferred to the Administrator unless within thirty days after receipt of such notice such owner of record requests a hearing before a Board of Patent Interferences on the question whether any such false representation was contained in such statement. Such question shall be heard and determined, and determination thereof shall be subject to review, in the manner prescribed by subsection (d) for questions arising thereunder. No request made by the Administrator under this subsection for the transfer of title to any patent, and no prosecution for the violation of any criminal statute, shall be barred by any failure of the Administrator to make a request under subsection (d) for the issuance of such patent to him, or by any notice previously given by the Administrator stating that he had no objection to the issuance of such patent to the applicant therefor.

"(f) (1) Whenever any person has made any invention which under subsection (a) is the exclusive property of the United States, such person may make written application for the transfer to such person of all or any part of the interest of the United States in that invention under such regulations as the Administrator shall prescribe in conformity with the provisions of this section. Each such application shall contain a full and complete (A) description of the invention as to which the application is made, (B) statement of the circumstances under which that inven-

tion was made, (C) statement of the relationship, if any, of such invention to any contract, lease, grant, or program of the United States or any department or agency thereof, and (D) statement of such other information as the Administrator shall determine to be necessary for a determination of action to be taken upon such application. Each application for the transfer of any property interest of the United States shall be accompanied by a sealed bid specifying the sum which the applicant offers to pay to the United States in compensation for such interest if transfer thereof is granted.

"(2) Each application made under paragraph (1) of this subsection shall be transmitted to an Inventions and Contributions Board (referred to hereinafter in this section as 'the Board') which shall be established by the Administrator within the Administration. Upon receipt thereof, the Board shall accord to the applicant opportunity for hearing thereon. Notice of hearing upon each such application shall be published by the Administrator in a publication of general national circulation at least once not less than ninety days before the date of such hearing, and a second time at least sixty days after the first such publication but not less than thirty days before the date of such hearing. Under such regulations as the Administrator shall prescribe, any person shall be entitled to intervene as a party to such proceedings in opposition to such application upon a showing of probable public or pecuniary interest in the determination to be made upon such application. Each such hearing shall be subject to the provisions of the Administrative Procedure Act.

"(3) Upon the basis of evidence received in such proceedings the Board shall transmit to the Administrator its written report thereon. If the Administrator determines, upon the basis of the report made by the Board upon any such application, that considerations of equity clearly favor the granting of such application and that the public interest would be served thereby, he may transfer to the applicant the whole or any part of the interests of the United States in the invention as to which such application was made. Any such transfer shall be made upon the payment of an amount equal to the fair market value of the interest transferred as of the time of the transfer, and upon such other terms and under such other conditions as the Administrator shall determine to be required for the protection of the interests of the United States. In no case shall such fair market value be less than the amount of the applicant's sealed bid. Each such transfer made with respect to any invention shall be subject to the reservation by the Administrator of an irrevocable, nonexclusive, nontransferrable, royalty-free license for the practice of such invention throughout the world by or on behalf of the United States or any foreign government pursuant to any treaty or agreement with the United States.

"(4) Under such regulations as the Administrator shall prescribe, any person who intervenes, in any proceeding under this subsection with respect to any patented or patentable invention, in opposition to the transfer for which application was made under paragraph (1) may in such proceeding offer evidence to the effect that the Administrator in the public interest should grant to him authorization for the use of such invention, and may file with the Administrator at the time of his intervention an application for the purchase of one or more specified interests in that invention subject to the conditions prescribed by this paragraph. Each such application made under this paragraph shall be accompanied by a sealed bid containing an offer to purchase such interest or interests in the invention for a sum or sums specified therein. If the application made under paragraph (1) with respect to that invention is denied, the Administrator shall determine whether it is in the public interest to grant one or more of the applications made by intervenors under this paragraph for the purchase of interests in the invention. If he determines that it is in the public interest to grant any such interest, he shall consider the bids made therefor by intervenors, and shall grant such interest to the intervenor who is the highest responsible bidder for such interest. Any such grant shall be conditioned upon the reservation by the Administrator of an irrevocable, nonexclusive, nontransferrable, royalty-free license for the practice of the invention throughout the world by or on behalf of the United States or any foreign government pursuant to any treaty or agreement of the United States. If, after the denial of an application made with respect to any invention under paragraph (1), the Administrator determines that it is not in the public interest to grant any interest under this paragrah, he shall return unopened all sealed bids made by intervenors.

"(5) Each determination made by the Administrator in or with respect to any proceeding under this subsection shall be made in writing, and shall be

accompanied by a report in which the Administrator shall set forth fully the facts and circumstances upon which reliance was placed in the making of that determination. Within sixty days after the final determination of any such proceeding by the Administrator, any party to such proceeding who is aggrieved by any determination made therein by the Administrator may institute action in the District Court of the United States for the District of Columbia for the review of such determination. Upon service of the complaint in any such action upon the Administrator, he shall certify to the court a true and correct copy of the transcript of all evidence taken in such proceeding and a true and correct copy of each determination and report made therein by the Administrator or by the Board. Such court shall have jurisdiction to hear and determine any such action, and to enter therein such orders as it may deem proper to affirm, modify, set aside, or enforce as affirmed or modified any determination made by the Administrator in such proceeding. In any such action, findings of fact made by the Administrator shall be conclusive if supported by substantial evidence. Upon application made by any party to any such action, the court in its discretion may order additional evidence to be taken before the court or before the Administrator upon such terms and conditions as the court may deem proper. Process of the district court in any action instituted under this paragraph may be served in any other judicial district of the United States by the United States marshal thereof. Whenever it appears to the court in which any such action is pending that other parties should be brought before the court in such action, the court may cause such other parties to be summoned from any judicial district of the United States.

"(g) To the extent to which disposition of rights to any invention has not been made under subsection (f), the Administrator shall determine, and promulgate regulations specifying, the terms and conditions upon which nonexclusive licenses will be granted by the Administration for the practice by any person (other than an agency of the United States) of any invention for which the Administrator holds a patent on behalf of the United States.

"(h) The Administrator is authorized to take all suitable and necessary steps to protect any invention or discovery to which he has title, and to require that contractors or persons who retain title to inventions or discoveries under this section protect the inventions or discoveries to which the Administration has or may acquire a license of use.

"(i) Whenever any person has appropriated to his own use or benefit any invention which under subsection (a) is the exclusive property of the United States, without authority therefor conferred upon him pursuant to subsection (f) or subsection (g), the Attorney General, upon his own motion or upon request made by the Administrator, may institute action against such person in the district court of the United States for any judicial district in which such person resides or is found. Such court shall have jurisdiction to hear and determine such action. If the court determines that any such unlawful appropriation has occurred, it shall enter such judgment, orders, and decrees as it shall determine to be required to provide for the establishment of title to such invention in the United States and for the recovery by the United States of a sum equal to the aggregate amount of all income derived by the defendant through the exploitation of such invention. Any private citizen of the United States having knowledge of any such unlawful appropriation of any such invention by any person may on behalf of the United States institute action against such person in any such district court for any relief which would be available to the United States under this subsection in an action instituted hereunder by the Attorney General. A successful plaintiff in any such action instituted by a private citizen shall be entitled to recover from the defendant, in addition to any relief granted to or on behalf of the United States, a sum equal to the aggregate amount of the expenses actually and necessarily incurred by the plaintiff in the preparation and prosecution of such action, including a reasonable attorney's fee, as determined by the court. If, in any such action instituted by a private citizen, the court renders judgment requiring the payment of any sum to the United States, the plaintiff shall be paid, from the sum so recovered by the United States, an amount equal to 10 per centum of that sum, or the amount of $50,000, which ever amount is smaller. Process of the district court in any action instituted under this subsection may be served in any other judicial district of the United States by the United States marshal thereof. Whenever it appears to the court in which any such action is pending that other parties

should be brought before the court in such action, the court may cause such other parties to be summoned from any judicial district of the United States.

"(j) Whoever, with knowledge that an invention is the exclusive property of the United States, (1) appropriates or attempts to appropriate such invention to his own use or benefit without authority for such appropriation conferred upon him under subsection (f) of subsection (g), or (2) knowingly conspires with any other person to appropriate any such invention to the use or benefit of any person not lawfully entitled to the use or benefit of such invention, shall be fined not more than $10,000, or imprisoned not more than five years, or both. Any person who commits any offense under this subsection with willful intent to defraud the United States of its right to such invention or to the exploitation thereof shall be fined not more than $50,000, or imprisoned not more than ten years, or both.

"(k) As used in this section—

"(1) the term 'person' means any individual, partnership, public or private corporation, association, institution, or other entity;

"(2) the term 'contract' means any actual or proposed contract, agreement, understanding, or other arrangement, and includes any assignment, substitution of parties, or subcontract executed or entered into thereunder; and

"(3) the term 'made', when used in relation to any invention, means the conception or first actual reduction to practice of such invention."

SEC. 2. The amendment made by this Act shall have no application to any invention made in the performance of any work under any contract entered into by the National Aeronautics and Space Administration before the date of enactment of this Act.

APPENDIX VII

DETAILED COST COMPARISONS OF PKU TESTS UNDER PUBLIC AND PRIVATE PATENT OWNERSHIP

It has been brought to my attention that on August 12, Senators Prouty and Edward Kennedy introduced S. 2402, a bill to promote the detection of phenylketonuris (better known as PKU) and other inborn errors of metabolism leading to mental retardation.

Such legislation would allow the Surgeon General to make grants of "such sums as are necessary" to the States to pay the cost of blood-testing programs and other screening examination expenses. The simple blood test used to detect PKU in infants which was developed with public funds by Dr. Robert Guthrie at the University of Buffalo, has been the subject of much discussion since it was brought to the attention of the Senate and the public by the Senator from Louisiana (Mr. Long).

Senator Long pointed out that Miles Laboratories, having secured an exclusive license from Dr. Guthrie for the life of the patent, reportedly wanted to charge $262 to produce a test kit for 500 babies. Dr. Guthrie's cost to produce the kit was $6. Fortunately, dedicated public servants in the Department of Health, Education, and Welfare became aware of this situation and determined that ownership of the invention belonged to the United States and the proper action was taken to annul the license to Miles.

If each newborn child is to be tested for PKU, and the Government is to subsidize this effort, the market for the test kits is virtually limitless; the normal risks of production are eliminated. Therefore, the customary justification for the granting of exclusive rights to produce the kits would have no merit. The projected figure for the average annual number of births in the United States over the next 5 years is 4,960,000 annually. If Miles had been allowed to sell the kit for 52 cents per child as it had planned to do, the annual cost to the Government for the kits alone under the program proposed by S. 2402 would have been $2,579,200 per year. With title to the invention vested in the Government, however, it is possible for hospitals to purchase the kits commercially for less than 2 cents per infant, and for those hospitals with adequate facilities to produce the kit themselves to do so for 1.2 cent per kit per child.

This is a difference of over 50 cents per kit per child based upon the difference between a "title" and a "license" policy.

The costs of producing kits for all newborn infants in a year under the two policies would be $59,520 versus $2,519,600.

A license policy would thus have cost an additional $2 million annually to purchase something that had originally been paid for by an estimated $1 million in appropriations.

APPENDIX VIII

THE UTILIZATION OF GOVERNMENT-OWNED PATENT INVENTIONS

Inventors indicated that the amount of necessary development for commercialization of most Government-owned patents is slight or moderate (see table 10). Approximately 35 percent of all Government-owned patents require slight development, 40 percent moderate, and 18 percent extensive.

TABLE 10.—*Inventors' estimates of the amount of further development required for commercialization of sampled patented inventions*

Agency or department	Total number	Extensive		Moderate		Slight		Blank	
		Number	Percent	Number	Percent	Number	Percent	Number	Percent
Department of Agriculture	10	1	10.0	5	50.0	4	40.0	0	0
Atomic Energy Commission	22	5	22.7	7	31.9	9	40.9	1	4.5
Department of Defense	46	8	17.4	19	41.3	14	30.4	5	10.9
Other agencies	2			1	50.0	1	50.0		
Total	80	14	17.5	32	40.0	28	35.0	6	7.5

"The Utilization of Government-Owned Patented Inventions," Mary A. Holden, assistant research professor of economics, George Washington University, Washington, D.C., reprinted from the Patent, Trademark, and Copyright Journal of Research and Education, vol. 7, No. 2, Summer 1963, p. 153.

Senator MORSE. Then, sir, in fairness to you and the committee as well as other witnesses, I wish you would instruct your assistants to keep time on me and stop me at, I think, the end of 15 minutes, so that I will not exceed a reasonable time.

Senator MCCLELLAN. We will not stop you. We will alert you as to that length of time. Fifteen minutes?

Senator MORSE. I think you want me to testify for 15 or 20 minutes, and I want to be sure that I stay within that time.

Senator MCCLELLAN. No, Senator. We were just trying to expedite the hearing for the benefit of people from out of town, but we have not adhered to that rule. You may have all the time you wish.

Senator MORSE. No, I do not want to do that, because it is important that you hear the other people. I have put my whole statement in, and I know you well enough, and the committee well enough, to know that my statement will be carefully analyzed by you and the staff. That is the important thing, to get it in the record.

Senator MCCLELLAN. Very well.

Senator MORSE. I would like to say at the outset, Mr. Chairman, that I have been the beneficiary for almost 4 years now of an association with a brilliant young lawyer, who sits at my right, Mr. Herbert Spira, who is on the legal staff of the Small Business Committee. He and I have worked on this patent issue for that period of time.

I never believe in cribbing, Mr. Chairman, without acknowledging the cribbing in advance. I want to say that this is a mutual effort of Mr. Spira and your witness this morning. I want the record to show that I am very proud to present Mr. Spira for this record, so that future reference to it will show that he and I have worked together on this matter.

Since 1947, the American taxpayer has spent $85 billion on Government-financed research and development. In the next 6 or 7 years $85 billion more will be contributed by the taxpayer and appropriated by the Congress for these purposes. The commitment of public funds on this scale to scientific research and the development of advanced systems is surely one of the most significant economic events of modern history.

This subcommittee has the task of formulating national policies for disposition of the rights to the commercial exploitation of patent property created as a result of these public expenditures.

The chairman's letter of invitation to Members of the Senate is one more indication of thorough and conscientious approach which the subcommittee has taken to this extraordinary and complex task. I feel that the Nation is fortunate in having such consideration by the chairman, and the diligent participation by the members of the subcommittee, which is being brought to bear on these problems.

My formal statement is rather lengthy, since there is a good deal of statistical and historical material which I would like to have available to the subcommittee. I would like to proceed with the summary. If there is time remaining, I would be glad to go into a particular area which the subcommittee believes it would like to ask me about.

I am aware that the subcommittee is very much concerned with the commercial utilization and exploitation phase and I will place my emphasis there.

In accordance with the chairman's wishes, I have included in my statement an outline of my activities in the patent and public property areas, including the history of the Morse formula, my participation in the Atomic Energy legislation, and the legislation which I have introduced on NASA patent policy during the 88th and 89th Congresses. My position, as embodied in S. 2160 on NASA patent policy, is that taking of title by the Government in behalf of all of the people should be coupled with a flexible system of licensing, such as was discussed with Dr. Shannon on Tuesday morning, August 17. Under procedures which I envision, this system will provide equal protection, and even greater incentives than waiver of patent rights, for contractors developing and marketing inventions.

A precondition for such a flexible policy is, of course, the assertion of title by the Government agency concerned in the first instance. Once patent rights are waived to an individual contractor for 17 years, flexibility is lost forever.

At the opening session of the hearings, the President's Science Adviser gave great emphasis to this issue of utilization. My experience makes me sensitive to additional considerations of great importance. An excellent summary of these factors is found in the findings and conclusions of the Attorney General's report of 1947, which I would like to take a moment to read:

IV. Inventions Made by Government Contractors

1. Where patentable inventions are made in the course of performing a Government-financed contract for research and development, the public interest requires that all rights to such inventions be assigned to the Government and not left to the private ownership of the contractor. Public control will assure free and equal availability of the inventions to American industry and science;

will eliminate any competitive advantage to the contractor chosen to perform research work; will avoid undue concentration of economic power in the hands of a few large corporations; will tend to increase and diversify available research facilities within the United States to the advantage of the Government and of the national economy; and will thus strengthen our American system of free enterprise.

This work, entitled the "Investigation of Government Patent Practices and Policies," was begun at the request of President Franklin D. Roosevelt in 1943, and during its course, 14 Federal agencies and 10 national governments were consulted. It was ultimately published in 1947, and has formed the foundation for a position in favor of the public interest, which the Justice Department has adhered to from that day to this. I invite the subcommittee's attention to this document, because I do not believe it was mentioned either in the Presidential patent statement of 1963 or before this subcommittee, as it is the most comprehensive and persuasive study I have been able to find.

I believe that these considerations, together with the evidence gathered by Secretary of Agriculture Benson—cited at page 7 of my statement—that Government title does not impede the commercial development of inventions, are convincing of the value of a basic title policy for Government-financed R. & D.

However, the subcommittee is quite correct in coupling its consideration of ownership provisions with the system of utilization. The two should go hand in hand.

It is my feeling that contractors should feel that they are receiving completely fair treatment from the Government in this area, just as small businessmen, taxpayers, and individual inventors should feel that their interests are getting an even break.

In contrast to the bright successes of title policy, in the areas of agriculture, TVA, and atomic energy, let us examine the consequences of the license policy, as exemplified by the Department of Defense, and more recently of NASA. I have spent a considerable time analyzing the effects of our Government contract and patent policies on increasing concentration of wealth and assets among the Nation's largest companies. At this time, I am pleased to make these findings available to the subcommittee.

As the subcommittee is aware, the Council of Economic Advisers told the President in January that:

> * * * Within the important manufacturing sector, certain structural trends have emerged since World War II: (1) Through internal expansion and merger, large firms have grown more rapidly than the manufacturing section as a whole * * *.

I am sorry, Senator. I have jumped over to page 10 in the interests of time. I should have told you that.

I am informed that mergers hit an alltime high of 991 in the first 6 months of 1965.

Of course, the agency which has the greatest effect upon these figures and trends is the Department of Defense, which spent more than 70 percent of all Federal R. & D. money in 1961 and still spends more than half. It is also pertinent to note that NASA, which now spends close to 30 percent, has increasingly adopted the Department of Defense position.

To illustrate the seriousness of the concentration issue, particularly in the Department of Defense, may I quote the testimony of Dr. Robert F. Lanzillotti, chairman of the Economics Department of Michigan State University, before the Senate Small Business Committee in 1963, as follows:

> The Government R. & D. contracts appear to be highly concentrated among the very large firms. While small business averages around 16 to 17 percent of Department of Defense procurement, when it comes to research and development small business accounts for some 2 to 3.5 percent. In fiscal year 1961, 20 corporations accounted for nearly 75 percent (of total military R. & D).
>
> * * * is it not inconsistent—not to say dangerous—for the Federal Government to nurture each concentration in the technologically most advanced fields which can be preempted by the particular firms selected by military officials? ("Economic Aspects of Patent Policies," hearings, Mar. 8, 1963, p. 121).

The seriousness of this matter of selection is indicated by the fact that in fiscal year 1962, 97 percent of Department of Defense research awards were made on a nonprice, noncompetitive basis. (Hearings, testimony of Dr. R. J. Barber, Southern Methodist University Law School, p. 52.)

It should be further noted that for the same year, 10 firms received 56 percent of Department of Defense's total research money; and for NASA, for top 10 companies received 54 percent. Furthermore, five of these contractors are on both lists. (Hearings, loc. cit., Mar. 7, 1963, p. 56–7.)

Now, in the face of these tendencies, which as I document in an appendix to my statement, and which the Justice Department has viewed with alarm under both Democratic and Republican administrations since 1947, the following question arises: What has been the impact of Federal research and development policy?

In brief, Mr. Chairman, the charts which appear at pages 20 and 21 of my statement show that the Federal Government is concentrating a greater proportion of its R. & D. funds in the top eight firms in each industry than private business is itself spending. The charts also demonstrate that this relative Federal concentration was worse in 1962 than it was in 1958.

I jump now, in the interests of time, to the top of page 14, Mr. Chairman.

A most trenchant analysis of the dangers in these trends was made by a Republican Attorney General, Herbert Brownell. In 1956, he declared in the following language his concern—

> with the future of competitive enterprise, and it is important that its share of this [research] activity be administered to promote competition * * *. [W]hat indications that are available warn that the Government expenditures may not run counter to the industrial trend toward concentration, but in some degree may actually enforce it. * * * The disproportionate share of total industrial research and development in the largest firms may foreshadow a greater concentration of economic power in the future. * * * (A) present concentration of such manpower and progress means that in the future an increasing share of anticipated improved technologies and new production lines will be introduced by the industrial giants.

These trends are relevant to the question of who would receive the benefits of a policy of granting exclusive commercial rights to contractors. At a minimum, Federal R. & D. policy, in the administration of contracts, as well as in the allocation of patent rights, should at-

tempt to counteract trends toward monopoly and concentration rather than reinforce them, as these policies have been doing.

To return to the issue of utilization, my position has been that private enterprise, as in S. 2160, should be given the sole task of developing and commercializing inventions arising out of Government-financed research.

However, there must certainly be appropriate safeguards for the economy, the taxpayer, the small businessman, and the consumer in the form of the terms and conditions on which this development is carried out. These terms and conditions now engage our attention.

Going to page 16, after the first paragraph:

Seventeen years is a long time in this era of breathtaking technological change. One company, General Electric, is fond of saying in its annual report that half of its sales are attributable to products which did not exist 10 years ago. A system where the Government takes title and provides for a liberal granting of exclusive and nonexclusive licenses would allow a more realistic period of 2 or 3 to 5 years for a company to proceed with development and marketing phases, with absolute incentives and absolute protection. At the end of such a period, the company could come back into the agency and make a showing of what it had done, as a basis for a possible renewal of this license for a renewal period.

I digress just for half a moment to say that one thing we have been on guard against is that after the Government, with the taxpayers' money, really develops the patent, if that patent is then going to be turned over to a company, and the company is allowed to put it on the shelf for a period of years, 2, 3, 5 or x period of years (because of some other developments in its own research laboratory, and that from its commercial standpoint it would rather not develop that patent), who loses? Well, the public loses, the consumer loses.

But, under an exclusive or nonexclusive license system, after the money has been spent and the research has developed the invention or the product, so to speak, then you are going to have to go ahead and commercialize it. It seems to me that the taxpayers are entitled to that procedure.

To understand my position in this whole field, you have to understand that I am concerned about putting to use immediately the results of the taxpayers' expenditure.

Not only would this give a complete flexibility as to the number of years involved, but as to other terms and conditions of the grant. For instance, there could be consideration of States and municipalities which must provide services for all of the people, and of hospitals and universities which are rendering services in the public interest. Such a system could provide for equitable access for small businesses which did not participate in the original contract for research or development. They could also provide for a determination of royalties, in certain cases, which would provide a return to the taxpayer of some of his $15 billion annual investment. An additional feature should be that the so-called walking-in provisions should require walking in by the contractor, who desires to retain a preferred position. This would save the Government the administrative burdens and expense of monitoring and enforcement. A renewal proceed-

ing would also provide an opportunity for other parties to present their views and claims on the basis of changing circumstances.

To digress again for just a short period, I am not proposing and would not support a plan whereby a company entered into a contract, developed a product or an invention that was patentable, the Government took out the patent on it, and then that patent was to be made available to everyone at that point. That is not my proposal.

I think that the contractor that did the research, although it was paid for by the taxpayers, ought to have what might be called a walking-in privilege. He ought to be able to show his contribution. That ought to be on the basis of the facts shown. He ought to get a license.

In many of those cases it would be an exclusive license for a period of 2, 3, 5 years, and at the end of that period, he could show what he had done to commercialize it. He could show what he might have done to improve it, and he would walk in again, and on the basis of a hearing and a review, if he demonstrates a justification for a continuation, his license is extended for another period of 2, 3, or 5 years.

I am not seeking to follow a course of action that is going to discriminate against the developer. At the same time, I say the public has got to be protected against giving patents for long years of patent life to the disadvantage of the rest of the economy and the rest of the businesses of our country. If this particular individual does not go ahead and commercialize and does not go ahead and continue the maximum use and development of the product.

I think my time is up, Mr. Chairman.

Senator McCLELLAN. Your time is not up, Senator, except that you asked us to advise you at the end of 15 minutes.

Senator MORSE. I want to accommodate myself to the convenience of the committee.

Senator McCLELLAN. You may continue, if you would, if you have the time. I thought you had another committee meeting.

Senator MORSE. I do. But I would like to read one or two more pages.

Senator McCLELLAN. I would just like to ask you one question for clarification before you go, if you have time.

Senator MORSE. Well, I have time. My time is yours. Don't worry about that.

Senator McCLELLAN. You have all the time you want here. I do not want you to think you are limited.

Senator MORSE. I know. You have been very kind. But it is my request to which you are responding.

I do want to take just a minute on procedure. As the chairman and the Senator from North Dakota are aware, I do not know of anyone who is more conscientious in attempting to provide fair procedure. As you have heard me say to your boredom so many years on the Senate floor, substantive rights are, after all, determined on procedural rights, and your procedure has determined in some measure what substantive rights shall be available. This is true here, too.

As the chairman knows from his long career in public life, the procedural section of any bill is just as important as the policy declaration, if not more so. My formal statement contains several recommendations as to the procedural devices, and I would like to point up a few of these.

I have been especially concerned with the status of small business under patent legislation that may be enacted. May I say that my small business philosophy is not the protective variety. I believe that we must give small business of today an even break so that they can grow up to be the large substantial businesses of tomorrow. This keeps our economy dynamic. It is particularly important in new fields which are being opened up by Government-financed research and development. Firms like IBM, Texas Instruments, or Tektronics, from my own State of Oregon, which will be testifying before you today, were all once small businesses.

In fact, may I say, Mr. Chairman, that the experience of the Tektronix firm has put them into a unique position, and that their testimony should be very helpful to the subcommittee in exploring the litigation aspects of patent utilization. I am very proud to have them as witnesses before your committee today.

That does not mean that they agree with me at all in all the aspects of my position. Nevertheless, they have a position and I know you will give a very fair hearing to, and I know they are going to make an important contribution to the record of this hearing.

The problem is now to provide access to the $15 billion products of Government R. & D., which is performed by relatively few firms, for all of the small business community. The subcommittee has a golden opportunity to do this.

I say particularly to my brother member of the Small Business Committee, Senator Scott of Pennsylvania, that Congress should take the time and trouble to devise the procedural features which will carry out this access. I say that because I know of his great interest in it.

This would not be a Republican measure or a Democratic measure but a bipartisan effort to strengthen the foundations of our economy by giving the small man a fair shake.

In S. 2160, my bill on NASA patent policy, which I have attached as an appendix to my statement, several of these procedures are set forth. I would like to advance them for the committee's consideration. Since there are few landmarks in this area, I would like to stress that these suggestions should not be regarded as definitive. These are efforts which I hope might contribute to the creation of a workable system. They include 90-day notice, a hearing, and limited judicial review, with the findings of fact of the Administrator or the reviewing officer to stand unless the court finds that they are not based upon substantial evidence.

I am about to close by going to the bottom of page 19.

I am also concerned, as is the subcommittee, with the interests of the taxpayer. The taxpayer would benefit, under the licensing system described in my statement, from increased competitiveness and lower prices of the finished product. He could also benefit immeasurably from the institution of a general policy of sale or royalty of the patent

rights in areas where this is a practicability. I have recommended in my statement that the committee secure the opinion of a fiscal expert on the amounts that might be realized through such a royalty system.

The cause of the individual inventor has also been mentioned. I believe that consideration of this legislation presents an outstanding opportunity to give greater standing and possible financial reward to the individual inventor. Any provision governing the relationship between the Government and the contractor on this point should probably be conditioned upon the relationship between the contractor and the individual employee.

To conclude, I shall attempt to sum up the directions I believe the committee should take. With respect to S. 789, Senator Saltonstall's bill, I belive it is a fine example of a procedural trap. As stated by the Department of Health, Education, and Welfare, "the entire thrust of the bill is thus to impede the Government's taking and retaining of ownership in inventions derived from federally financed research, by making this a long, arduous and exceedingly difficult, and in many cases, impossible task."

S. 1809 is, of course, the principal bill before the committee. I commented upon the provisions of this bill in considerable detail in my formal statement. I might repeat that I consider section 11, which repeals the public-interest patent provisions of the last 30 years, to be unsound and undesirable. The current legislation, rather than reject the past, should be built on its monumental successes.

At this point I shall discontinue reading my summary, Mr. Chairman, since the entire summary has already been inserted in the record. Thank you very much.

Senator McCLELLAN. Very well.

Senator, do you have any questions?

Senator BURDICK. I am sorry I was a few minutes late, Senator.

Do you think the patents should be taken in the name of the Government and then exclusive license granted in certain instances?

Senator MORSE. In certain instances, exclusive license permits; in other instances, nonexclusive license permits. It all depends upon what the developer can show has been his contribution to the development, and what he is able to accomplish in getting the product on the market.

I have stressed, Senator Burdick, that if the Government is going to spend all this money, then the result should not be locked up; it should be put on the market just as rapidly as the developer can put it on the market. And he should be given a license permit if the hearing shows that he made a great contribution in its development.

Senator BURDICK. What procedure would you recommend for determining when an exclusive right or a nonexclusive right or any right should be granted?

Senator MORSE. Well, I would provide for a hearing where he comes in and presents his case, asking for an exclusive license, and the Government agency decides whether or not he should get it, or get a nonexclusive license.

Senator BURDICK. Have you read the bill submitted by Senator Long?

Senator MORSE. Yes; I have.

Senator BURDICK. S. 1899?

Senator MORSE. Yes; I have worked with Senator Long over the years in regard to his patent position.

Senator BURDICK. I noticed that you did not comment on S. 1899, maybe by inadvertence. What is your opinion of that legislation?

Senator MORSE. Well, I yield to Senator Long for authoritative comment on that bill.

Senator BURDICK. On page 25 of your prepared statement, you say: "I realize that S. 1809 contains a special exception for 'fields which directly concern the public health, welfare, and safety.' But this is a limited field, where less than 5 percent of R. & D. funds are spent."

I want to advise you that yesterday a few witnesses felt that was going too far. What is your opinion of that?

Senator MORSE. Well, I think Dr. Keppel in his outline had a pretty reasonable approach to it.

We have the subject before our committee at the present time, I may say. We have not come to any final conclusion. But my tentative opinion is to support Dr. Keppel in his announcement of administrative policy, and I have expressed such an opinion on the Senate floor. (See daily Congressional Record, August 17, 1965, p. 19918).

What Dr. Keppel is saying, in effect, is what the Department of Justice has said for years, going back to the Attorney General's pronouncement of policy in 1947.

Senator BURDICK. Do you agree with the exception in S. 1809, then, in regard to public health?

Senator MORSE. Yes; I would go along with the exception.

Senator BURDICK. Regardless of modification or qualification?

Senator MORSE. Well, as I said, our Senate Committee on Labor and Public Welfare is grappling with patent amendments to various health and education bills. But I would not commit myself to any qualification or modification at the present time.

I really think the trouble is, the policy expressed as to public health and safety in S. 1809 is not carried far enough.

Senator BURDICK. That is all I have, Mr. Chairman.

Senator MCCLELLAN. Senator, thank you very much for your statement. It is quite lengthy, and I am sure it is quite informative. I assure you that the Chair will examine it with an impartial approach, insofar as I know how to do it.

Contrary to any implications that may have been made or might be made, or any aspersions that might have been cast with respect to this committee's work or the chairman, I have no preconceived ideas here, none that I could not reconsider. I have tried to approach this whole problem on the basis of an exploration, to find out what is best.

The bill I introduced, of course, as everyone knows, is largely an administration bill, at least based upon the President's memorandum of December 1963.

I have proceeded since then with a view to hearing all sides, getting all the information I could, so that we might in due course examine these different new thoughts, resolve them as best we could, and present legislation to the Senate for its enactment.

One thing that I have had trouble with, I guess we all do—and again I say that those who say this is a simple issue are not correct. It is

complicated. When you undertake to find equity and do justice, it is not easy or simple.

We have an illustration of this complexity in the fact that there may be three or four contributors involved in the financing; the talents of others; and others' skills in the research and development field.

Of course, ultimately we want to get the product, if it has value, if it has use, we want to get it into use, we want to get it to the user and the consumer. But where there is a university involved or a foundation may have made a contribution in a given area of research, where corporations or individuals may have made contributions to the university to carry on their research in that field, and then the Government makes a contribution to carry on in that field, and they come up with some discovery, how do we do equity in that situation? How do we do equity? They are joint ventures of private enterprise in which eleemosynary foundations or others have made a contribution, as well as the taxpayers. How do we do justice in handling a patent on a discovery in that situation? I don't have the answer.

Senator MORSE. I don't have the answer.

I will make a very brief observation. But before I do that, Mr. Chairman, I want to say that as far as the senior Senator from Oregon is concerned, he has said, out of your presence in many places, and is pleased to say it in your presence, that I have no question at all about the impartiality of this committee and its chairman in trying to resolve this matter on the basis of what the facts show.

I am chairman of the Subcommittee on Education, where there was a move made yesterday to add the Long amendment to the higher education bill.

Now, to divide up my attitude on a percentage basis, I suppose you would say that I lean strongly in favor of the Long amendment in the matter of education, copyrights, and in some instances with these new audiovisual patents. But I say it should not be added to this bill. We should wait until the McClellan committee finishes its hearings and comes forward with its recommendation. We should not be going off here at a tangent, and having different policies in connection with different agencies.

I think we need a governmental policy instead of having a diversity of policies such as now characterizes the handling of patents that flow from the expenditure of taxpayers' money in research and development.

Now, you raise a hypothetical situation. It is not completely hypothetical, because we can cite specific instances in which it is true. But I am talking about it hypothetically.

You raised a hypothetical situation in which you have a multiplicity of contributors to the brains, techniques, and know-how in the development of an invention or a product or other patentable item. Certainly, the patent in such a case should not be given to one of them to the exclusion of the others.

It is pretty hard, because of the nature of some of these situations. You talked about eleemosynary institutions and foundations, and Government contributions, and so on. It is always dangerous to lay down a general rule, but I am going to.

Generally speaking, I would say that in that situation your license permit program is much preferable, in my judgment, than giving what I call a frozen patent.

Now, even I as a lawyer know and Senator Burdick knows, as a lawyer, that although this is a complex problem, we do not admit that there is anything too complex factually so that we cannot at least do reasonable equity.

I think you are just going to have to have a procedure that provides for a hearing and gives every person involved an opportunity to make his case and then have the judgment rendered, providing for limited appellate review, as I set forth in my statement.

I do not know how else you are going to do it, gentlemen. I do not think you can do it by rule of thumb. Because the application of a rule of thumb without the hearing and without the opportunity to present the evidence, and without the review, I think, is bound to work injustices in those multiparty contributing situations.

So I say as a tentative answer to your questiton, Mr. Chairman, that I think it is better to have a license approach to that situation than a patent approach.

Senator McCLELLAN. Senator Morse, I have said before that I find no way to write language into a bill to cover every situation. In my judgment, judgment ultimately has to be reposed in someone with a measure of discretion. I do not know how you are going to avoid it.

Senator MORSE. You are not going to be able to avoid it.

Senator McCLELLAN. I do not know how you can avoid it.

Senator MORSE. The provisions of my NASA bill, on the basis of what you have brought out in this hearing, are going to need great modification to apply generally; I have no doubt of that. I am not married to that bill.

But on the basis of the facts that we do know about, I felt that this was a bill that ought to serve as a basis for hearing and for modification.

I think that more important than my bill, may I say most respectfully, is my statement. Because I think you will find in my statement some information that you are not going to find anywhere else—at least, I have not found it anywhere else.

As I said, we have worked on this general problem, Mr. Spira and I, for 4 years. We have tried to help the committee by bringing forth in the statement some material and trying to coordinate it with other material to help the committee form what I think would be a better public policy than we have on it at the present time.

I just do not think, Mr. Chairman and Senator Burdick, we can very well justify continuing a governmental policy of such diversity as we have at the present time, with the Defense Department and NASA going off in one direction, the Department of Justice going off in another, some of your health agencies in a somewhat modified position but still in another direction.

Now you have got this issue raised in the Department of Health, Education, and Welfare; you have got those new procedures announced by Dr. Keppel, which I think are meritorious as far as

I have analyzed them. We are going to have him come up to discuss those procedures before my subcommittee within a few days.

But what I am pleading for is an end to what I think is a diversity of treatment that is not fair, because its lacks uniformity of Government policy.

Senator McCLELLAN. I agree with you, there ought to be an overall statute.

Senator MORSE. You have got to have it.

Senator McCLELLAN. That is all I have argued for up to now. I have not taken a final position on the immediate issue before us. I am still searching and exploring.

Yesterday there was some testimony, if I remember correctly, that quite surprised me, and I thought it pointed up one of the problems in this field. This was in the field of medicine, where they do a lot of research which result in discoveries, some of which are patentable.

It was brought out that probably 1 out of 10, only 1 out of 10 of those discoveries is ever taken down off the shelf, so to speak, and an undertaking made to process it. And out of those instances of 1 out of 10, a great many of them fail to develop into something that is commercially profitable or really beneficial.

In other words, after the discovery is made, the testimony showed here that it took from maybe $200,000 to $400,000 to test it, refine it, and get it adapted to human use and medical use, and that a lot of times some money was spent that way that never produces anything.

So, just getting a patent and getting it on a government shelf is not the answer.

Senator MORSE. That is correct.

Senator McCLELLAN. There has to be a way of providing an incentive somewhere to get somebody to put in the risk capital, try to take it and develop it and bring it into a state of usefulness and a readiness for the commercial market.

Senator MORSE. You will find that I stress that in many places in my statement.

Now, there is another phase of that. You have to have an incentive. Here you have 20 research findings involving various phases of the same potential product. You also have to have a program flexible enough, in my judgment, so that you do not let "X" take it just exclusively, when "Y" or "Z" or "A" or "B" would like to make another approach to the handling of that end product as it comes out of the research laboratory, and they might be more successful than "X" in developing it for commercial uses. You have to try to find how many of them you are going to allow to have a chance in developing it.

In my final appendix, I set forth data concerning the fact which was discussed on Tuesday morning before this committee, that as we move forward—as we move toward fields where the Government needs end items the proportion of development paid for by the Government becomes very high.

For instance, there is almost complete transference between items such as military planes and the Boeing 707; and the military synchronous satellite and the Early Bird commercial satellite.

My plea is that we not get ourselves in a position where we freeze the results of this Government-paid-for research and development so

that other companies that might have scientists and technicians of a different background and interest are going to be denied the opportunity to bring their brains to bear upon the laboratory results. But at the same time, as you pointed out, you should also have an incentive for the fellow that helped develop it in the first place, although you and I as taxpayers paid for it. Therefore, give him 2 or 3 years' exculsive permit or license, see what he can do with it, and then let him come in and show what he is doing. If the other people can show that he is not doing what he ought to be doing, then make it nonexclusive rather than exclusive at that point.

Senator McClellan. The point I am making, Senator, in addition to that, is this: You get the discovery, the patent; it is on the shelf. The Government now has complete control of it. As illustrated yesterday, less than 1 out of 10 has anybody manifest any interest in it. When someone does manifest such an interest, he says, "I'm going to spend $200,000, $500,000," whatever it is, "to see if I can develop this thing."

You say that others should have an equal opportunity. I agree that everybody should have an equal opportunity, but when someone selects it and says, "Now, I want to take it and try it. Nobody else has. If you will give this to me, you call it an exclusive license, I'll take it and spend some money on it and see what I can do"—you say, "Well, he may not be doing all he should. He may take it and drag his feet."

Well, you would not give him the license until he brought it into a state of usefulness, where he said it was not a marketable product.

Senator Morse. I would not renew it——

Senator McClellan. If he does drag his feet and produces nothing within 2 or 3 years, then you might very well have some limitation in time in which he has to make a development. But if you say to him, "Well, now, any time we get dissatisfied about that, we are going to take it away from you and give it to somebody else," I think it is going to destroy the incentive.

Senator Morse. If he comes in during my administrative procedure hearing, Mr. Chairman, and shows what he can do, he is going to have it renewed and renewed. On the other hand, if he takes it and, in effect, uses his license to put it on the shelf, when others want to develop it, we will not renew his license at the end of 2 or 3 years, or whatever period you give it to him in the first place.

But there again, it becomes a question of a finding of fact as to what he has done.

Senator McClellan. You have to use a lot of discretion. I do not see how you can get away from vesting discretion in a responsible authority.

Senator Morse. You cannot possibly do it. I do not propose that we try.

Senator McClellan. Well, thank you very much, Senator. I appreciate your staying long enough to answer a few questions.

Senator Morse. Well, you are very kind of hear me. Thank you very much.

Senator McClellan. I notice you have a copy of your bill S. 2160 attached to your statement as appendix VI. We will appreciate your making it available for the record.

Senator McClellan. Our committee will be in recess for 5 minutes. We will resume in 5 minutes.

(Brief recess.)

Senator McClellan. Dr. Seevers?

STATEMENT OF MAURICE H. SEEVERS, PROFESSOR AND CHAIRMAN OF THE DEPARTMENT OF PHARMACOLOGY OF THE UNIVERSITY OF MICHIGAN MEDICAL SCHOOL

Dr. Seevers. Yes, sir.

Senator McClellan. All right, Doctor. Please identify yourself for the record. I believe you have a prepared statement. You may proceed in your own way.

Dr. Seevers. I am Maurice H. Seevers, a professor and chairman of the Department of Pharmacology of the University of Michigan Medical School.

Senator McClellan. First I would like to say I am sorry we did not get to you when you were scheduled yesterday, or the day before yesterday, I believe.

Dr. Seevers. It worked out all right.

Senator McClellan. We have tried to move along here with all deliberate speed.

Dr. Seevers. It worked out all right with me, so thank you very much.

I am a physician and have been engaged in teaching research and administration in academic pharmacology since 1930, at the Universities of Wisconsin and Michigan. I am professor and chairman of the Department of Pharmacology of the University of Michigan Medical School in Ann Arbor, Mich. I received a Ph. D in pharmacology from the University of Chicago in 1928 and an M.D. from Rush Medical College of the University of Chicago in 1932. I am licensed to practice medicine in Wisconsin and Michigan.

During the last 35 years I have worked with, or served as a consultant to, many organizations which deal with the effects of drugs and chemicals upon health and welfare, both here and abroad. I have been fortunate in having had the opportunity to walk in the halls of learning, professional societies, Government, and industry, and am able to distinguish but one high level of public morality among the leaders in these several facets of American society as it relates to the public health and welfare.

I am a past president of the American Society for Pharmacology and Experimental Therapeutics.

I served as chairman of the Section of Experimental Therapeutics and for 10 years as a member of the Council on Drugs of the American Medical Association. Currently I am chairman of the committee for research on tobacco and health and a member of the committee on alcohol and addiction of the same organization, and have acted in an advisory capacity to many Government agencies.

I have served the Government as a consultant to the Food and Drug Administration, the Department of Defense, the Veterans' Administration, the U.S. Public Health Service, and the Office of Science and

Technology. I was a member of the Surgeon General's Advisory Committee on Smoking and Health, and am currently Chairman of the Committee on Behavioral Pharmacology of the National Institutes of Mental Health.

I have served as a consultant to the pharmaceutical and chemical industry for remuneration.

My principal area of competence is in the field of narcotics and drug abuse, and I served as a member of the Ad Hoc Panel for the White House Conference on this subject in 1961.

I have read the statements of the American Council on Education and of Austin Smith, M.D., president of the Pharmaceutical Manufacturers Association, concerning S. 1809. I believe the essential facts are presented fairly and rather completely in these two documents, and I will not reiterate most of their points.

I wish to comment especially on the detrimental effects on the quality and quantity of research in the drug field, not only that conducted in universities, but also in Government laboratories, and its effect on training of new scientists if a Government-take-all policy is applied to Government-sponsored research in the health-related sciences.

In the field of drug development the role of the pharmacologist differs significantly from that of the chemist, and his findings are much less subject to exclusive control. The chemist, for example, invents a new compound or develops a new process for manufacturing an old chemical, and can obtain exclusivity for the duration of the patent under the present circumstances.

A pharmacologist, on the other hand, studies the effects of new or old chemicals in animals or man in the hope of finding a cure for disease or a substance which will speed recovery or make the patient more comfortable. Usually these observations cannot be controlled exclusively. They come under the public weal.

To cite an example: In our laboratory we are studying the effects of morphine-like narcotics on the monkey in the hope that a new pain-relieving drug will be found which will be nonaddicting. During the last 15 years we have screened over 600 new drugs from all of the major domestic and foreign pharmaceutical companies. This, in fact, represents the world supply. This program is supported by contributions from over 40 pharmaceutical manufacturers through the Committee on Drug Addiction and Narcotics of the National Academy of Sciences and National Research Council. Any chemist, domestic or foreign, may submit new compounds through the secretary of this committee for study. He sends them to our laboratory for testing as unknowns under code number, and the information is channeled back to the supplier.

Under this program we are able to maintain an on-going university laboratory for research and training in this field of behavioral pharmacology. Industry retains exclusively of drug control. Under present Government policies, conducting such a program with National Institutes of Health support would not be possible since industry would not make the compounds available to our laboratory. Maintenance of a laboratory of this type by an individual company would be pro-

hibitively expensive, and this joint effort of the industry reduces the total cost of production of what may ultimately be a clinically useful compound.

I might depart from my statement to say that several clinically useful compounds have come out of this program and are currently in clinical use.

Senator McClellan. Do I understand you to mean by your sentence just above there, "industry retains exclusivity of drug control," that they get the patent, they own it?

Dr. Seevers. Yes, they own the patent.

Senator McClellan. In other words, if they send you a drug for experimentation and you develop it, they retain the patent?

Dr. Seevers. That is right.

Senator McClellan. And you say that if the Government makes a contribution and takes that, then they are not going to send it there for——

Dr. Seevers. They won't send the drugs.

This is one of our biggest problems today in pharmacology and clinical pharmacology, because the industry will not send drugs into many university laboratories, because of the fact that we are supported by Government in some of our activities.

Furthermore, if we find, for example, that a drug under a certain name is metabolized in the body to create a new substance, which turns out to be the active substance, this new substance then completely wipes out everything that happened with the old one. It now becomes the useful substance. And if it is discovered in a Government-supported laboratory project, the Government holds the patent.

So industry automatically has lost its hold over that compound, simply because a new substance which is developed by the metabolism of the body now becomes a useful substance. Because of this, many industries will not send drugs into the clinical pharmacologists for drug development.

Senator McClellan. Now, is the public health served or is it not served in the circumstance that you are illustrating and testifying about? Are the public health and welfare served by permitting the patent on any discovery to remain in the ownership of the one that transmits the drugs to you?

Dr. Seevers. We feel it is, because it is not possible, for example, for the university to develop a drug clear through to the point of marketing. We have no facilities for doing this. The Government does not have the facilities for doing it, either.

In fact, there is only one group that can operate independently of the Government or the university, and that is the industry. They have their own chemists, their own pharmacologists. They have their own drug control laboratories. If necessary, they could develop—which I think would be exceedingly unwise—their own clinical facilities in a group of smaller hospitals which are not university associated.

Senator McClellan. This would have its impact on the university, would it not?

Dr. Seevers. Not only on the university, but an impact ultimately on the public health, for the simple reason that most of the smaller

hospitals, even though the doctors are qualified, are not qualified in the problem of drug development. They do not have the facilities to carry on the laboratory work that is necessary in relationship to it.

Furthermore, it would in the long run interfere seriously with this problem of the ultimate public health, as far as new drugs are concerned.

I might say just for your own information that 90 percent of all the drug information that we teach medical students today did not exist 40 years ago, and 70 percent of it did not exist 20 years ago.

This was brought about largely by the fact that we had a strong cooperative program of Government, industry, and universities, during the war. The large antimalarial program, and the large program associated with the development of chemical warfare promoted such a large chemical development that many of these compounds naturally were found to be biologically useful. This effort, of course, involved everybody's dropping what they were doing to work on these major programs to aid the war effort.

This, then, was probably the best example of a large cooperative effort even though it was not voluntary.

I think there are still some people that believe that all drug development should be carried on on this basis. This could be done in wartime; but today, to get this kind of cooperation requires that it be done voluntarily. It means very simply that the interests of everybody have to be engaged, there has to be mutual respect and confidence between industry, Government, and the universities.

I do not think it is possible to administer or legislate or regulate or coerce this type of research. It never has been in the past, and I think real cooperation is always on a voluntary basis.

I might depart further from my statement simply to say that the pharmacologist is not particularly interested in exclusivity of control. We are interested basically, as individual scientists, in getting new compounds to study biological processes. Most of these are not subject to patent, anyway, except as use patents and they are not as useful as invention patents.

One other point I would like to make, which I think has not been brought before you, is that a patent in the drug field today is not worth too much, anyway, except for a short-lived term of exclusivity. The movement today in the drug field of the development of new chemical compounds is so fast that about the time a drug reaches the market, a better one is on the drawing boards, and in a year or two it will supplant one that is currently marketed.

Senator McClellan. Let me ask you a question at this point. What profit is there to the Government and the public, the people as a whole, for the Government to take that patent or that new discovery and put it on the shelf?

Dr. Seevers. I didn't quite understand you. What does the Government gain?

Senator McClellan. Yes. What would the Government profit out of it, what would the public profit out of it, if as you say, by the time you got that drug well developed and on the market, a new one will be coming along that would probably be a better one and take its place, then, not within the 17 years in the patent statute, but maybe 2 or 3 years after it first hit the market?

Dr. SEEVERS. I think the 17-year matter is completely unimportant in this field.

Senator MCCLELLAN. It has no applicability?

Dr. SEEVERS. The Government would not profit very much, to answer your question directly.

Senator MCCLELLAN. Well, the point is, if the Government takes it, and then somebody according to some of the proposals here was able to get an exclusive license to further develop, refine, and put it on the market, by the time they would do that, the Government would give them the license, for a period of 2 or 3 years, and they wanted to spend $200,000 or $300,000 on it, somebody else might come along with another drug or an improved product that would destroy their market for this one.

Now, who gains and who loses by that sort of thing?

Dr. SEEVERS. Well, my feeling is—and this is not derogatory of the Government—that by the time this gets through the wheels of redtape, there would be two or three new drugs on the market that would be better than the one that they had a patent for.

Senator MCCLELLAN. Well, this is the point I am trying to examine: Although the Government may have made a contribution to the processing and exploration that discovered the drug, the formula, the compounds, however you refer to it, although it may have made a contribution, that is the taxpayers' money, now you have the thing and it becomes a discovery, a patentable discovery that may have useful benefits, and the Government takes it. As you point out, by the time a private firm could get that drug well advertised and on the market, and so forth, some new one may actualy have come out that would be a great improvement, to the extent that this one no longer would be in demand.

Dr. SEEVERS. That is the reason it is such a high-risk industry.

Senator MCCLELLAN. It is a high-risk industry.

But the originator, in whom you are leaving the control now as you propose, would naturally exploit his product, in other words, to try to get it on the market, try to get his money out of it, and try to make a profit out of it before some new drug came along.

Dr. SEEVERS. If he does not have any incentive, this will not be done.

Senator MCCLELLAN. But if it is given to him, if he owns it for a period of time, if he owns the patent and the control of it, obviously if he spent some money on it, he would undertake to get it on the market as quickly as possible, to recover his investment and to make a profit.

Dr. SEEVERS. I think that is a very important point. Because, as I heard earlier from your statement to Senator Morse, a large fraction of the drugs that would be patented would never reach the market, simply because of the facts that I have indicated. They would not be developed.

Senator MCCLELLAN. Would there be more of them that never reached the market if the Government took the patents to all of them?

Dr. SEEVERS. I don't believe so.

Senator MCCLELLAN. Sir?

Dr. SEEVERS. I think not.

Senator MCCLELLAN. Well, I do not know whether you understood my question. Would there be more or less of them reach the market?

Dr. SEEVERS. I would say there would be less if the Government took control.

Senator McCLELLAN. That is what I thought. Less than now.

Dr. SEEVERS. Less than now. That would be my opinion.

It is, in fact, currently defeating cooperation between industry and the universities. The university is sort of in a middle position in this.

Senator McCLELLAN. It serves both.

Dr. SEEVERS. It serves both.

As a matter of fact, you see, the university makes a tremendous contribution to this business without any incentive except the fact that the investigators get renown, maybe, for discovering a new compound. But the university doesn't get much out of this business except in carrying on its natural function of training of people.

Senator McCLELLAN. In other words, it makes no real profit out of it.

Dr. SEEVERS. The university doesn't make any significant profit.

Senator McCLELLAN. What profit it does make goes back into the public service.

Dr. SEEVERS. Exactly.

Senator McCLELLAN. All right. You may resume your statement. I just wanted to get the record pretty clear at this point.

Dr. SEEVERS. I had been speaking about our laboratory for research and training in the field of behavioral pharmacology. I cite this as a proven and useful example of voluntary cooperation between the industry, a university, and a quasi-governmental organization. In this instance a good screen is available since the monkey shows a very close parallelism to man in his response to this class of drugs. But this is rarely the case, and preliminary studies on animals must be carried through to man in order to obtain a satisfactory answer. The development of a marketable new drug is so costly in time and money that the role of the pharmacologist becomes exceedingly important. The academic pharmacologist can neither conduct developmental research nor train students in the drug field without close association with the chemist. Restrictive patent legislation by cutting off the supply of chemicals would only aggravate the acute shortage of biologically trained scientists in pharmacology, physiology, microbiology, and all of those basic fields of medicine dealing with biological responses to chemicals.

What about the chemist? For practical purposes the chemist means industry. Why not the university chemist? The answer is quite simple. Both chemists and pharmacologists are specialists. Only rarely do these specialists coincide in the same university so that a joint effort is possible. But this is not the main point. University departments of pharmacology have neither the interest, the space, nor the staff to do large-scale drug screening. This is a routine and expensive operation which is possible only in industry or government.

Take an example of the university chemist who operates under a Government-sponsored research contract. He invents a new and patentable series of compounds designed to exert a specific biological effect which may be useful in human therapy. Under current Government practices he is unable to utilize the biological screening facilities of industry formerly available to him. Since this is a trial-and-error game in which each change in chemical structure must be correlated with observed changes in biological activity the university chemist finds himself stymied in his developmental program, with no

place to get biological testing done. Even if these facilities were available, there are very few universities with chemical facilities to produce a sufficient quantity of a new drug even for satisfactory screening purposes, or with biological control laboratories to guarantee the uniform purity, stability, and reproducibility necessary in a drug before it can be subjected to human trial.

Without belaboring the point, satisfactory drug development cannot occur in the absence of industrial know-how and facilities and commonsense tells us that this will not be available for cooperative research under unwise patent restrictions.

Current NIH policies virtually preclude joint university-industry research on drugs or chemicals at the exploratory level before patent protection is assured to the manufacturer. The large bulk of drug research in medical schools is Government-supported. In operation, a department having a dozen major investigators with their students may operate 30 or 40 individual research grants from Government, industry, or health agencies, making it impossible to maintain strict cost barriers between grants with respect to animal food and care, supplies, et cetera. Furthermore, a scientist commonly studies a certain family of drugs on a single biological system. He may obtain these drugs from a dozen sources. Today a pharmaceutical manufacturer will not risk submitting an unprotected drug to such a laboratory because of the chance that it may accidentally or otherwise become associated with Government-supported research.

As a member of the pharmacology panel which was assigned the task of reviewing the activities of the Cancer Chemotherapy National Service Center for the Woolridge committee, the results of which were published in "Biomedical Science and its Administration," we observed that Government restrictions including patent policies made it exceedingly difficult and complex for those administering this program to carry on an adequate cooperative program. Neither the Government, as evidenced by the statements of Director Dr. K. M. Endicott, nor industry, from statements to our panel, were happy about the situation. Little initiative could be taken by the industry which could contribute to the program as a whole. Old chemicals which have been sitting on the shelf for many years were channeled into the program. Some new compounds were manufactured by industry on a contract basis, with Government furnishing the specifications, but many of the real leads in the field disclosed by industry research never found their way into the program at all.

It is my view that cooperation between industry, academic institutions, and Government, which is so vitally necessary to any successful program in such a high-risk area as drug development, will not be forthcoming unless some degree of exclusivity is granted to the inventor under a broad and flexible but uniform policy. The traditional position of university faculties as arbiters of industrial and Government disputes suggests that the university may be the best instrument through which exclusivity arrangements can be administered, especially those relating to Government-sponsored research in the health field.

In closing permit me to say that I sense a rising and accelerating tide of discontent among university scientists relating to excessive governmental control of pharmaceuticals and other chemicals. This

is manifest primarily as a strain on university-industry and indirectly on university-Government relations which have flourished so well in the past in developmental drug research. In the long-range interests of the public welfare Government would be wise not to alienate further that segment of the scientific community which contributes such a substantial fraction of new concepts and ideas in health-related research.

Senator McCLELLAN. Let me say that the more we proceed in this inquiry, in these hearings, the more concerned I become about the gravity of what is involved here. You have the public interest at stake, and some argument is made that this would be in the best interests of the public, rather than some other procedure. I just do not find it easy.

Dr. SEEVERS. It is a very difficult and complex problem.

If I may comment, I have listened to your discussion with Senator Morse about the matter of uniform Government policy, and I am in favor of uniformity, but you cannot equate health research with the development of airplanes. They just don't fit in the same category.

Senator McCLELLAN. Well, what we really had in mind, what he may have had in mind, and what I have in mind is to let the Congress fix the policy. But even when you do that, I do not know any way to do equity and justice except by leaving a measure of discretion in someone, in some public official, some administrator. I do not know how you can write a statute covering every aspect of this.

Dr. SEEVERS. It is my own feeling that in the health-related sciences, the last thing we would want to have would be unwise legislation that would prevent the longstanding cooperation between Government, industry, and universities. That has really been the solid foundation on which all the drug development has been based.

This means that each one of us has to carry on our own function. The university has primarily a training function, and that of basic research and development, and the industry has to put this into practical application.

I do not think either one can deal without the other, or either can stand alone, and it would be an unwise policy which would interfere seriously with this type of development. I think it would be against the public interest.

Senator McCLELLAN. Are you familiar with the bills that the committee is considering?

Dr. SEEVERS. In a general way.

Senator McCLELLAN. Which one of the bills, in your judgment, comes nearer to carrying out the policy or philosophy that you advocate?

Dr. SEEVERS. I think the chairman's bill comes the closest to carrying on the philosophy that I believe should be followed.

Senator McCLELLAN. Would you have any specific suggestions or any modifications or amendments?

Dr. SEEVERS. Obivously, I know very little about patents, but my feeling is that some provision should be made by which exclusivity can be granted for a period of time to those that have an equity in the invention. How this is done, I think, would take fine statesmanship; and this is something that you and your committee have wrestled with a long time.

I have heard the suggestion that universities that operate under Government-sponsored research programs in which an invention occurs might be the licensor for a period of time and make this arrangement with the idea that the university would get a little out of it, and the industry would get its seed back, and the ultimate end would be the introduction of a product into the market.

Now, this seems at first blush to make pretty good sense. I don't know whether most universities want to get into this kind of business. But it at least puts it in a group of nonprofit agencies, and would at least plow back any profits into educational function and training of people.

Senator McCLELLAN. Well, to say the least, while the original contractor with the Government is doing research, and so forth, it might very well be claimed that if he is granted the patent where the Government makes a contribution in the research and development cost, if he is granted a patent, he will exploit it, and therefore he is profiting off of the taxpayers' investment.

But that certainly would not apply to your university. You would be making no profit. You are not in a position to exploit it or to make a profit from it in that way.

Dr. SEEVERS. The university is contributing manpower and know-how and everything that goes along with the development, without any idea of doing anything except continuing to do the same thing.

Senator McCLELLAN. I only bring that out to emphasize that you are impartial, that you are not acting from a selfish motive. No selfish motive could be ascribed to the universities for seeking to do what they think will protect the cooperative working arrangements that exist now, which apparently seem to be satisfactory. Also, under this procedure that you generally follow now, the public, you think, gets the greatest benefit from it.

Dr. SEEVERS. That is my opinion.

Senator McCLELLAN. That is your opinion.

Thank you very much, Doctor.

Dr. SEEVERS. Thank you, sir.

Senator McCLELLAN. Mr. Munns. Will you come around, please, sir?

STATEMENT OF WALTER A. MUNNS, PRESIDENT, SMITH KLINE & FRENCH LABORATORIES, PHILADELPHIA, PA., ACCOMPANIED BY DR. J. KAPP CLARK, VICE PRESIDENT OF RESEARCH AND DEVELOPMENT

Mr. BRENNAN. Mr. Munns, you have a prepared statement. Do you wish to read it or have it printed in the record?

Mr. MUNNS. If you will, please, sir.

Mr. BRENNAN. Have it printed in the record?

Mr. MUNNS. I'll read it, please.

Mr. BRENNAN. Would you identify your associate for the record?

Mr. MUNNS. I have that all in my statement, if I may proceed accordingly.

I am Walter A. Munns; I am president of Smith Kline & French Laboratories of Philadelphia, a manufacturer of prescription drugs. I am accompanied by Dr. J. Kapp Clark, vice president of research and development.

My career with the company started 36 years ago. In 1945 I was named a vice president, became executive vice president in 1956, and in May of 1958 was elected president of the company.

The history of Smith Kline & French Laboratories goes back through 124 years of continuous operation. More than 5,000 people are employed by the company, 3,500 in this country and about 1,500 abroad. We have 30 foreign subsidiaries or branches, and own and operate manufacturing plants in five foreign countries. Our products are marketed throughout the world. With annual sales around $200 million, the company is among the top 10 prescription drug companies in America and has approximately 14,000 shareholders. In 1965, we plan to spend about $23 million for research.

I have requested an opportunity to testify before this subcommittee in order to comment broadly and generally on the impact upon my company of Government patent policy.

I should like to emphasize, however, that although in this testimony I represent the point of view of Smith Kline & French, I am also firmly convinced that I represent the interests of the American people. Our common objective is certainly the health of our Nation, which has already so greatly benefited by the development of the breakthrough drugs that have practically eliminated some diseases and greatly reduced the death rate and length of illness from others. Our objective must be the most rapid possible development of new medicines, and whatever legislation is proposed should in the public interest be geared toward the greatest possible stimulation of medical and drug research.

First of all, I would like to make clear the tremendous gulf there is—in terms of time, research effort, and money—between a new and patentable chemical compound and a safe and effective medicine in a bottle that can be used to treat human beings.

I should like to begin briefly by describing the background of the latest product we introduced, a new diuretic discovered by my company and marketed in 1964. The work on this product is typical of pharmaceutical research and development, whether or not Government funds are involved, and a description of it will, I believe, give you an idea of the great amount of time and money we spend on our R. & D. programs.

Indicated for the treatment of water retention in body tissue from widely varying causes, this product is effective in many patients resistant to other diuretics and, in combination with other diuretics, potentiates their effect. It has the advantage of not causing a loss of potassium from the body, an undesirable characteristic of many other diuretics.

This compound, whose generic name is triamterene, was discovered as part of a program of research we were conducting on diuretic agents, and a patent was applied for in 1959. Though it is impossible to allocate the exact costs, the expense of this patentable invention probably did not exceed $50,000. Then came the major part of the research and development effort, the transformation of the compound triamterene into the medicine we market under the trademark "Dyrenium." This work on Dyrenium took 5½ years and cost over $2 million.

As the table in my prepared statement indicates, our activity from the beginning of animal tests to the decision to test in man required 15 months and cost $350,000; from the beginning of clinical testing to new drug application submission required 18 months and a cost of $735,000; and then, from the time the new drug application was submitted to the time that we received Food and Drug Administration approval to market required 33 months and a cost of a little over a million dollars. The sum total of all this was 5½ years of time, and a little better than $2 million cost.

This was a hazardous speculation. At any time during this process the product might have been shown to have some property that would have made it unsuitable for human administration, and our work and expenses to that date would have gone for nothing. We could never have justified this speculation without the exclusivity provided by a patient.

In the case of Dyrenium, there was, of course, no question of patent protection. We have the patent rights. The cost of the original research and the subsequent development was paid for by Smith Kline & French Laboratories alone.

But many of the important drugs now in use or under current investigaton have been discovered through collaboration between academic scientists and drug companies, and, with proper legislation, this collaboration should become even more productive in the future because of the great expansion in the Government's investment in medical research. Although the subcommittee is undoubtedly familiar with the process of collaborative research in the health field, I would like to amplify certain aspects of it, since it is so different from that in certain other fields where the Government normally makes a research contract with a commercial concern.

What usually happens in the health field is this: The Government makes a research grant to an academic scientist in a nonprofit institution, such as one of our great universities, to investigate a given field. In the course of this investigation, the scientist discovers a new compound, but he does not know what this compound will do to human beings. He may have a hunch that it has medicinal use because of its chemical relationship to known medicinal agents. But he cannot be sure, and the odds against it being a valuable medicine are estimated to be 5,000 to 1. It is rare indeed that the chemist has the biological data about his compound upon which to base a prediction. The only way in which the medicinal value of his compound can be demonstrated is by exhaustive testing, first in animals, then in humans. For the most part, universities do not have the time and facilities for the required animal testing, nor is this type of testing in keeping with their academic purpose. It is logical, then, that the discoverer of a new compound goes to a drug firm for help since, as the subcommittee knows, industry does have complete facilities and long experience in testing chemicals in animals. For example, in 1964 S.K. & F. used more than 500,000 animals in its testing program. Let me again emphasize that such tests offer the only way in which knowledge can be gained about the therapeutic action of a drug before it is evaluated in man.

Drug testing in animals has today become so complex that new methods of testing are often invented as the investigation proceeds. For

example, in the research on the diuretic project I mentioned, conventional tests had failed to show diuretic activity, and on that basis the compound might have been shelved. In devising ways to test other agents for diuretic activity, however, a new test was developed, and this test revealed that our compound did have diuretic activity.

After it has been determined in animals that a compound has an activity which suggests a medically useful effect in humans, the even greater hurdle of determining its activity, safety, and effectiveness in man must be overcome. Drug companies work closely with hospitals and other medical centers to study drugs in humans, and they have techniques and specialized skills for evaluating the resulting data. This phase of developing a medicinal product, known as clinical testing, involves hundreds of physicians, thousands of patients, and takes at least 2 years to carry out. If the evidence shows that the drug is safe and effective in humans, the final step is to secure marketing approval from the Food and Drug Administration.

Another complication in this process I have been describing is the development of a suitable dosage form, one that will permit the patient's body to absorb and utilize the active ingredient of the drug product. Work on this task begins fairly early in the process and requires the solving of a number of difficult technical problems.

I have emphasized the role of our industry in making a medicine available to the public because I would like the subcommittee members to bear this point in mind as I now discuss the kind of patent policy I believe is needed to stimulate drug research and to bring new medicines to the American people.

First of all, is it not true that the keystone of a sound policy as to Government patents is to lay out a system which will produce the maximum utilization of inventions for the benefit of the public?

With "maximum utilization by the public" as the criterion, certain facts would appear pertinent:

1. Our American patent system is almost universally considered as being one of the most potent factors producing this country's industrial and scientific progress. It is based on the premise that the granting of marketing exclusivity for a given period of time is the best way of bringing new inventions into widespread use.

2. If this reasoning is sound, it is obvious that it should apply to the health field to the same extent that it applies to other fields. A new chemical compound will not help a sick person until it has been made into a medicine, and the whole reason for medical research is to help cure sick people.

3. Any patent legislation or any Government patent policy that discourages collaboration between university scientists and drug companies is likely to slow up the development of new medicines.

As I mentioned earlier, the discovery of new medicines should, in the public interest, more and more involve the collaboration of university scientists and drug companies. For effective collaboration, both the university scientist and the drug company must have incentives, first to invent the compound and then to make the speculative investment required to turn it into a medicine. These incentives have traditionally been provided by our patent system. Indeed, the en-

couragement to invent—to "promote the progress of science"—is the only purpose of the patent system. It seems contradictory to remove this incentive from the health field.

In my opinion, the existing Government patent policy for the health field discriminates against academic-industry collaboration by providing that, if Government money is given to the university scientist, the Government takes the patent rights. With rare exceptions, the university, the university scientist, or the drug firm, which may have spent many hundreds of thousands of dollars for development, do not get any exclusive rights.

I can illustrate the complications that now arise under present patent policy by another example from our own experience. Back in 1959, my company began working with a university scientist who had been studying certain steroids for several years under a Public Health Service grant of $26,000 a year.

We have a program in the field of atherosclerosis and heart disease, and we were determining the effect of compounds on blood cholesterol. This effect was not one of those specifically under investigation by the scientist, nor was it contemplated in the PHS grant. We were able to demonstrate through exhaustive tests in animals that the compound in question lowers the cholesterol level of blood without the side effects which, in the past, have limited the use of other drugs.

We are now at the point where the compound should be given to humans for preliminary evaluation. But to date we have been unable to conclude an agreement that will give us reasonable exclusive rights, even though our investment in development already amounts to approximately $250,000 and may well amount to a couple of million dollars before the compound becomes a medicine for human use. We are continuing to negotiate.

Senator McCLELLAN. Now, as I understand it, this is a case where the Federal Government has made a contribution to your research.

Mr. MUNNS. Not to my company, sir.

Senator McCLELLAN. Well, I mean to the university.

Mr. MUNNS. To the university where the scientist was working.

Senator McCLELLAN. Yes.

Well, you say, "We are continuing to negotiate." Who is trying to negotiate?

Mr. MUNNS. We are trying to negotiate with the university or the Research Corp., the university's patent agent, or HEW, or NIH, as to what kind of exclusivity may be possible under this arrangement.

Senator McCLELLAN. Well, If I understand, this is a case where the Federal Government, the NIH, has made a contribution to your research effort.

Mr. MUNNS. To that of the university.

Senator McCLELLAN. The university. But you are the one that discovered the product.

Mr. MUNNS. Discovered the utility of that compound.

Senator McCLELLAN. The utility of it. What do you mean by the "utility of it"?

Mr. MUNNS. A different utility than was anticipated under the grants given by the NIH.

Senator McCLELLAN. In other words, the grant was given for one purpose, and in pursuing that purpose you made the other discovery.

Mr. MUNNS. The grant was given to the university. The findings of that scientist were published. We became interested in the compounds because we were working with steroids, and we asked whether we could examine those compounds and put them through our screening to see whether they would have some value in the field in which we were interested. That was agreed upon, and then we worked with those compounds and with that scientist to some degree.

Senator McCLELLAN. Now, you have gotten to the point where you think it does have a value?

Mr. MUNNS. We think it does have a medicinal value. We don't know yet.

Senator McCLELLAN. You don't know.

Mr. MUNNS. We know it has a use, but whether it is going to be an acceptable medicine is still quite unknown.

Senator McCLELLAN. Well, it at least gives some promise.

Mr. MUNNS. Yes, sir; it gives some promise.

Senator McCLELLAN. Enough that it would be attractive to you to take the risk of expenditures to explore and develop further and test, and so forth?

Mr. MUNNS. That is correct; yes, sir.

Senator McCLELLAN. Which you say may cost as much as $2 million?

Mr. MUNNS. It could run that much; yes, sir.

Senator McCLELLAN. Now, what position are you in if you do not get some exclusive use of it?

Mr. MUNNS. Well, if there were no exclusivity at all, sir, I don't believe we could afford to run through this whole process of developing a medicine, because then the whole information would be in the public domain, which would permit our competition to move right in at the same level we were, with no expenditures. We have got to recoup.

Senator McCLELLAN. In other words, you might spend a million dollars on it and then find out that it did not have the value you thought, and that would be a loss.

Mr. MUNNS. Yes; that would be down the drain.

Senator McCLELLAN. It would be down the drain.

Mr. MUNNS. Yes, sir.

Senator McCLELLAN. Now, if you spend, say, $2 million on it and found it did have a value, then what is your position? That you should have some protection and some opportunity to recoup that investment, plus a profit?

Mr. MUNNS. Yes, sir.

Senator McCLELLAN. And the only way you can do that is by having an exclusive right as granted by a patent?

Mr. MUNNS. That is correct, sir.

Senator McCLELLAN. Well, now, the argument here is, maybe a license should be given to you for just 2 or 3 years.

Mr. MUNNS. Well, if you will let me finish my statement, I do get into that.

Senator McCLELLAN. Very well. I have heard so much of this already, I can almost anticipate it.

Mr. MUNNS. You know it by heart.

Senator McCLELLAN. I do not really mean to get ahead of you, but these thoughts arise. All right, proceed. Just go on with your statement.

Mr. MUNNS. Very well.

The situation I have just described will increasingly be a problem in the future as more and more Federal money is contributed through grants to hospitals, universities, medical schools, and medical centers. Can drug firms collaborate with these institutions if industry is denied a reasonable equity in resulting discoveries? My own opinion is that drug firms will have to shy away from such collaborative research under existing Government patent policy, as indeed they are already doing.

Senator McCLELLAN. Now, there you conclude that sentence by saying, "as indeed they are already doing." Do you have concrete evidence of that work?

Mr. MUNNS. I think that could be developed, sir. The witness before me laid stress on that, where other drug companies were hesitant——

Senator McCLELLAN. Do you have any personal knowledge of such an instance?

Mr. MUNNS. It is a consideration that we have to think about when we have our own drugs, and we want——

Senator McCLELLAN. In other words, your own case is an instance.

Mr. MUNNS. Yes.

Senator McCLELLAN. The one you have just cited.

Mr. MUNNS. Yes; because if we went to a university or asked a scientist to collaborate with us, one who was under a Government grant, and in that process he found a variable use or a different use for this same substance, under those circumstances that new use patent would revert to the Government.

We in turn, working in our own shop, let us say, might easily have discovered the same thing. We would or we would not, but at least that possibility is always a distinct one, so that it would make us hesitant.

Senator McCLELLAN. All right.

Mr. MUNNS. I therefore urge the subcommittee, in considering legislation, to aim at providing the maximum—not the minimum—incentives for medical discovery to university scientists and to the drug industry. I urge this because I sincerely believe that such a policy is in the national interest, and that it will bring the greatest good to the American people.

A very clear principle is involved. Our patent system stimulates the discovery of new and useful products and processes, and its incentive should not be reduced or denied in the field of health.

I would like to suggest the following principles which, in my opinion, should be considered in determining the form of any new patent legislation involving inventions with Federal support:

1. Where a scientist working in a nonprofit institution and supported by Government funds discovers a new compound that may have medicinal use, the patent rights should belong to his institution, subject to certain Government-retained controls.

2. The nonprofit institution should have the right to negotiate with industry to carry out screening, testing, and development work, and may further negotiate a royalty-bearing license with industry upon such terms as they may agree upon, subject again to Government-retained controls. The license agreement may also define the respective rights of the nonprofit institution and the industrial concern as to new uses and related development and improvements which may result from collaborative work between them.

3. In view of the substantial expenses which must be borne by the industrial concern to develop and test the compound, and considering that the royalties will accrue to the institution and be available for further research, with such award to the individual inventor as the institution deems appropriate, the license to the concern must be attractive enough to invite its participation in this research and development.

We have given considerable thought to specific amendments to S. 1809 and plan to submit them to the subcommitee at the earliest possible date.

That concludes my comments, Mr. Chairman. Thank you for your courtesy.

Senator McCLELLAN. Thank you. Are you prepared to submit the amendments today, or do you wish to submit them later?

Mr. MUNNS. I would like to submit them later, if I may.

Senator McCLELLAN. Very well.

Mr. MUNNS. They have not been—we haven't completely finalized them.

Senator McCLELLAN. I personally appreciate it when those of you who have an interest in this, if you find some way that the bill can be improved, make your suggestion and then prepare the amendments that will carry out your recommendation so that we can better understand exactly what you wanted and what you mean and what the effect of your recommendation would be if adopted.

Mr. MUNNS. Well, you can appreciate that this is a very important piece of legislation that you are considering.

Senator McCLELLAN. That is right.

Mr. MUNNS. And we are working, just as diligently as we can, to send to this committee our proposed or suggested amendments to your bill.

Senator McCLELLAN. Thank you. I was just trying to emphasize that we will welcome such assistance from interested people.

Mr. MUNNS. We will try to get them to you just as quickly as we can, sir.

Senator McCLELLAN. Very well. Thank you very much.

All right, Dr. Zucker, will you come around, please. We are ready to hear you.

STATEMENT OF WILLIAM ZUCKER, PRESIDENT, SOUTHEASTERN PENNSYLVANIA ECONOMIC DEVELOPMENT CORP.

Senator McClellan. Very well, Doctor. You may proceed. You have a prepared statement.

Mr. Zucker. I have, sir.

Mr. Chairman, I am William Zucker, president of the Southeastern Pennsylvania Economic Development Corp., a nonprofit organization created last year with the support of the business and financial community in the 5-county industrial area of which Philadelphia is the center, and which is composed of the counties of Bucks, Chester, Montgomery, and Philadelphia.

I have this prepared statement, which I would like so much to read if I may, and then be available for questions.

One of the concepts on which Spedco—which is what we call our organization—is based is that of encouraging economic development and industrial growth by creating an environment where new ideas in research and development of individual inventors who lack financial resources of their own can be translated into actual industrial production.

The patent incentive is an essential element of this process, and with Federal research and development programs expanding as they are, the potential impact—good or bad—of Federal agency patent policy on science-based, non-Government sectors of the economy cannot be overemphasized.

This is why the organization directed me to make known to your subcommitee, Mr. Chairman, our views on these important issues.

Let me briefly outline for you one key portion of our program which, by the way, is the first of its kind ever undertaken in this country, and which is jointly supported by our own business, financial, and academic communities and by the Federal Government itself through a technical assistance contract with the Commerce Department's Area Redevelopment Administration.

We have set up a new regional development laboratory, where inventors and researchers can obtain space in which to work up and test out their ideas, using our laboratory's specialized equipment and facilities, and having available to them a wide range of technical consulting services.

We designed this laboratory to provide the inventor or researcher with the best possible conditions in which to develop marketable, job-producing, economy-building products and services in the shortest possible time.

We believe it is important to take the individual inventor out of the basement, kitchen, or garage and give him the advantages enjoyed by his counterparts in well-supported industrial and academic laboratories.

Spedco's development laboratory will provide space for 12 "research associates," as we call them, who will pay service fees ranging from

$500 to $2,000 a year, depending on the extent of the R. & D. support that they require. All other costs are underwritten by the sponsoring organizations—ARA during this first year; Spedco and the West Philadelphia Corp.

The latter, parenthetically, is a second nonprofit corporation founded by the University of Pennsylvania, Drexel Institute of Technology, Philadelphia College of Pharmacy and Science and Philadelphia's Presbyterian Hospital to coordinate and stimulate the construction of University City, a 2,000-acre area being developed by private and public capital into a new urban community in West Philadelphia, distinguished by 16 educational and medical institutions. Our development laboratory is in the University City science center complex.

The length of time a Speco research associate will be permitted to occupy space in the laboratory varies with the product or service he is trying to develop and the progress he is making. When an idea has reached the prototype or model stage, the inventor will move out so that others may have access to the laboratory's facilities and opportunities for cross fertilization of ideas.

We already have 4 of the 12 research associates that our laboratory is equipped to house, and discussions are going forward with others.

One is working on electronic devices for fire detection and for burglary detection.

A second is developing a low-temperature (cyrogenic) surgery probe and an instantaneous blood-flow reading device.

Polymer chemistry is the third associate's field, and the fourth is medical information retrieval.

Just before I came down last night, we signed up our fifth one, who is developing an electronic scanning device for the golf swing, so that if it is successful——

Senator McClellan. For what?

Mr. Zucker. For golf swing, sir. So that if it is successful, there will no longer be golf duffers in America. [Laughter.]

Senator McClellan. Say that again.

Mr. Zucker. This man has invented a scanning device hooked up by electronic devices with an IBM program device which examines the person's golf swing, his stance, the weight of the club, the way in which the golfer approaches the ball; and, hopefully, he will develop through this testing device a new way of approaching the ball and swinging the club. It will be sold to golf pros.

Senator McClellan. Is there any stock for sale in that? [Laughter.]

Mr. Zucker. I would like to point out, if I may just proceed, Mr. Chairman, that all of these are new and novel ideas that we are trying to develop.

Now, the Area Development Administration of the Department of Commerce is providing us with $120,000——

Senator McClellan. On this particular thing?

Mr. Zucker. On the entire laboratory, not on this device. No, sir.

We then provide some $45,000 in additional funds. But the patent device and the patent rights belong to the research associate. They

do not belong to the Federal Government, nor do they belong to Spedco, nor do we have any financial rights in the product at all.

But this is one of the first times in which a Government contract was written in which the research associate's patent rights belong to him and do not revert to the Federal Government.

We pioneered in this R. & D. facility because it represents a single approach, a first approach which we hope will be duplicated throughout the country.

We have emphasized the fact that our area, our five-county area, has indeed quite a complex of R. & D. going on, and we have issued just recently this brochure (indicating), which I would like to leave with the chairman, not to put it in the record.

Senator McClellan. It may be received as an exhibit for reference, appropriately numbered. We have already had a number of exhibits for reference, and this will be appropriately numbered for reference.

(The brochure referred to will be found in the files of the committee.)

Mr. Zucker. Thank you, sir.

In it, we have listed a directory of research and development, and we have found that there are more than 425 laboratories employing about 15,000 scientists and engineers and spending more than $500 million a year in R. & D. R. & D. programs span the entire range of science and technology, with the greatest concentration in aerospace, chemicals, electronics, instruments, machinery, materials, development, medicine, and physics.

When it is completed, the $50 million University City Science Center in West Phildelphia and its already functioning Science Institute will be able to make available to government and industry alike—provided equitable Federal patent policies are developed by Congress and enacted—the research talents of a dozen or more universities, technological institutes, and medical centers.

The interdependence of science and technology, the frequent intermingling of research activities, and the participation of the Federal Government to industrial and academic research cannot be better demonstrated than in southeastern Pennsylvania.

As I mentioned, we had prepared this detailed directory of R. & D. organizations, facilities, and capabilities in southeastern Pennsylvania and, where possible, the sources of support for the work conducted in each.

We found that activities in the area's 425 research centers and laboratories included (1) research supported entirely by industrial concerns; (2) programs supported entirely by the U.S. Government under contracts or grants, and (3) also it had programs in which Government projects are going forward side by side, with research being conducted with a company's or university's own funds and with other, nongovernment contract or grant-supported work.

Monitor Systems, at Fort Washington, for example, is a small company with $2.5 million research volume in communications. All its work, at the time of our survey, was for the Government.

General Electric's Missile and Space Division employs 5,500 research personnel in a broad range of disciplines, with 95 percent Government support and 5 percent funded by GE itself.

Kellett Aircraft has a $500,000 research volume; is doing 20 percent of its work for itself, 70 percent for the Government, and the other 10 percent under contract for other industry.

Atlantic Refining, on the other hand, has a research staff of 362, doing 95 percent company work and 5 percent Government work.

Rohm & Haas, a major chemical concern, spends $15 million annually for research, all on its own account.

Intermingling of research and research support is most evident on the university campus. For example, Villanova's research, which runs to $90,000 a year, is supported 10 percent by the university, 75 percent by the Government, and 15 percent by industry.

At Hahnemann Medical College, with a $2.3 million program, the support ratios are: the college 8 percent; Government 80 percent; industry 10 percent; and "other" 2 percent.

Our area's biggest academic research center is the University of Pennsylvania, with its $27.5 million program and 2,000 research people. The Government supports 90 percent of this work, the university 5 percent, and industry the other 5 percent.

The difficulty of devising a Federal patent policy that will preserve all the equities in these varied factual situations has long since become clear to this subcommittee, I am sure.

I appreciate your courtesy and your patience, Mr. Chairman and members of the subcommittee, in permitting me to make these general comments about Spedco and its interest in these issues.

Our testimony on the specific legislative proposals will be directed only to S. 1809, introduced by Senator McClellan, and S. 2326, introduced by Senator Dirksen after this subcommittee held its patent hearings during June and July.

We understand that S. 1809, Mr. Chairman, was intended to write into statutory language the provisions of the late President Kennedy's patent policy memorandum of October 10, 1963, to Federal agencies.

We also understand that Senator Dirksen's bill incorporates the recommendations of the American Bar Association and the American Patent Law Association.

In our view, neither of these bills, as introduced by the chairman or by Senator Dirksen, resolves with equity for all concerned the complex issues of Federal agency patent policy, nor do they sufficiently protect the public interest in the context of the Constitution's mandate to Congress (art. I, sec. 8), "to promote the progress of science and useful arts" by means of a patent system.

By comparatively simple amendments, however, either or both could be adjusted, in our view, appropriately to advance and protect the public interest, safeguard the equities of all concerned, and indeed "promote the progress of science."

Section 3(b)(3), on page 4 of S. 1809, reserves to each contractor an irrevocable, nonexclusive, royalty-free license for the practice of any invention arising from research conducted for a Government agency. However, such license is nontransferable except within affiliated companies or successor companies.

This language is sufficient to protect the rights of the contractor if that contractor is a commercial concern with developmental and marketing resources.

But if the contractor is a university, medical school, or comparable nonbusiness enterprise, the license must be transferable by that enterprise if the provision is to place the academic contractor on equal terms with the commercial contractor.

No academic institution of which I am aware has the capacity to reduce an invention to practice and put it on the market, nor any interest in doing so. The only way it can benefit from this clause is to be able to license a company with resources to develop and market a product, and so receive royalties.

We are sure this discriminatory treatment of academic institutions was an inadvertence.

Section 4(a) of S. 1809 describes situations in which an agency head would be required to take principal or exclusive rights for the Government, with a proviso for waiving such taking by the Government in exceptional circumstances.

The purposes of 4(a)(1) and 4(a)(2) are, we believe, laudable. But because the language of 4(a)(1) is inexact, it would extend far beyond any foreseeable requirement of the public interest.

This is particularly true of the phrase "for commercial use by the general public," which could extend to virtually every kind of product, new or old, conceivable by the mind of man.

As for 4(a)(2), its requirement of Government taking of principal or exclusive rights in fields which directly concern the public health, welfare, or safety could well have exactly the opposite effect of that intended in the Kennedy policy memorandum and in this implementing legislation.

This provision would deny to the fields of health, welfare, and safety the incentives of the patent system which has brought so much progress in every field, including these three crucial fields, since the first patent law was enacted 175 years ago.

We agree that these fields are so important in the lives of every citizen that Government should give every encouragement to rapid advancement. But to take away the patent incentive would be to impede advances, not encourage them.

We believe the American Bar Association and American Patent Law Association have worked out a reasoned approach to this specific problem, which has been incorporated in S. 2326.

Its 4(a)(1) would require a Government taking of rights if—

> the purpose of the contract is to produce one or more end items, the use of which is or will be required by law or governmental regulation in furtherance of the public health or safety, and the invention covers such an end item * * *

This phraseology, we believe, fully protects the public interest in the fields of research and development encompassed by both 4(a)(1) and 4(a)(2) of S. 1809. We suggest that both be deleted from S. 1809 and that 4(a)(1) of S. 2326 be inserted in their stead.

S. 1809, in 4(b), discriminates once more against academic and other nonprofit enterprises. This provision would allow the contractor to retain all rights but a nonexclusive Government license, when the research is for products or methods for use by the Government and the work is in a field where "the contractor has acquired technical competence directly related to an area in which he has an established nongovernmental commercial position * * *."

A nonprofit institution like a university or medical school can qualify for these additional rights on the basis of its existing technical competence, but not if it is required to have an established nongovernmental commercial position.

This discriminatory treatment of our great nonprofit research centers can be corrected by additional language limiting the "commercial position" requirement to commercial contractors.

Additionally, we believe it would be good public policy for the Government to avail itself of the outstanding technical and administrative competence of our universities and our medical and other scientific colleges in the handling, on a public interest basis, of patent rights to inventions made in the course of research conducted by the institutions under Government grants or contracts.

This can be accomplished by incorporating a provision in this legislation directing the agency head to acquire no more than a nonexclusive license for the Government if the contractor (1) is a nonprofit institution, (2) has a patent policy approved by the agency head. The institution would hold and exploit the patent.

This system has been used for many years by the Public Health Service in administration of inventions made in the course of NIH-supported research, as the subcommittee knows.

The provision should, we suggest, contain language requiring the agency head to approve an institution's patent policy if such policy will advance the public purposes of the institution, and specifically allowing approved policies to include appropriate incentive payments, based on a percentage of royalties or other reasonable criteria, to the individual inventor or inventors.

S. 1809 wisely provides authority for Federal agencies to grant exclusive or nonexclusive licenses for the practice of inventions on which the agency holds patents, with or without the payment of royalties, and for as long as the life of the patent, if this is in the public interest. We strongly support this.

On the other hand, S. 2326 in 4(c), while it reserves to the contractor "at least a nonexclusive, royalty-free right to practice the invention * * *," can be construed as requiring the Federal agency head to grant to any citizen of the United States or any citizen-controlled enterprise "an irrevocable, royalty-free nonexclusive license to any patent" held by the United States.

This would seem to be required whether the citizen or citizen-controlled enterprise was a participant in the development or not, and would seemingly prohibit use of the frequently essential tool of exclusive licensing.

In fact, this language can be interpreted as requiring that strangers to the contracts and to the research be favored over contractors who made the invention. They would be accorded "an irrevocable, royalty-free nonexclusive license in any patent" held by the United States, while the contractor would be entitled only to a "nonexclusive, royalty-free right to practice the invention."

This would seem to be required whether the citizen or citizen-controlled enterprise was a participant in the development or not, and would seemingly prohibit use of this frequently essential tool of exclusive licensing.

If this phraseology of S. 2326 is intended merely to reserve to contractors alone a royalty-free nonexclusive license to every patent held by the United States that arises out of the research they contract to perform, it should say so more precisely.

However if this section 4(c) is intended to prohibit exclusive licensing of patents held by the United States under any and all circumstances, and your subcommittee adopts this policy, contractors should at least be placed on a par with strangers to the contracts by being accorded the same irrevocable, royalty-free nonexclusive license in patents held by the United States.

We urge the subcommittee not to bar exclusive licensing of patents held by the United States, because forbidding such a licensing on reasonable terms, to encourage private investment of the sometimes large sums necessary to fully develop an invention to the point of practical application, would not be in the public interest.

In the pharmaceutical and medical sciences, for example, the investment of capital and of human and laboratory resources required to bring what pharmacologists call an "interesting" compound to the point where the physician can prescribe it for his patients often involves years of research and millions of dollars.

If the Government should offer this "interesting" compound to every pharmaceutical house qualified to undertake its development, chances are that none would be willing or able to take the risk.

It is only by reasonable market exclusivity that a pharmaceutical company has a chance of recovering its investment and perhaps realizing a profit.

I would like to make one final point on the granting by Federal agencies of exclusive licenses in practice inventions to which the Government holds title.

In today's intermingling and interdependence of research and development, situations may arise where the Government holds a patent or has principal or exclusive rights even when other sponsors—such as a medical school or university or a publicly supported health organization like the American Cancer Society—or a company have made equal or greater contributions than the Government to the research and to the discovery. Equity demands that in cases of this kind the Federal agency be compelled to recognize the contributions and the rights of the cosponsors of the research.

This can be readily done by adding a new clause in section 8 of S. 1809 that would require the agency head to grant an exclusive, royalty-free license to the contractor and/or other persons associated with the contractor in making the invention if the aggregate financial contributions of these persons is greater than that of the Government.

Also, the agency head should be required to grant an exclusive royalty-free license to the contractor and/or his associates in the research if the agency head determines that substantial additional expenditures of nongovernmental funds are needed to bring an invention to the point of practical application and that such exclusive licensing would accelerate final development by the contractor and/or his associates and expedite availability of the end product for public use.

Applications for this kind of exclusive licensing are based on equities derived from work already performed or commitments to perform

developmental work in the future. Applicants should have available to them, we believe, the same kind of administrative hearings and judicial review provided for in sections 5 and 6 of S. 1809, in the event of agency denial of a reasonable period of exclusivity.

Thank you Mr. Chairman and members of the subcommittee, for this opportunity to present the statement to you.

Senator McCLELLAN. Thank you very much, Dr. Zucker. That is a very interesting statement. I appreciate, too, your suggestion about what amendments would be advantageous and beneficial to the proposed legislation.

Mr. ZUCKER. Thank you.

Senator McCLELLAN. Off the record.

(Discussion off the record.)

Senator McCLELLAN. Very well. Our next witness?

Mr. BRENNAN. Mr. Robert F. Conrad.

Senator McCLELLAN. Will you come around, please, Mr. Conrad?

Mr. CONRAD. Yes, sir.

STATEMENT OF ROBERT F. CONRAD, REPRESENTING TEKTRONIX, INC.; ACCOMPANIED BY THE VICE PRESIDENT, WILLIAM WEBBER, AND J. RUSSELL VERBRYCKE III, AN ATTORNEY

Senator McCLELLAN. All right, Mr. Conrad, if you will identify yourself and also your associate, then you may proceed. I see you have a prepared statement.

Mr. CONRAD. Yes, sir; I also wish to make additional comments.

Mr. Chairman, I am Robert F. Conrad, a patent attorney with offices at 815 Connecticut Avenue NW., Washington, D.C. I am a member of the bar of the District of Columbia, and of the American Patent Law Association. My practice is concerned almost exclusively with patent litigation. My appearance is on behalf of Tektronix, Inc., a manufacturer of electronic equipment, including oscilloscopes, which are electronic devices designed for precision measurement.

On my right is Mr. Verbrycke, who is an associate in my office. We also have with us, in the back row, Mr. Webber, who is an officer of the Tektronix, Inc.

Senator McCLELLAN. Very well, you may proceed, Mr. Conrad.

Mr. CONRAD. Our comments will be directed exclusively to section 8 of the bill S. 1809.

We have comments of two kinds about the provisions of section 8. The first is with respect to the technical language of the bill.

It appears to us that under the present language, the purposes which the committee have in mind may not be accomplished; and secondly, we object to some of the philosophy of section 8, particularly that which enables the Government to bring suit on Government-owned patents against citizens of the United States and collect damages.

First, with respect to the technical matters, which I think can be discussed with reference to the first sentence of section 8(b). You will notice that the first sentence of section 8(b) provides that: "Each agency head may grant an exclusive or nonexclusive license for the practice of any invention for which he holds a patent acquired under this act on behalf of the United States."

Now, at the moment, the Government owns somewhat more than 10,000 patents. Those patents are presently existing, and their average remaining life may be in the neighborhood of 8 years.

Senator McCLELLAN. This is the overall total, is it? The aggregate?

Mr. CONRAD. Yes, sir.

Senator McCLELLAN. This is not in just one specific field?

Mr. CONRAD. It is the overall, Your Honor. The last statement I saw was in the neighborhood of 13,000.

Now, of course, section 8(b) obviously is directed to the administration of patents which are owned by the Government. It details the kind of license that may be granted under the act.

The point which we wish to bring to the committee's attention is that the present language of the act would leave completely in limbo the patents presently owned by the U.S. Government, which number well over 10,000.

Senator McCLELLAN. When you say "the act" you mean the bill that I introduced, S. 1809?

Mr. CONRAD. Yes, sir; I meant the bill S. 1809.

Senator McCLELLAN. Yes.

Mr. CONRAD. We assume that it was intended that the provisions of 8(b) apply to Government-owned patents, presently owned as well as those acquired in the future. This appears in the technical amendments which would repeal certain administrative rules with respect to patents now owned by particular departments.

So, if it was the intention of the committee to bring within the ambit of 8(b) the presently owned patents of the Government, which, of course, will represent the real problem over the next several years, then some amendment to the present language will have to be made.

Now, another technical aspect with respect to section 8 is that the sentence which I have read also provides that the agency head may grant an exclusive license. Ordinarily an exclusive license is literally what the word "exclusive" means, and the agency head, under the present language of 8(b), would be entitled to, if not actually required to, grant a license which would even preclude any rights in the Government.

For example, under this section, the agency head might grant an exclusive license. That exclusive licensee might later turn around and insist that the Government pay a royalty on the very patent which had been exclusively licensed by the Government, the development of which had, of course, been fully paid for by the Government.

This result could be avoided simply by saying that the exclusive license which the agency head is entitled to grant shall be subject to the same kind of a reservation which is described in section 3(b)(5) of the bill.

Those are the only two comments we have with regard to the language of the bill.

The provision that we are most concerned with is made in the last two sentences of section 8(a). These sentences read:

> Each agency head shall take such action as may be required to protect and preserve the property rights of the United States in any patent so issued to him. Upon request made by any agency head, the Attorney General shall take such action as he shall determine to be required for that purpose.

Now, I think this might be regarded, really, as a rather significant piece of antitrust legislation. What this provision represents is a departure from historic Government patent policy. Except for one single recent instance, the Government has never brought suit against any of its citizens for infringement of Government-owned patents. This language which I have read would seem to authorize such suits.

Now, we know that suits on Government-owned patents could be—and according to the present policy of the Department of Justice would me—used to actually regulate competition in an industry, and suits on such patents could be usd to regulate competition within industry, even thought that industry or that particular company in the industry was not involved at the moment in anything that was in violation of present antitrust law.

In other words, this provision would give the Department of Justice a new and additional tool with which to regulate competition in any given industry.

The regulation, of course, would be achieved by filing an infringement action against a particular company, and not against others in the industry, with the idea that it would saddle onto that particular company the requirement to pay a royalty which its competitors would not be paying.

It would, of course, undertake to do this only when it thought that adding such a royalty to the costs of one company would result in equalizing the competitive situation in that company's industry.

Now, this is not a speculation on my part. This is the position which the Department of Justice has actually taken in a case which is now pending in the U.S. Court of Claims.

Another aspect of giving the Government the right to sue on its patents is that it really sets up a very unfair contest. For example, there is a very clear Supreme Court law on the proposition that the Government is not subject to any statute of limitations.

Now, with respect to authorizing the Government to bring suits on its patents against its citizens, that rule would have this effect: The Government could today file suit in a U.S. district court and ask for damages for infringement of a Government-owned patent which, say, might have expired as many as 30 years ago.

It could, for example, under the provisions of this section authorizing infringement actions, go back and sue, for example, the electronic companies such as Westinghouse, RCA, and General Electric, for infringement of Government-owned patents which occurred during the last war.

The fact that it has delayed suing for so long a time has led these companies, and perhaps also its policy of not suing on any of its patents for so long a time, into the reasonable belief that it would never sue on them, could not be raised as a defense in any such action, because another firmly established rule of law is that an estoppel or laches cannot be urged against the Government.

Consequently, we would suggest some change in language in section 8 which would put the onus of suing for infringement of any Government-owned patents on the exclusive licensee. This would then set up the usual situation one faces in court in a patent litigation case. In connection with a free, nonexclusive license, of course, the Government

couldn't show any damages, even if it did sue for infringement, so it is unlikely that such actions would be brought.

In connection with a royalty bearing nonexclusive license, a complaining licensee might be authorized to bring the suit.

But, in any event, it seemed to us that this provision, section 8, should be amended in some way that takes the Government out as a litigant in patent cases involving Government-owned patents on which infringement suits are brought, simply to avoid the inequities which would follow from the Government participating as a plaintiff.

Now, one other comment we have about section (b) is that it provides that licenses such as are authorized by portions of the provision should be granted with or without the payment of royalty.

Now, it seems that the suggestion that the Government might in some cases want to collect a royalty was simply based on the thought that it would be a sound business practice to do so, it would be prudent as a business matter to collect a royalty where the Government could collect a royalty practically.

We think this overlooks a rather basic consideration. Of course, the Government should follow prudent business practices wherever it can, but we think that such practices have to give way where they conflict with some basic governmental principle such as a provision, for example, in the Constitution.

Now, the patent provision in the U.S. Constitution has, of course, been commented on a great deal by the courts, and over a long period of time the courts have analyzed its purpose as being to increase the storehouse of knowledge which is freely available for all to use. The particular way in which the constitutional provision is written seems to require this interpretation.

Now, of course, when the Government charges a royalty for use of patented knowledge, it is to that extent discouraging the use of that knowledge, and it certainly is not increasing the storehouse of knowledge which is freely available for all to use. To that extent, where it charges a royalty, it is taking a position which seems to us to be inconsistent with the purposes of the constitutional provision.

Also, it is said that the reason for providing for the issuance of exclusive licenses is to encourage the use of these ideas which might otherwise die on the shelf. That, of course, is a laudatory purpose. But consistently with the purpose of the Constitution, it could be even still furthered by omitting to charge a royalty for the exclusive license. That would be, of course, an even further inducement to exclusive licensees to make a success of their ventures with the Government.

Now, in connection with this purpose of encouraging industry to develop, make things practical which otherwise would remain simply as patents on the shelf, gathering dust, I would like to point out that the provision which enables the Government to bring suit on Government-owned patents, under the present policy of the Department of Justice, thwarts this objective.

You might be interested in the case of Tektronix. Tektronix started out not many years ago on a capital of about $20,000, I believe. They were in competition in the oscilloscope business with RCA, Westinghouse, Dumont, and a number of other very large companies, but they offered a better product at a lower price, and the public rewarded them

by buying their products, and they are now a very, very substantial company.

They made the developments at their own expense. These developments, for the purposes of this discussion, can be regarded as improvements on two Government-owned patents which were in fact gathering dust on the shelf until Tektronix improved them and made them practical and embodied them in a commercially useful instrument.

Now, what was the accolade which this company gathered as a result of making this development of the patented Government idea which was moldering away on the shelf? They were rewarded as follows: They were the first company in the history of this country that was sued for infringement of a Government-owned patent. The Government procured their competitors to manufacture Chinese copies of the instrument which the company had developed at its own expense.

Now the Government is taking the position that if Tektronix wishes to use these Government-owned patents, then it must pay damages—that was its first position. It then altered its position to say, "Well, at least you must give to the Government and your competitors, insofar as Government use is concerned, rights under the developments which you made."

We think this is manifestly unfair.

Senator McCLELLAN. How much did you spend on the development?

Mr. CONRAD. Sir?

Senator McCLELLAN. How much did you spend on the development of the product?

Mr. CONRAD. Well, I don't have the exact figures, Senator, but I could say very safely that it was in the hundreds of thousands of dollars and took place over quite a long period of time.

Now, the provisions of the bill, rather than discouraging this kind of actual retribution against one who develops a Government idea, makes it possible and actually confirms the position which the Department of Justice has recently taken on this.

The Department of Justice has taken a position that it needs no legislation in order to sue on Government-owned patents. But whenever it thinks it is in the public interest to do so, it will bring suit; this, despite the fact that there is no statute authorizing such action; this, despite the fact that there are no standards set out as to what shall govern this determination of public interest, nor who shall make it, and despite the fact that there are no regulations on that.

They also take the position that once they make this determination, it is not subject to review by any court. Well, we think that suit on Government patents is properly a matter that should be resolved by Congress, if in fact any branch of the Government has power to authorize such suits in view of the purpose of the patent provision of the Constitution.

Mr. Chairman, we have prepared a supplement to our prepared statement, in which we make suggested amendments to section 8.

Senator McCLELLAN. Very well. Let it be filed and put in the record, along with your prepared statement.

Mr. CONRAD. We think it will continue to carry out the objectives the committee had in mind in writing section 8 and, at the same time, avoid some of these matters which we regard as problems.

Senator McCLELLAN. All right, sir. Do you have anything further?

Mr. CONRAD. No, your Honor.

Senator McCLELLAN. As I said, your statement and the supplement will be inserted in the record.

(The prepared statement of Mr. Conrad together with the supplement referred to follow:)

STATEMENT OF ROBERT F. CONRAD ON BEHALF OF TEKTRONIX, INC.

Mr. Chairman and members of the committee, I am Robert F. Conrad, a patent attorney with offices at 815 Connecticut Avenue NW., Washington, D.C. I am a member of the Bar of the District of Columbia, and of the American Patent Law Association. My practice is concerned almost exclusively with patent litigation. My appearance is on behalf of Tektronix, Inc., a manufacturer of oscilloscopes, which are electronic devices designed for precision measurement.

While we have an overall interest in Senator McClellan's bill, we are primarily concerned with a portion of section 8(a) and with certain of the licensing provisions which would involve the use of that section. The partciular part of section 8(a) which we wish to discuss consists of the last two sentences of that subsection which extend from line 23 on page 14 to line 2 on page 15, which read as follows:

"Each agency head shall take such action as may be required to protect and preserve the property rights of the United States in any patent so issued to him. Upon request made by any agency head, the Attorney General shall take such action as he shall determine to be required for that purpose."

This language appears to give congressional sanction to an administrative concept which has recently resulted in a complete reversal in the Department of Justice of a patent policy which has been recognized by both Congress and the executive departments since World War I. Specifically it would authorize the U.S. Government to sue its citizens for the infringement of Government-owned patents.

It is our belief that this committee has not been fully advised how section 8, if enacted, will be administered by the executive departments. Tektronix, Inc., is currently engaged in patent litigation with the United States in the Court of Claims. In this action the Government is attempting, through a patent infringement counterclaim instigated by the Department of Justice, to accomplish the following results:

(a) To extend the antitrust authority of the Department of Justice beyond its present statutory limits.

(b) To control competition within a particular industry, by using Government-owned patents as a means for prosecuting acts which are not violative of the antitrust or any other laws.

It also appears that section 8 involves complications of basic law which also have not been presented to this committee:

First, a serious question of constitutional law is involved. The obvious purpose of article 1, section 8 is to promote the useful arts by enlarging the storehouse of knowledge concerning them to which the public has free and unrestricted access. Any action which the Government might take to prevent the free use of knowledge concerning the useful arts through enforcement of a Government-owned patent thwarts the purpose of this constitutional provision. Therefore, a suit upon a Government-owned patent necessarily wrongfully delays fulfillment of the primary purpose of article 1, section 8.

Second, the enactment of section 8 of the bill would create an injustice by placing the Government in a legal position superior to that of the private patent owner. For example, the Government as a sovereign would have the following unfair advantages in patent litigation:

(a) *Statute of limitations.*—The private owner of patents as plaintiff may not bring an action for any infringement which occurred more than 6 years prior to his action by virtue of 35 U.S.C. 286. The U.S. Government on the other hand has long been held by the Supreme Court not to be prevented by a statute of limitations from asserting rights vested in the Government as a sovereign power. *United States* v. *Nashville, Chattanooga, and St. Louis R.R., etc.*, 118 U.S. 120, is typical of many such decisions.

(b) *Laches.*—The United States as plaintiff, unlike a private company, is not barred by the laches of its officials, however gross, from bringing a suit as a

sovereign government to enforce a public right or to assert a public interest. *United States* v. *Insley*, 130 U.S. 263.

(c) *Declaratory judgment actions.*—Where one is accused of infringing a privately owned patent he may bring a declaratory judgment action to test the validity of that patent. The United States, however, cannot be sued under the Declaratory Judgment Act, 28 U.S.C. 2201, even though it may threaten to enforce its patents against persons accused of infringement. The United States can be sued only to the extent that it has waived its sovereign immunity, and it has not consented to be sued under this statute.

(d) *Patent misuse.*—The courts in a long series of cases have refused to allow the patent owner to enforce his patent, even though it be of unquestioned validity, where he has been guilty of some one of the many practices which constitute "misuse of patents." Again the unique position of the United States as sovereign would make it impossible to assert these defenses should the Government institute an action for patent infringement.

(e) *Right of licensee to test validity.*—In a number of decisions the Supreme Court has stated that it is in the public interest to insure a licensee the opportunity to free itself from licensing restrictions which are imposed under a patent which may be invalid. It has recognized that the licensee must have access to the courts to test the validity of the patent where the restrictive conditions, but for the patent, would be contrary to the Sherman and Clayton Acts. *Katzinger Co.* v. *Chicago Metallic Mfg. Co.* (329 U.S. 394), *Macgregor* v. *Westinghouse Elect. and Mfg. Co.* (329 U.S. 402). Where the Government is licensor, the licensee is deprived of this means of litigating the patent under this body of case law, and the United States has still another unfair advantage when compared to private owners of patents.

CONCLUSIONS

One does not have the same rights against the Government as the party asserting the proprietary rights under a patent as one does against a private patent holder. The unfairness of creating a litigant in the unique position of a sovereign becomes even more serious when it is considered that the Government is one of the world's largest owners of patents, and that these patents cover inventions in virtually every technology. Additionally and aside from the constitutional and other legal questions, it is inappropriate for the Government with its limitless resources of public funds and vast legal staff, to set itself up in the patent business. The average litigant is simply not able to exercise his normal legal rights where the Government is a party litigant.

Therefore, the last two sentences of section 8(a) should be deleted. The United States has all the authority it needs to carry out its historical functions of obtaining and preserving patent rights. These include:

(*a*) Authority to acquire title to inventions financed with public funds;

(*b*) Authority to assert invalidity of patents defensively in the Court of Claims on which infringement claims are filed against the Government; and

(*c*) Authority to participate in interference proceedings in the Patent Office.

In order to eliminate any need for the portion of section 8(a) to which objection is made, section 8(b) should be amended to eliminate the authority of the agency head to issue any license which is not nonexclusive, royalty-free, and equally available to all applicants.

Should the committee, however, feel that in exceptional circumstances the public interest requires the granting of an exclusive license, such license should be royalty-free, and should provide that the licensee would be solely responsible for the prosecution of infringers and defense of the patent to the same extent as if it were the owner as well as the licensee. The bill should also contain a provision which would prevent any participation whatsoever in any such litigation by the United States as either plaintiff or defendant.

If thus amended, the more serious objections to the bill would be eliminated. The Government's traditional role in patent litigation would not be enlarged, and it would continue to participate as defendant in the Court of Claims under section 1498 of title 28.

Having concluded my comments as to the bill itself, I will briefly highlight the case of *Tektronix, Inc.* v. *The United States*, so that the committee will be completely aware of the manner in which the Department of Justice will exercise the authority which section 8 would confer.

In 1961 Tektronix brought a patent infringement action in the Court of Claims against the United States. In patent parlance it took the position that the United States had awarded a series of contracts to Tektronix's competitors to make "Chinese copies" of Tektronix's patented oscilloscope. This was an ordinary infringement suit, which became unique when 2 years later the Government filed a counterclaim against Tektronix. This is the first time in history that the United States has asserted a patent against one of its citizens, and has thus questioned the right of all people to make free use of its patents. From its briefs and oral arguments the Government's position is as follows:

(*a*) Tektronix patented oscilloscopes employ two patented electric circuits the ownership of which was assigned by the inventors to the Departments of the Army and Navy, respectively. These two Government patents as well as those of Tektronix are embodied in the Tektronix instrument.

(*b*) Tektronix made use of the two Government-owned patents without having first applied for a license from the Army and the Navy.

(*c*) Tektronix must now agree to a cross-license under which the Government and its contractors will be licensed retroactively to use the patents of Tektronix in exchange for the right of Tektronix to use the two Government patents.

(*d*) There is no statutory authority for the compulsory cross-licensing which the Department of Justice is attempting to force upon Tektronix, but it has the inherent authority to determine where the public interests lie and to use its patents to enforce such determinations.

(*e*) It is "in the public interest" for the Department of Justice to promote competition in the oscilloscope industry and to put Tektronix "in the same position as other members of the oscilloscope industry" and to "equalize opportunities" in the competition for Government purchases of oscilloscopes.

The Department of Justice states that it has the inherent authority to make the determinations involved and to enforce them even though the action was taken without the knowledge of either the Department of the Army or the Navy, the Departments to which these two patents are assigned. The Justice Department states that it needs no authority from Congress to make and enforce these "public interest determinations." It even goes so far as to contend that these decisions are beyond the reach of the courts in that they are the exercise of administrative discretion.

The main theme of President Kennedy's directive on Government patent policy and the announced objective of this committee is to foster the commercial application of Government-owned inventions. It should be assumed for purposes of this discussion that Tektronix did make use of the Government-owned patents in producing its new oscilloscopes. No one contests the fact that Tektronix did introduce a new instrument which is cheaper and far superior to any oscilloscope which had been available previously. It is also admitted that the new instruments were the result of the expenditure of a great deal of time and money, all of which was borne by Tektronix. Nevertheless the United States is now suing Tektronix for developing two Government-owned patents to the point of great commercial utility because it did not first obtain a license to do so. Obviously the patent policy currently being followed by the Department of Justice is completely at odds with the objectives of this committee. There can be no clearer indication of the manner in which the broad delegation of authority contained in section 8 would be administered, if this section should be enacted.

I fully concur in the recommendations of the American Bar Association, the American Patent Law Association, the National Association of Manufacturers, the National Small Business Association, and the many others who appeared before this committee and recommended against the enactment of so much of section 8 as authorizes the U.S. Government to initiate patent litigation against the citizens of this country.

The opportunity to present these views is greatly appreciated, and it is hoped that the information which has been furnished will focus attention upon an area which requires careful study by this committee.

SUPPLEMENT TO STATEMENT OF ROBERT F. CONRAD ON BEHALF OF TEKTRONIX, INC.,

SUGGESTED AMENDMENTS TO SECTIONS 8 AND 3 OF S. 1809

SEC. 8. (a) Whenever an agency head has taken title to any invention by declaration of acquiring which has become final or by authority of any other provision of this Act, *or otherwise has heretofore acquired ownership of an invention*, and he has reason to believe that such invention is patentable, he may make application to the Commissioner of Patents for the issuance of a patent therefor to such agency head on behalf of the United States. If the Commissioner determines that such invention is patentable, he shall issue to such agency head on behalf of the United States a patent therefor. [Each agency head shall take such action as may be required to protect and preserve the property rights of the United States in any patent so issued to him. Upon request made by any agency head, the Attorney General shall take such action as he shall determine to be required for that purpose.]

(b) Each agency head [may] *shall offer to* grant an exclusive *license subject to a reservation to the United States the same as that set forth in Section 3(b)(2)* or non-exclusive licenses for the practice of any invention for which he holds a patent *heretofore or hereafter* acquired [under this Act] on behalf of the United States. Any such *exclusive* license shall *convey the sole right to sue for infringement and shall* be granted *royalty free to a citizen of the United States* under such *additional* terms and conditions as the agency head shall determine to be in the public interest. Any such *non-exclusive license shall be irrevocable, for the life of the patent, and royalty free and shall* be granted [for the effective period of the patent or for a more limited period of time, and may be granted with or without the payment of royalty to the United States] *to any United States citizen who applies under such additional uniform terms and conditions as the agency head shall determine to be in the public interest.*

To make the remaining provisions of the bill consistent with the changes suggested above with respect to section 8, the following change should be made in section 3(b)(5):

Page 5, line 2, following "licenses" add "such as provided for in section 8(b)".

Page 5, lines 3 and 4, cancel "upon such reasonable terms and conditions as the agency may prescribe".

Senator MCCLELLAN. I believe there is one witness remaining on the list of those scheduled for this morning, Dean Nobles. Will you come around, please.

STATEMENT OF DEAN W. LEWIS NOBLES, GRADUATE SCHOOL, UNIVERSITY OF MISSISSIPPI

Senator MCCLELLAN. I note that you have quite a lengthy statement. Are you willing to have it printed in the record in full, and then just comment on it?

Mr. NOBLES. Yes, Mr. Chairman, I would like to request it, please.

Senator MCCLELLAN. Just glancing at your statement, I would think it will take 2 or 3 hours to read it.

Mr. NOBLES. Yes.

Senator MCCLELLAN. So let it be printed in the record, and you may highlight it now.

Mr. NOBLES. Yes.

Senator MCCLELLAN. Off the record.

(Discussion off the record.)

Senator MCCLELLAN. Back on the record.

(The prepared statement of Dean Nobles follows:)

STATEMENT OF DEAN W. LEWIS NOBLES

Mr. Chairman and distinguished members of the Subcommittee on Patents, Trademarks, and Copyrights, of the Senate Judiciary Committee, my name is Lewis Nobles and I appear before you today as an individual vitally interested

in the matters now pending before this subcommittee as they relate to discoveries and inventions which may be forthcoming from our scientific and technological community and the relationship of such discoveries and inventions as they pertain to the welfare of the people of the United States.

I am a professor of pharmacy and pharmaceutical chemistry at the University of Mississippi, where I also serve as dean of the graduate school. I hold membership in the American Chemical Society, the American Pharmaceutical Association, and the New York Academy of Sciences. I am a fellow of the American Association for the Advancement of Science. I am the author or coauthor of some 60 scientific papers in the field of pharmacy and pharmaceutical chemistry. I have no connection with any industrial organization interested in the pending legislation. For the information of the committee, I am enclosing as appendix I a curriculum vitae to give more detailed information relative to my education and experience. I have no connection with any industrial organization interested in the pending legislation.

As I understand it, you have four bills before your committee for consideration:

S. 1899, introduced by Senator Long;
S. 1809, introduced by Senator McClellan;
S. 789, introduced by Senator Saltonstall; and
S. 2326, introduced by Senator Dirksen.

Since I am not a lawyer by profession, I am not acquainted with the possible legal ramifications of many aspects of these individual bills; I do wish, however, to address myself to certain aspects of what I believe to be a desirable end result in patent legislation so as to insure its maximum usefulness to all those concerned with this problem.

I have been quite interested in this area as it relates to matters concerning health, since this is my particular area of greatest concern; I do not believe, however, that we should be deluded into compartmentalizing this problem. It is broad in scope and demands the kind of serious, earnest consideration that this subcommittee is giving the matter.

In the specific area of health-related research, there appear to me to be many rather specific types of circumstances which should be recognized insofar as academic institutions are concerned; I should like to address myself to four of them:

1. Those circumstances in which private industry or the institution provide total support for the project and all ancillary enterprises; I believe that the case here is rather clear and all would agree that the patent rights should be negotiated between industry and the university or reserved exclusively to the university in the latter case. (This type of instance would be rare, indeed, if not nonexistent, but the case needs to be recognized, anyway, in my opinion.)

2. The case in which the Government enters into a contract for a specific purpose—the creation of a new drug, poison antidote, medical device or instrumentation—and pays the total cost, including physical facilities, personnel, equipment, supplies and all such related items. This is a relatively new concept in American life. There is no question in my mind that programs largely supported by Government funds must be consistent with the public good and the political philosophy of our country. Health is a special area which affects every person in contrast to other segments of our economy. We cannot argue that the Government does not have a lien on discoveries made with Government funds. The question is how to motivate development of observations and discoveries made in these instances in light of the enormous effort and dollars needed to transform them into useful products. How can this be done and still be consistent with free enterprise system?

3. The cases in which there is joint support of the effort, either by the Government, industry and the university, or any other combinations thereof. I am using the term "support" here in the context of sponsorship of research, not as a distinctly mission-oriented operation to "produce a better mousetrap by use of procedures a through d."

4. Among the areas that require clarification is the disposition of rights stemming from nonfederally financed research involving cooperative programs between industry-sponsored grantees and industry sponsors where either the personnel or the academic institution have benefited from Federal funds for prior or concurrent federally financed projects or facilities. Those contacted in Government circles do not feel that it is even necessary to spell out the disposition of rights in these situations. Yet HEW persists in holding up decisions in this area, even where, for example, the only contact with Government funds has been

the use of a centrifuge or a beaker paid for by the Government in a prior federally financed project.

It is in these last two instances in which we find very little black and white but a great deal of gray area; and I believe that general agreement could be reached that it is in this area in which we find the greatest difficulty of resolution.

I believe that the crux of this problem was summed up very well in a draft of a letter to me last year by Senator McClellan in response to a letter I had written Senator Eastland in regard to this matter:

"The issue of Government patent policy has for a long time caused serious controversy, and perhaps the most difficult phase of this question is the one which you have raised concerning inventions which relate to public health or safety. As I am sure you appreciate, there is considerable sentiment that when an invention effecting public health is produced under a Government contract or grant, the patent rights covering such invention should reside in the Government or that the invention should be freely and fully available to the public. For my part, I fully understand the reluctance of industry to expend funds in the necessary further development of an invention if they are not to enjoy some type of exclusive rights."

The need to arrive at some basis for the equitable measurements of rights was not so great in health research until Federal support reached the extent that the great majority of qualified investigators in every field began to receive some of their support from one or more Federal agencies and virtually every nonprofit research center was similarly involved. Nonetheless, wisdom in the drafting and application of Federal agencies' patent policies has always been of great importance to the scientific community. But in the last decade the growth of Federal programs for conduct and support of research and development in industry and on the campus has been so staggering that the effects of Federal policy are felt today in virtually every laboratory in every community in this country.

If the equities cannot be reasonably defined and rights judiciously assigned, the facilities of the pharmaceutical industry—in certain areas—may well be cut off, at least almost entirely, from the academic investigator and from those in scientific operations within the Government itself. This can only result in harm to all three.

Just as an example, 10 years ago the total budget of the National Institutes of Health for its own research and for grants to medical scientists throughout the United State swas $183 million. This year the overall NIH budget for research and research training will exceed $1 billion.

Ten years ago, perhaps 1 out of 10 of the biochemists and other medical scientists in university research was receiving Federal funds for the support of his projects.

Today, the great majority of competent scientists who can obtain the support of their universities or medical schools in grant applications to the NIH or some other Federal agency are reasonably certain to receive some measure of support for their research proposals in a reasonable percentage of the cases.

With Federal money thus reaching into every laboratory where competent work is being conducted, the impact of Federal patent policy has been staggering.

As Federal programs continue to expand, it will be impossible for any business or nonprofit research organization to work in collaboration with an academic scientist without finding that many of these same scientists are collaborating in Federal Government programs.

The proliferation of Government research and development activity demands that Federal patent policies be developed to assign equitably rights of all of the interests engaged in scientific research whether they be Federal agencies, universities or medical schools, or private business enterprises.

The need for careful resolution of this problem was beginning to emerge a decade ago. It was not, however, as urgent at that time because nongovernment interests were usually able to cooperate with scientists who were not associated with Federal programs and so avoid involvement with Federal patent problems if that was a necessary factor in the advancement of the research underway.

Before and immediately after World War II many graduate students in the sciences studying for advanced degrees were supported by grants from chemical or pharmaceutical companies, from their universities, or from educational and professional societies or publicly supported health organizations like the American Heart Association or the American Cancer Society.

The grants from pharmaceutical and chemical companies were usually outright gifts to support the student with little or no supervision by the granting company of the research being conducted by the student.

Most often the academic scientist had no idea whether his new chemical had any physiological or therapeutic activity until it was subjected to a battery of screening tests by the granting chemical or pharmaceutical company.

Results of the screening were customarily reported back to the academician, who would then synthesize other, hopefully more active, compounds on the basis of the test data.

This collaboration between academic and industrial science advanced the competence of the individual student or professor and also contributed to the general advancement of knowledge, for the test data supplied by the company were also frequently published in the scientific literature that is studied by the entire pharmaceutical-chemical profession.

There usually was no formal contract between the pharmaceutical company and the university. It was understood, however, that the chemicals synthesized in the university laboratory would usually be screened by the granting company for possible therapeutic activity.

Only if the compound appeared to have possibilities as a drug in the treatment of some disease would a specific agreement be negotiated between the granting company and university administrators.

Quite often, chemicals prepared by academic scientists under grants from nonindustrial sources were also screened by pharmaceutical companies as a service to a university.

The tremendous expansion of grant funds available from the U.S. Public Health Service (NIH) has been accompanied, as is quite proper where public funds are being disbursed, by a tighter administration of Public Health Service grants and the development of procedures designed to insure that the Public Health Service's traditional public dedication policies are carried out.

As part of the regular procedure, recipients of Public Health Service (NIH) grants are required to submit reports on inventions they develop. They must agree, in essence, when they accept the grants, that the patent rights, if any, will be disposed of by the Surgeon General of the Public Health Service.

If a grantee synthesized an interesting chemical compound or a series of such compounds and wishes to have them screened by a pharmaceutical house, he is required to notify the Public Health Service before entering into any screening arrangement. The pharmaceutical house then is required to sign an agreement relinquishing any patent rights in the test area involved before it is permitted to undertake the screening work. A copy of such an agreement is inserted later in this statement.

A most serious result of this restrictive Federal patent policy, at a time when expansion of Federal research programs has put Federal money into a great many academic laboratories is that many new chemicals are not being tested at all or are not being fully evaluated because drug companies are not able to undertake the work under conditions required by the patent policies of the Public Health Service and its parent agency, the Department of Health, Education, and Welfare.

Why is this taking place?

A pharmaceutical house, which must make a return on any investment in order to survive in this country's competitive economic system, cannot afford to invest the great numbers of dollars required for comprehensive pharmaceutical screening and development without some assurance that it will have a chance of getting its money back and perhaps making some fair profit on its endeavor.

A related consideration is that even if a company were in a position to undertake a screening project for an academic scientist without regard to financial loss, it would be compounding its investment in this nonprofit kind of work because of the fact that it would have to divert its laboratory facilities and its scientific and administrative manpower from its own independent research, thereby losing an opportunity to make some useful invention on its own.

In addition, by incorporating research with some Government-owned compound in laboratories where work of its own is going on, the company takes the risk of having questions raised about possible Government rights to the projects it is conducting in the laboratory at its own expense.

I know that some have written (Science, Jan. 8, 1965, p. 134) that the asserted breakdown in industry-university relations seems remote since it is reported that the industry "appears to" (I have quoted these two words because they are key ones, in my opinion) have spent over $2 million more in R. & D. experiments at academic institutions, medical schools, and related institutions in 1964 than in 1963. These figures are probably true, but they overlook at least

two important aspects of this problem and thus "appear to" tell a side of the story that is not correct, in my opinion:

1. From 1959 to 1964 the number of new chemicals introduced into the prescription market declined from 63 to 17; this despite an increase in expenditures by the industry for research from about 200 million to 300 million. This simply tells me that costs in R. & D. have risen along with the costs of most other items.

2. Much of the research sponsored by industry in academic institutions does not involve a product or idea that is patentable; it involves basic research in human physiology, pharmacology, and biochemistry, to mention only a few. This has come about because of the realization of the tremendous importance of concepts developed here and the implications implicit in them for new drug design while not relating to any specific new drug.

The average academic chemist has extremely limited facilities for testing new chemical compounds prepared by himself or by his advanced students.

Some universities have test facilities in certain specific areas of interest.

Some Government institutions also have limited test facilities.

A few commercial laboratories have been organized to conduct tests of new chemicals with the standard animal screens.

But such facilities, even in combination, are not adequate to handle the testing of the large numbers of compounds now being synthesized in university laboratories. Even where test facilities are available in the nonindustrial sector, many of the more sophisticated screening methods are not in use. For instance, I am told that it is comparatively simple to run a chemical compound through a preliminary screen for antibacterial activity, but it is far more complicated to do screening for neurological and antiviral activity.

Another paradox arises here, in view of the fact that one of the Federal Government's most active and promising research and development programs today is its search, both in its own laboratories and in grant or contract-supported laboratories, for antiviral agents.

At this point, I should like to make specific reference to some of my own personal experiences along this line:

1. One area in which we are quite interested in our own laboratories has been that of the synthesis of possible antiviral agents. Prior to the procedure of NIH which substituted a patent agreement for clause 4(a) on the face of the sheet of the application for research grant, we had received agreement from one of the major pharmaceutical houses to test compounds synthesized under the terms of a grant from NIH for the synthesis of heterocyclic compounds as possible antiviral agents. Following the implementation of this policy (between November of 1961 and the spring of 1962) the pharmaceutical house was placed in the position of having to indicate that they could not sign the new patent agreement, since they were concerned over the scope of its text, which is as follows:

"DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

"Public Health Service

"National Institutes of Health

"Bethesda 14, Md.

"PATENT AGREEMENT

"(substitute for clause 4(a) on the face sheet of Application for Research Grant E-4701)

"Institution:
"Investigator(s):
"Title of Research Proposal:

"The following amended patent agreement is accepted by _____ _____ and becomes a part of the official application for Public Health Service support, identified as _____:

" 'if any invention arises or is developed in the course of the work aided by the grant, the undersigned will refer to the Surgeon General for determination as to whether patent protection shall be sought and how the rights in the invention, including rights under any patent issued thereon, shall be disposed of and administered in order to protect the public interest.'

"In connection with the compounds to be synthesized and/or developed under the subject grant, which are submitted to a pharmaceutical company for screening purposes, the grantee and the pharmaceutical company hereby agree to the following conditions:

"1. The pharmaceutical company shall not make disclosures of the results of testing for a period of 12 months, except with the consent of all parties concerned.

"2. The pharmaceutical company shall report the results of testing promptly to the investigator and will furnish to him, for use by the PHS in connection with any application for patent which the PHS may file, the information demonstrating any utility or new use of the compound.

"3. The pharmaceutical company shall be permitted to obtain patent rights to new uses of the compounds developed at its own expense, except where the grantee contributed or participated in the conception or reduction to practice of such new use, or where such new use patent would hamper, impede, or infringe on the intended use of the invention covered by the product application, or where such new use is within the field of research work supported by the grant.

"4. There shall be reserved to the Government under any new use patent obtained by the pharmaceutical company a nonexclusive, irrevocable, royalty-free license to the Government, with power to sublicense for all Governmental purposes."

"(Accepted) _____
(Pharmaceutical company)

"(Signed) _____
(Principal investigator or project director)

"(Title) _____

"(Date) _____

"(Accepted) _____
(Institution official responsible for patent matters)

"(Title) _____

"(Date) _____"

As you can readily observe from this agreement, any pharmaceutical company that would have agreed to it would have been donating its services without hope of compensation, based particularly on item No. 3 above.

In another area, we were preparing compounds for possible use in the general field of mental health; arrangements through NIH were possible for the screening of only four compounds prepared during the course of this work. In this connection, I received a document summarizing the results obtained in connection with the screening of these compounds; this is a document of some 55 pages on only three compounds. The result of this are summarized in a paper recently published in the Journal of Pharmaceutical Sciences; copies of this paper are attached as appendix II to this statement. There are several dozen other compounds in our laboratories now awaiting such testing, but, thus far, we have been unable to get them tested. As an indication of the difficulty in this area, the summary statement of one of the compounds submitted indicated that it demonstrated certain CNS depressant effects in mice, indicating that it might well be considered as a tranquilizing agent for further studies. Until the present policy situation is clarified, I should like to ask the committee: Where is this further study to be done? At a pharmaceutical company which can hope to gain nothing from such studies? This does not appear likely to me.

Perhaps typical of the type of problem noted by many in this field is that cited in appendix 4 of the Woolridge Report, "Biomedical Science and Its Administration." Much of this section is devoted to the Cancer Chemotherapy National Service Center. The reviewers did not judge the CCNSC unsatisfactory, but they blamed its patent policies in part for the lack of followup of possible anticancer drug effects.

"It should be noted that many compounds found to have no carcinotoxic activity but which possess other biological activity have not been studied further because of patent, contact, and other restrictions." Page 87.

As an alternative to these types of procedures, many academic scientists in the field of medicinal chemistry, are turning to their academic colleagues in pharmacology for such screening as can be had; but I would emphasize that no university to my knowledge is so organized as to be in a position to develop a new drug from the moment of the inception of the idea of the structure to the final dosage form. Furthermore, I personally do not believe that any university should be so equipped or so engaged. This is essentially not the function of university research.

I need not belabor this point; most compounds synthesized will have no practical value as medicinal agents. Nonetheless, you have already heard in these committee hearings or from other sources of the basic discoveries that have gone from the university laboratory to the patient by the collaboration of industry with the university; these include such items as insulin, discovered at the University of Toronto, "Theelin" discovered by Dr. Doisy's group at St. Louis University, cyclopropane discovered by a group of scientists at Purdue, "Benadryl" synthesized by Dr. George Rieveschl while at the University of Cincinnati, and chloramphenicol ("Chloromycetin") discovered by Dr. Burkholder at Yale University. For every success, there have been thousands of examples of lack of success; yet for every single drug so conceived and ultimately marketed, there has been remarkable relief for thousands, yea, millions of sick people. I believe that the policy developed in the Congress as a result of these hearings and other studies should leave the door open for such future contributions.

As an indication of the type of difficulty that the academic scientist encounters in the evaluation of his compounds currently, I am submitting as appendix III a copy of a letter in reference to the matter of the antiviral agents previously mentioned above; please note the sentence in the second paragraph which indicates that this group, the U.S. Army Chemical Research and Development Laboratories at the Army Chemical Center, Md., "can only assay compounds of proven antiviral activity." This is one of many letters that I wrote at the suggestion of an official at NIH in an effort to derive suitable means of testing our compounds. Needless to say, I cannot disagree with the Director of Research of this group, for he has a mission-oriented program. Nonetheless, this offers the individual academic scientist little hope of success in obtaining biological screening for his yet unproved compounds.

Even if the academic scientist manages somehow to overcome all of the difficulties in getting a compound screened, and it is found that his compound has significant activity, this is only the beginning.

After the first promising indications of biological activity have been uncovered, many additional studies must be carried out before the compound can ever reach the hands of the medical profession for the treatment or prevention of disease.

Among such studies, which are customarily carried out by the pharmaceutical industry, are further testing in several different animal species, metabolic studies, various subacute toxicity and chronic toxicity studies, development of commercial methods of synthesis, formulation into pharmaceutical dosage forms and finally, most important of all, the completion of broad clinical studies sufficient to prove the efficacy and safety of the potential new drug in human patients to the satisfaction of the FDA.

Such development programs can take years to complete and the costs can run from $500,000 to $3 or $4 million or more.

I assume there has been or will be detailed testimony from pharmaceutical executives on the difficulties and the costs of drug development, and I will leave such testimony to the industry witnesses.

I would not want the Subcommittee on Patents, Copyrights, and Trademarks to overlook the fact that the country's universities and medical schools can play a very useful role in administration of these complex patent issues if Congress sees fit to permit this.

Increasingly large numbers of universities are financed primarily with public funds, either State or Federal. Today, the patient policies of many universities reflect a strong public interest philosophy which is asserted in negotiations with pharmaceutical houses for commercial rights to therapeutic agents discovered in collaborative university-industry research. For the universities to enter into such agreements it is necessary, of course, for them to have title to the inventions either because no Federal interest was involved or because the Federal interest was waived by the granting agency's head.

In both kinds of cases, licenses agreed to by universities usually provide for a reasonable period of market exclusively (1) to compensate the cooperating company for its development costs, (2) to acknowledge the company's participation as a partner in the original research, and (3) to insure prompt development of the compound into a useful therapeutic agent.

In turn, under these agreements, the company pays royalties to the university and a major portion of them are plowed back by the university into its various research and educational programs.

At times, university policy provides that the individual inventor or inventors may share appropriately in the royalties paid by the pharmaceutical company.

The traditional collaborative research programs of university and pharmaceutical scientists have worked well in the past, before the Federal involvement became so great as to create a bar to such collaboration. I believe the principles that have guided this collaboration in the past should be applied by Congress to the patent policy now being worked out for Federal agencies.

Specifically, I believe that patent rights, certainly most of them, arising from Public Health Service (NIH) grants to university personnel should be released by the Public Health Service, with reasonable safeguards, to the universities.

If desirable, a period of market exclusivity would be negotiated by the university with a commercial company. Royalties would be paid to the university.

In every instance, of course, the Federal Government would obtain a nonexclusive, royalty-free license for its use.

Under a procedure of this kind, the public would be served by expeditious marketing of new drugs, by having private funds funneled into university programs, and by having Government retain a nonexclusive license for its own use.

I hope that any patent bill which emerges from these important hearings contains provisions authorizing such a procedure, particularly in the health field which is so crucial to all of us.

SPECIFIC COMMENTS ON THE PENDING LEGISLATION IN THIS AREA

Section 3(b)(3) of S. 1809 (Senator McClellan's bill) reserves to the contractor not less than "an irrevocable, nonexclusive, royalty-free license for the practice throughout the world of each such invention." If the contractor is an academic institution, such a nontransferrable license is meaningless, since no university or medical school is in a position to practice an invention in the sense intended by this provision.

Obviously, the license accorded to a university must be transferrable to accomplish the intent of the provision.

Another serious objection to S. 1809 is section 4(a)(2), which prohibits any contractor, including a university or medical school, from acquiring any rights to a discovery in the health field and reserves such rights to the Government except in "exceptional circumstances."

The field of health should not be singled out for tighter control by the Federal Government. The patent system and the incentives created by it should be brought to bear more in the field of health than in any other, not less.

At the very least, this clause should be modified to enable universities with public-interest patent policies to retain rights to inventions derived from Government supported research for exploitation under reasonable terms.

General grants for the provision of original facilities and the expansion of existing facilities for university education and research programs are designed to strengthen these institutions and enable them to play an effective role in the national economy and the national security.

In this connection, I should like to quote from title VII of the health research facilities bill as originally passed by the Congress—section 701(a) and (b):

"SEC. 701. (a) The Congress hereby finds and declares that (1) the Nation's economy, welfare, and security are adversely affected by many crippling and killing diseases, the prevention and control of which require a substantial increase, in all areas of the Nation, of research activities in the sciences related to health, to house such activities are inadequate.

"(b) It is therefore the purpose of this title to assist in the construction of facilities for the conduct of research in the sciences related to health by providing grants-in-aid on a matching basis to public and nonprofit institutions for such purpose."

The provision of adequate university research facilities in today's world is a very costly undertaking and one that has been achieved in substantial measure by the use of private funds, supplemented to whatevery extent is found necessary with Federal funds. The donors of funds for such general grants, either private or government, do not intend that rights stemming from research conducted in such institutions become the property of the donors. The purpose behind the expenditure of such funds is accomplished when the institution becomes effective

in its role of education and research. The fruits of such research, in the form of royalties from patent rights, serve to reduce the financial burden on the institution and thereby to reduce the sum necessary for maintenance and expansion of the facilities for further research efforts. These institutions thereby become more nearly self-sustaining.

Equipment and facilities for conducting research are capable of reuse many times. They are not in the category of "disposables." For example, an instrument (such as a Parr hydrogenator) used for a specific federally financed research project is not to be discarded when the project is completed. Nor is it practicable to return it to the source from whence it came. Present practice is for the title to such equipment to be invested in the grantee either during the course of the investigation, at the end of the investigation, or by negotiation at the end of the project. It would be rather incongruous for the Government to attempt to confiscate patient rights arising out of nonfederally financed research merely because such equipment may subsequently be used on a nonfederally financed project.

Even the foremost advocates of a "government take all" policy would probably agree that it is the specific federally financed research project and not the financing of facilities for general or specific separately indentifiable federally financed research projects that is the area of concern about title to inventions.

When the foregoing arguments are made to those in various Government circles, the conclusion seems so clear that several have indicated that it should be unnecessary to express this concept in legislation. Yet HEW policy, as outlined earlier in a copy of the patent agreement document, frequently delays action on such situations.

There has been substantial confusion concerning exclusive rights in cases where nonfederally supported research carried on cooperatively between industry-sponsored university grantees and industry sponsors involve some contact with federally supported grants or where federally financed equipment or facilities have been used in conducting nonfederally financed research. The following are illustrative examples of typical situations:

1. Where the field of nonfederally financed research and development is not related to a prior or concurrent federally sponsored research and development program, in the same institution by the same or different grantees.

This covers those situations where the nonfederally supported program is totally different from the federally supported program but the same grantee or contractor is involved. For example, a grantee may have a grant from the NIH to conduct research in the area of one disease, and subsequently or concurrently he receives a nonfederally supported grant to conduct research in the area of a related disease. While there appears to be a clear-cut division of the equities, the experience of non-Federal grantors has been that NIH personnel are reluctant to agree that the rights should remain with the grantee or contractor in either instance.

2. Where the fields of research and development are related but the research and development programs are different.

The grantee has a federally and nonfederally supported grant in the same general area, for example, research concerning a particular virus. The nonfederally supported grant is for a specifically defined program which does not overlap with the scope of the research program included in the grantee's application for a federally supported grant. The grants may be concurrent or consecutive. Situations of this type have formed a major area of uncertainty.

3. The program is conducted in or with facilities or equipment originally purchased, built, or acquired with Federal funds for general use or for use in connection with a prior or concurring Government-sponsored research project.

(*a*) Under a prior Federal grant the nonfederally supported grantee's institution built the laboratory in which the nonfederally supported grantee is working.

(*b*) Under a prior federally supported grant, the grantee or his institution purchased or acquired laboratory equipment which has remained in the laboratory of or is accessible to the nonfederally supported grantee. This equipment is then used by the grantee on a nonfederally supported grant.

These aspects are brought out rather clearly in the proposed amendment to H.R. 2984, section 3(b)(1), which stated:

"(b)(1). No part of any appropriated funds may be expended pursuant to authorization given by this act for any scientific or technological research or developmental activity unless such expenditure is conditioned upon provisions effective to insure that all developments resulting from that activity will be made freely available to the general public. The Secretary of Health, Education, and Welfare shall include in each grant or contract made or entered into under such authorization for any such activity provisions under which the United States will acquire exclusive right in and to any such development. Nothing contained in this paragraph shall be construed to deprive the owner of any background patent relating to any such activity, without his consent, of any right which that owner may have under that patent."

It is believed that the resolution of the foregoing situations should be mandatory and not discretionary, assuming of course that the Government agency can satisfy itself that the circumstances are as represented.

In this connection, I should like to offer for your consideration a specific suggestion as an addition to pending legislation so as to clarify this area.

I believe that the exclusive rights in and to developments stemming from nonfederally supported research and development should remain with the grantee or the sponsor where the field of research and development is not related to a prior or concurrent Government-sponsored research and development program or where the fields of research and development are related but the research and development programs are different. The exclusive rights in and to a nonfederally supported research and development program should not be lost by the grantee or the sponsor because the program is conducted in or with facilities or equipment originally purchased, built, or acquired with Federal funds for general use or for use in connection with a prior or concurring Government-sponsored research project.

At this point, I should like to offer one other suggestion for consideration. Perhaps the members of this committee will recognize this clearly as an indication of my own naivete in regard to this pending legislation.

It appears that one of the great concerns is that of the giveaway of inventions based on Government grants to assist in the financing of research. Personally, I believe, as indicated elsewhere in this statement, that the major purpose in such research expenditures is accomplished when the institution or institute becomes effective in its role of education and/or research. I recognize that this is not so clearly the case when the grant is made by a highly mission-oriented agency of the Government. Nonetheless, in the normal course of events, when industry sponsors research in the area of medicinal chemistry in a university, clear recognition is given to the contribution of both sides. The university gets title to the invention, but an assignment is generally made in order to develop the invention most effectively. Now, despite the fact that industry may have already made a substantial contribution in the way of a grant in the development of the research, the final contract usually contains a proviso in which the institution shares in the profits made and the individual investigator also receives a share for his contribution to this in the form of the idea and the creative ingenuity that allowed for the development of the idea.

In the jointly sponsored industry Government projects or those sponsored by industry in a facility constructed with Federal funds, I believe that a part of the difficulty could be resolved by a policy that would require industry, if it wishes to acquire exclusivity, to repay the amount of the Government grant plus a negotiated percentage. Certainly, under these conditions, the people of our country could, in essence, have their cake and eat it. The funds expended by the Government would be recouped together with a reasonable percentage. This would, of course, have to be negotiated in each instance, due to the different circumstances involved in virtually each case, and then the patents could, where appropriate, be assigned to the university, a public institution devoted to the welfare of the whole, and these could then be reassigned, for an appropriate period, to the cosponsoring industry with a period of exclusivity which would encourage the risk-taking or venture capital necessary for development of the idea. The Government would be repaid monetarily by having its contribution, in dollars, rebated and by seeing more rapid developments take place insofar as the production and marketability of items designed to improve the health and welfare of the American people. Thus, a joint venture of the Government, industry, university,

and the private citizen, the investigator, would be encouraged, and all Americans would benefit. Such a proposal, as indicated at the outset, probably reveals a very naive approach to a quite complex problem, but I do believe sincerely that it could be made to work when men of good will set themselves to this task.

I can understand that this subcommittee, indeed all Federal officials with responsibility in this field, have concluded that health is different and that special steps should be taken to encourage programs where the lives and well-being of our citizens are concerned. I understand that it was because of the realization that health is different that the patent policy memorandum adopted by our late President Kennedy in 1963 established separate and special treatment for inventions in the field of health.

But it seems to me that this special treatment adopted in the Kennedy memo and carried forward in the McClellan bill, S. 1809, will have a result directly opposite from that intended by our late President and by the chairman of this subcommittee.

During the 175 years in which our country has had a patent law, it has become clear that patents do create progress, as our Founding Fathers were confident they would when they wrote section 8 of article 1 of our Constitution.

And if it is true that patents in general create progress in general, it is no less true that patents in the health field create progress in the health field. It would, therefore, seem far more sensible to expand the patent incentive in this field of health, with its special implications for the lives and happiness of all of us, than to remove or diminish the patent incentive that stimulates the discovery of new drugs.

Section 8(b) provides that a Federal agency head may grant an exclusive or nonexclusive license for the practice of any invention for which he holds a patent acquired under S. 1809.

This section should be modified to require each agency head to issue licenses with reasonable periods of exclusivity (1) when the contribution of funds, personnel, and facilities of either or both the university and/or cooperating industrial organization has been greater than the contribution of the Government to the making of the invention, or (2) when additional expenditures of non-Government funds will be necessary to develop the invention to the point of practical application and the granting of such reasonable exclusivity to the university and/or cooperating industrial organization is likely to assure or accelerate development of the invention and availability for public use.

To the extent that any contractor might attempt to abuse the rights retained and period of exclusivity, a compulsory licensing system, as is indicated in most of these pieces of legislation, as proposed could certainly be effectively utilized.

In regard to the above, the period of exclusivity is important. Once again, I cite a personal case, that of the synthesis of amopyroquine, a drug possessing antimalarial activity. This was synthesized by me as a graduate student at the University of Kansas in 1952. While I recognize that this is an exceptional case and also that the field of antimalarials was not a particularly "hot" one during the mid-1950's, it took a period of almost 10 years from synthesis to marketability. While this may be the exception rather than the rule, I simply cite it for the committee as some sort of guideline with regard to the establishment of the desirable period of exclusivity. With a very limited period of exclusivity, such a compound would never have reached the stage, in all likelihood, that permitted this compound to be tested by Dr. M. T. Hoekenga as was reported by him in the American Journal of Tropical Medicine and Hygiene in 1957. Admittedly, this may be a "marginal" drug, but, in some instances, it was able to accomplish results not achieved with other, according to Dr. Hoekenga's reports.

One of my major concerns in the enactment of such legislation is that we will not have such situations as existed for a great many years in which papaverine was treated as a narcotic by Federal law simply because it was derived from opium—yet it did not possess addicting tendencies. Similarly, the undesirable situation in which a prescription was required for Elixir of Benadryl (12.5 mgm. per teaspoonful dose) when one could purchase, over the counter, under sanction of Federal law the same drug, insofar as active constituent was concerned, in a tablet form containing 50 mgm. per does. I recognize that such discrepancies do exist under any "umbrella" type legislation; that is why I believe that

flexibility must be built into the framework of patent legislation if it is to be successful and accomplish its purpose.

In support of this concept of flexibility, I should like to enter the following excerpts from the testimony of Congressman Daddario before the House Committee on Public Works re water pollution control on February 15, 1965:

"Prior to the Atomic Energy Act of 1946 no Federal departmnt or agency was required by its organic act to handle rights to inventions growing out of its activities in any special way. This was left up to the agency, which could bargain for any patent right is wanted. As a matter of practice it was found most expedient to secure for the Government a royalty-free, irrevocable license to use, make or employ such inventions—either through the inventor-contractor or any other party chosen by the Government. Today every entity of Government always secures this right. Usually this is all the Governmnt wants, needs, or can use. In such cases title to the invention itself is left to the contractor—and he can patent it, if it is patentable, subject always to the Government's right to use it without charge.

"I am sure it is evident that the administration's balanced effort here is undercut badly by legislative provisions such as the patent amendment in this bill. The fact is that this provision is extremely rigid in its effect and is quite unfair in that it looks only on one side of the coin. Moreover, this amendment does not really prevent "giveaways," as is alleged, but to some extent promotes them—especially in the foreign market and at a time when we are seriously concerned about our balance of payments.

"If there is one thing that we have learned in our study of the matter, and with which the administration concurs and insists upon, it is the need for flexibility in our patent approach. We must have this, not only in order to be equitable in our relations with industry, agriculture, and labor, but in order to acquire sufficient experience on which to base general patent legislation if that becomes deisrable. We cannot be equitable and we cannot gain the necessary experience without administrative flexibility. The Senate amendment (re: S. 512) denies us this resource. It places all property rights in inventions connected with the pollution program in the public domain regardless of the fact that such inventions are freely available to the Government for public use anyhow. Its stipulation that no contractor be deprived of his "background patents" is virtually meaningless since there is no fixed definition of "background patents" and, in any case, the Government must often allow contractors foreground rights in exchange for "background" privileges in order to make the invention worthwhile.

"What else happens when flexibility is denied?

"For one thing, the Government may have to deal with reluctant contractors who tend to compartmentalize their Government research and isolate it from their most promising commercial ideas. We know, for example, that in many instances private contractors will separate their research teams working on Government projects from their other researchers working strictly on commercial ones. This happens mainly because the contractors feel the need for legal protection of their most profitable investments.

"For another, we fail to take into account that different Federal agencies have different missions and must handle their contractors in different ways. We need a single standard for guidelines, certainly, but a standard that permits enough flexibility to get the mission done. This is the most important matter.

I believe that the need for flexibility in the matter of public health is certainly equally great.

Emotionalism concerning the sick and the cost of drugs should not be allowed to distort the fact that the net effect of governmental legislation leading to the governmental ownership of the patent, whether partially or completely supported by Federal funds, defeats the basic purpose of research in the field of medicinal chemistry. Such procedures constitute a serious deterrent to essential collaboration between the Government, industry, and the universities and thus to the health of the Nation in the long run.

In addition, one might examine the basic philosophy to ascertain if such restrictions do not, in fact, violate simple legal and moral concepts. Does not the researcher hold the fundamental right to his invention? Is not something of human dignity lost when the Government confiscates—call it anything you

will, but it appears to me to be confiscation—an individual's knowledge in exchange for partial financial support?

It appears to me that all too much attention has been directed to the rights of the Government to the neglect of the right of the inventor, of his institution, and of others who may be concerned in the overall process. Can unilateral action on this front by the Congress, without due consideration of all these factors, be truly in the best interest of the Nation? The Congress fostered the foundation of the Federal agencies and supports them annually with appropriations derived from tax dollars. Thus, the Congress is charged with the responsibility of protecting the interest of the Government, true. But who, I ask, if not the Congress also, is to protect the interest of the individual, the academic institution, and the sector of industry vitally interested in these matters?

In conclusion, I should like to express my deep appreciation to the members of this committee for allowing me this opportunity of presenting my views on this most important segment of governmental activity.

Appendix I

Curriculum Vitae of William Lewis Nobles

William Lewis Nobles, dean of the graduate school and professor of pharmacy and pharmaceutical chemistry, the University of Mississippi, University, Miss.

Date and place of birth: Meridian, Miss., on September 11, 1925.

Married: Two daughters, Sandra, age 13, and Suzanne, age 7.

Education: Meridian Junior College, 1942–45; University of Mississippi, 1943–44; Ursinus College, Collegeville, Pa., 1944–45; University of Mississippi, B.S. in pharmacy, 1948; M.S., 1949; University of Kansas, Ph. D., 1952; University of Michigan, 1958–59, under a National Science Foundation postdoctoral award.

Professional experience: Teaching assistant, University of Mississippi, 1948–49; assistant professor, University of Mississippi, 1952–54; associate professor, University of Mississippi, 1954–55; professor, University of Mississippi, 1955–present; dean of the graduate school, September 1960–present; coordinator of university research, April 1964–present.

Honors: Sigma Xi; American Foundation for Pharmaceutical Education fellow while at the University of Kansas; Gustavus A. Pfeiffer Memorial Research fellow, 1955–58; 1959–60; National Science Foundation Postdoctoral fellow, University of Michigan, 1958–59.

Memberships held: Sigma Xi, Rho Chi, American Pharmaceutical Association, American Chemical Society, Chemical Society (Great Britain), American Association for the Advancement of Science, and the New York Academy of Science.

Publications: Total, 65. The last five are:

W. Lewis Nobles and B. Blackburn Thompson, "Mannich Bases and Alcohols From Hexamethylenimine" (J. Pharm. Sci., 53, 1154).

Heino A. Luts and W. Lewis Nobles, "Heptamethyleneimine in the Mannich Reaction I. Substituted β-Amino Ketones and Substituted γ-Amino Alcohols" (J. Pharm. Sci., 54, 67 (1965)).

W. Lewis Nobles, B. Blackburn Thompson, "Application of Mannich Reaction to Sulfones I. Reactive Methylene Moiety of Sulfones" (J. Pharm Sci., 54, 576, (1965)).

C. DeWitt Blanton, Jr., and W. Lewis Nobles, "Use of 3-Azabicyclo[3.2.2.]nonane in the Mannich Reaction IV. Additional Derived Products" (J. Pharm. Sci., 53, 1130 (1964)).

Charlotte H. Bruening and W. Lewis Nobles, "Synthetic Relatives of Reserpine" (J. Pharm Sci., 54, 925 (1965)).

APPENDIX II

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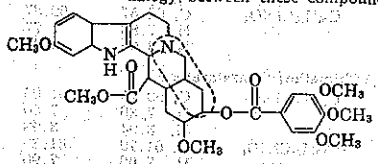
Synthetic Relatives of Reserpine

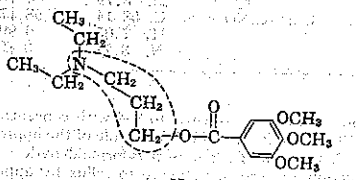
By CHARLOTTE H. BRUENING and W. LEWIS NOBLES

A group of Mannich bases, containing the 3,4,5-trimethoxyphenyl moiety as in reserpine, has been synthesized. Preliminary pharmacological screening suggests that one of the group, the morpholine Mannich base from 3,4,5-trimethoxybenzalacetone, demonstrated certain CNS depressant effects in mice, indicating that it might be considered as a tranquilizing agent for further studies.

MILLER AND WEINBERG (1) reported that 3-(*N,N* - diethylamino)propyl - 3,4,5 - trimethoxybenzoate (II) possessed approximately one-third of the tranquilizing action of reserpine (I). The structural analogy between these compounds



I



II

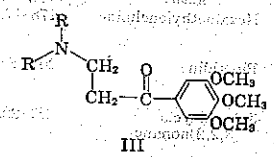
would indicate that some tranquilizing activity resides in a relatively small portion of the reserpine molecule. Since this report there have been several hundred publications dealing with the biological activity of compounds containing the trimethoxybenzoyl moiety of the parent molecule. Many of the aspects of this work have been reviewed by Schlager (2).

Recorded in the literature (3–11) are numerous ketonic Mannich bases, prepared for pharmacological testing as antispasmodics, analgesics, chemotherapeutic agents, and local anesthetics. Such compounds may in general be prepared readily by means of the Mannich reaction which utilizes the appropriate ketone, formaldehyde, or paraformaldehyde and the desired amine. This may be illustrated as follows:

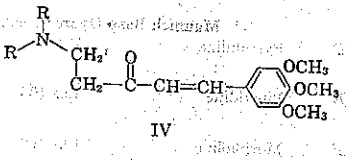
$$RCOCH_3 + HCHO + R'_2NH \cdot HCl \rightarrow RCOCH_2CH_2NR'_2 \cdot HCl + H_2O$$

The rather extensive literature dealing with this reaction has been reviewed by Blicke (12), Reichert (13), and Hellmann and Opitz (14).

In an effort to prepare synthetic relatives of reserpine utilizing the Mannich reaction, Mannich bases were prepared from 3,4,5-trimethoxyacetophenone and 3,4,5-trimethoxybenzalacetone. The structural analogy, albeit limited, can be easily seen from an inspection of the following structures (III and IV) and a comparison of them with the parent structure (I) above.



III



IV

Received February 18, 1965, from the Department of Pharmaceutical Chemistry, School of Pharmacy, University of Mississippi, University.
Accepted for publication March 16, 1965.
This investigation was supported in part by research grant MY-03232 from the U. S. Public Health Service, Bethesda, Md.

PHARMACOLOGICAL RESULTS

The three Mannich bases (*A–C*) obtained from trimethoxyacetophenone were subjected to a study of preliminary dose effects, pernicious preening, and maximal electric shock seizure utilizing Swiss-Webster mice.

With compound *A*, the oral administration of 250–2000 mg./Kg. produced asphyxial-like convulsions, cyanosis, and death within 4–10 min. The administration of 500–2000 mg./Kg. of compound *B* elicited ataxia, muscle weakness, asphyxial convulsions, cyanosis, and death. Dosages in the range of 250–2000 mg./Kg. of compound *C* elicited tonic-clonic seizures, motor deficits, followed by increased activity, tremors, cyanosis, asphyxial seizures, and death. Lower doses (100 mg./Kg.) produced CNS stimulant effects. Hypothermia followed doses of 500 mg./Kg. or greater of compound *C*. Compound *C* demonstrated enough activity to warrant further testing for analeptic activity.

Oral or intraperitoneal administration of 500 and 2000 mg./Kg., respectively, elicited no significant overt effects. Oral administration of 2000 mg./Kg. of compound *E* produced slight reduction in motor activity, lachrymation, muscle weakness, tremors, marked hypothermia, champing, and asphyxial seizures, terminating in death. Lower doses to 500 mg./Kg. were marked by slight lachrymation and motor disturbances.

Because of the particularly interesting activity demonstrated by 3,4,5-trimethoxybenzoyl morpholide in the work of Vargha (15), the Mannich base prepared from morpholine and the trimethoxybenzalacetone was subjected to intensive screening by Hazleton Laboratories, Inc.[1] For this compound, the estimated LD_{50} was found to be 112 mg./Kg. Analysis of the rat pharmacodynamic record showed that this compound elicited a transient

[1] The preliminary biological data on compound *F* were provided by the Hazleton Laboratories, Inc., under the supervision of the Scientific Staff, Psychopharmacology Service Center, and was supported under contract PH 43-63-555 from the National Institute of Mental Health, U. S. Public Health Service, Bethesda, Md.

TABLE I.

Compd.	Amine	M.p., °C.	Yield, %	Formula	Anal.	Found
Mannich Base Hydrochlorides of 3,4,5-Trimethoxyacetophenone						
A	Hexamethyleneimine	178–179	45	$C_{18}H_{28}ClNO_4$	C, 60.41	60.57
					H, 7.89	7.77
					N, 3.91	4.28
B	Piperidine	201–202	69	$C_{17}H_{26}ClNO_4$	C, 59.38	59.46
					H, 7.62	7.47
					N, 4.07	4.32
C	3-Azabicyclo (3,2,2)nonane	221–222	72	$C_{20}H_{30}ClNO_4$	C, 62.57	62.87
					H, 7.88	7.77
					N, 3.65	3.90
Mannich Base Hydrochlorides of 3,4,5-Trimethoxybenzalacetone						
D	Pyrrolidine	181–182	41	$C_{18}H_{26}ClNO_4$	C, 60.75	61.05
					H, 7.36	7.50
					N, 3.94	3.98
E	Piperidine	192–193	42	$C_{19}H_{28}ClNO_4$	C, 61.70	61.39
					H, 7.63	7.90
					N, 3.79	3.78
F	Morpholine	195–196	60	$C_{18}H_{26}ClNO_5$	C, 58.14	58.17
					H, 7.05	6.99
					N, 3.77	3.80

hypotensive effect at all dosage levels tested. Hexobarbital sleeping time was prolonged significantly at dosages of 11.2 and 33.6 mg./Kg. Analysis of the hotplate analgesia test data revealed that this compound possessed no analgesic properties, and the electroshock studies likewise indicated a lack of anticonvulsant properties. Analysis of the actophotometer data showed that this compound decreased spontaneous motor activity at all dosages tested (3.36–33.6 mg./Kg.). This compound interfered with conditioned avoidance responses in a dose related manner. No pathological changes were observed upon gross necropsy. A summary conclusion provided by Hazleton Laboratories indicated that this agent showed certain CNS depressant effects in mice, indicating that it could be considered as a tranquilizing agent for further studies. The compound, like many CNS depressants, elicited a hypotensive effect in the rat.

EXPERIMENTAL

Basic data indicating the structure, yield, melting point, and other such items for the six compounds presented in this study are indicated in Table I. 3,4,5-Trimethoxybenzalacetone was prepared according to the method of Burckhalter and Johnson (16) for 2,3-dimethoxybenzalacetone in a yield of 55%. The Mannich bases were prepared as follows.

In a 50-ml. flask containing 25 ml. of absolute ethanol was added 0.05 mole of the respective amine, and the pH was adjusted to 3–4 with concentrated HCl. To this was added 0.05 mole of the appropriate ketone and 2.3 Gm. of paraformaldehyde. The reaction mixture was allowed to reflux for approximately 3 hr. and was then poured into 100 ml. of dry acetone. After cooling in the refrigerator overnight, the precipitate was collected and recrystallized from an ethanol–acetone mixture.

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APPENDIX III

U.S. ARMY CHEMICAL RESEARCH AND DEVELOPMENT LABORATORIES,
Army Chemical Center, Md., July 10, 1962.

DR. LEWIS NOBLES,
Office of the Dean, The University of Mississippi, The Graduate School, University, Miss.

DEAR DR. NOBLES: I wish to acknowledge the receipt of your recent letter and to apologize for not being able to answer your request more quickly. Unfortunately, the chief of the screening group concerned with the assay of antiviral activity was not available. I could not commit his group without his permission.

It is true that determinations of antiviral activity are carried on as indicated in Dr. Silver's letter to Dr. Jeffery. However, the group has become quite selective in their choice of compounds. They are, unfortunately, not in a position to test compounds of unknown activity or even those suspected of being active on the basis of the analogy. The group can only assay compounds of proven antiviral activity. These are tested against those types of virus which are of interest to our biological laboratories.

It may be that Dr. Schabel of the Southern Research Institute would be able to assist you by recommending an antiviral screening program to which your compounds could be submitted.

Most of the screening programs in the Chemical Corps are quite as selective as that described above with the exception of two. These are broad screens for the purpose of seeking out new types of structures having an extremely high biological activity or ones having pronounced herbicidal (growth regulators, phytocides, defoliants, etc.) effects. I am inclosing copies of these procedures for your retention. We would be happy to have the opportunity to screen any of your heterocyclic structures in these screens. If both screens are to be run, we would require about 8 grams of material. I am also taking the liberty of inclosing a résumé of the policies of the corps' industrial liaison program.

I am sorry that we are unable to comply with your request. Perhaps, we can be of service to you in the screening of your compounds for other purposes.

Sincerely yours,

E. A. METCALF, Ph. D.,
Chief, Industrial Liaison Office,
Directorate of Research.

Senator MCCLELLAN. You may proceed to highlight your statement, sir.

Mr. NOBLES. Well, I will just pick up abstracts, actually, from the statement.

The need to arrive at some basis for the equitable measurement of rights was not so great in health research until Federal support reached the extent that the great majority of qualified investigators in every field began to receive some of their support from one or more Federal agencies and virtually every nonprofit research center was similarly involved.

Nonetheless, wisdom in the drafting and application of Federal agencies' patent policies has always been of great importance to the scientific community. But in the last decade the growth of Federal programs for conduct and support of research and development in industry and on the campus has been so staggering that the effects of Federal policy are felt today in virtually every laboratory in every community in this country.

If the equities cannot be reasonably defined and rights judiciously assigned, that facilities of the pharmaceutical industry in certain areas may well be cut off, at least almost entirely, from the academic investigator and from those in scientific operations within the Government itself. This can only result in harm to all three.

Moving quickly to page 5, I would point to an area that the chairman raised a question about with Dr. Seevers this morning.

If a grantee synthesized an interesting chemical compound or a series of such compounds and wishes to have them screened by a pharmaceutical house, he is required to notify the Public Health Service before entering into any screening arrangement. The pharmaceutical house then is required to sign an agreement relinquishing any patent rights in the test area involved before it is permitted to undertake the screening work. A copy of such an agreement is inserted later in this statement.

A most serious result of this restrictive Federal patent policy, at a time when expansion of Federal research programs has put Federal money into a great many academic laboratories, is that many new chemicals are not being tested at all or are not being fully evaluated because drug companies are not able to undertake the work under conditions required by the patent policies of the public health service and its parent agency, the Department of Health, Education, and Welfare.

Now we want to mention specifically in this regard in just a moment. On page 7 we have abstracted a copy of the patent agreement which the Department of Health, Education, and Welfare has, which it asks that the grantee as well as the pharmaceutical company sign.

We make reference to the point that one area in which we are quite interested in our own laboratories has been that of the synthesis of possible antiviral agents. Prior to the procedure of NIH which substituted a patent agreement for clause 4(a) on the face of the sheet of the application for research grant, we had received agreement from one of the major pharmaceutical houses to test compounds synthesized under the terms of a grant from NIH for the synthesis of heterocyclic compounds as possible antiviral agents.

Following the implementation of this policy, somewhere between November of 1961 and the spring of 1962, the pharmaceutical house was placed in the position of having to indicate that they could not sign the new patent agreement, since they were concerned over the scope of its text, including the following:

"The pharmaceutical company shall be permitted to obtain patent rights to new uses of the compounds developed as its own expense, except where the grantee contributed or participated in the conception or reduction to practice of such new use, or where such new use patents would hamper, impede, or infringe on the intended use of the invention covered by the product application, or where such new use is within the field of research works supported by the grant."

I think that anyone can readily observe from this agreement that any pharmaceutical company that would agree to do this would in a sense be agreeing to donate their services without hope of compensation.

As a part of the basic proposition, the pharmaceutical chemist or medical chemist in the university is concerned with these syntheses of compounds. These are then evaluated by an agency, as described by Dr. Seevers earlier this morning. Without having this information at hand, very little progress can be made.

With the knowledge provided by the pharmacologist and others associated in the screening and evaluation of the compounds, then further work can proceed to perhaps useful devices.

But in the area in which we are working and another area, for example, that of compounds in the general area of mental health, ar-

rangements were made by the National Institutes of Health for the testing of four compounds prepared during the course of this work. In other words, NIH originally let us send two compounds in, and then two additional compounds.

As an indication of the amount of work involved in screening 3 of these 4 compounds and reporting on it, there is a document of some 55 or 60 pages. So this is the amount of work and the cost that is involved in this type of venture. As has been previously indicated, it is obviously a high-risk venture.

As an indication of the type of difficulty that the academic scientist encounters in the evaluation of his compounds currently, I am submitting as appendix III a copy of a letter in reference to the matter of antiviral agents previously mentioned. Please note the sentence in the second paragraph which indicates that this group, the U.S. Army Chemical Research and Development Laboratories at the Army Chemical Center, Md., "can only assay compounds of proven antiviral activity."

This is one of many letters that I wrote at the suggestion of an official at NIH in an effort to derive suitable means of testing our compounds.

Needless to say, I cannot disagree with the director of research of this group, for he has a mission-oriented program. Nonetheless, this offers the individual academic scientist little hope of success in obtaining biological screening for his yet unproved compounds.

I would not want the Subcommittee on Patents, Copyrights, and Trademarks to overlook the fact that the country's universities and medical schools can play a very useful role in the administration of these complex patent issues if Congress sees fit to permit this.

I would like to move rapidly to page 12 with some specific comments on the pending legislation in this area.

One allusion has already been made, but since it was by a nonacademic witness, I would like to make it from the standpoint of the academic, university community.

Section 3(b)(3) of S. 1809 reserves to the contractor not less than "an irrevocable, nonexclusive, royalty-free license for the practice throughout the world of each such invention." If the contractor is an academic institution, such a nontransferable license is meaningless, since no university or medical school is in a position to practice an invention in the sense intended by this provision.

Another serious objection to S. 1809 of section 4(a)(2), which prohibits any contractor, including a university or medical school, from acquiring any rights to a discovery in the health field, and reserves such rights to the Government except in "exceptional circumstances."

We do not feel that the field of health should be singled out for tighter control by the Federal Government. The patent system and the incentives created by it should be brought to bear more in the field of health than in any other.

Then I wanted to pick up at the bottom of page 12 and page 13 of the printed statement, regarding title VII of the health research facilities bill as originally passed by the Congress. The intent is expressed there in just one sentence:

It is therefore the purpose of this title to assist in the construction of facilities for the conduct of research in the sciences related to health by providing—

grants-in-aid on a matching basis to public and nonprofit institutions for such purpose.

The provision of adequate university research facilities in today's world is a very costly undertaking, and one that has been achieved in substantial measure by the use of private funds, supplemented to whatever extent is found necessary with Federal funds. The donors of funds for such general grants, either private or Government, do not intend that rights stemming from research conducted in such institutions become the property of the donors.

The purpose behind the expenditure of such funds is accomplished when the institution becomes effective in its role of education and research. The fruits of such research, in the form of royalties from patent rights, serve to reduce the financial burden on the institution, and thereby to reduce the sum necessary for maintenance and expansion of the facilities for further research efforts.

We want to move quickly to a conclusion on this. We would like to cite particularly one problem, however, and that is brought out in the proposed amendment to Senate bill 512, relative to the health research facilities.

This is a very basic problem for all of the colleges and universities; that is, that it spells out specifically in the Senate bill or the proposed amendments to S. 512—I cannot find the language of it right now—that:

> No part of any appropriated funds may be expended pursuant to authorization given by this act for any scientific or technological research or developmental activity unless such expenditure is conditioned upon provisions effective to insure that all developments resulting from that activity will be made freely available to the general public.

Now, virtually every medical school in the country, chemistry departments and schools of pharmacy, have received support in the building of research facilities. A real question in the mind of everyone, then, is about the possible implication of carrying on nonfederally supported research in these facilities which were built partially with Federal funds.

The language of the proposed amendment, as it was proposed earlier in this session of Congress, would tend to indicate to us that if the Federal support went into the building, any moneys that might be channeled into a research program by non-Federal funds might be impaired by this.

The last thing that we would like to move to is right at the bottom of page 20 and on page 21 at the closing of our statement.

Emotionalism concerning the sick and the cost of drugs should not be allowed to distort the fact that the net effect of governmental legislation leading to the governmental ownership of the patent, whether partially or completely supported by Federal funds, defeats the basic purpose of research in the field of medicinal chemistry. Such procedures constitute a serious deterrent to essential collaboration between the Government, industry, and the universities, and thus to the health of the Nation in the long run.

In addition, one might examine the basic philosophy to ascertain if such restrictions do not, in fact, violate simple legal and moral concepts.

Does not the researcher hold the fundamental right to his invention?

Is not something of human dignity lost when the Government confiscates—call it anything you will, but it appears to me to be confiscation—an individual's knowledge in exchange for partial financial support?

It appears to me that all too much attention has been directed to the rights of the Government, to the neglect of the right of the inventor, of his institution, and of others who may be concerned in the overall process. Can unilateral action on this front by the Congress, without due consideration of all these factors, be truly in the best interest of the Nation?

The Congress fostered the foundation of the Federal agencies and supports them annually with appropriations derived from tax dollars. Thus, the Congress is charged with the responsibility of protecting the interest of the Government, true. But who, I ask, if not the Congress also, is to protect the interest of the individual, the academic institution, and the sector of industry vitally interested in these matters?

I appreciate the opportunity of appearing before the committee and of having our statement incorporated in the record, Mr. Chairman.

Senator McCLELLAN. Thank you very much, Dean Nobles. I am sure you have some very valuable information in your statement. I have not had the opportunity to read it, but I hope to review the many statements that have been submitted and to try to study the whole record.

We appreciate very much your contribution to the committee's work.

Mr. NOBLES. Thank you, sir.

(The following was subsequently reviewed and ordered printed at this point by the chairman.)

THE UNIVERSITY OF MISSISSIPPI,
THE GRADUATE SCHOOL,
University, Miss., August 25, 1965.

Hon. JOHN MCCLELLAN,
Chairman, Committee on Patents, Trademarks, and Copyrights,
Senate Office Building, Washington, D.C.

DEAR SENATOR MCCLELLAN: Indeed, I want to express my appreciation for the opportunity of appearing before your committee last Thursday with respect to the effect of pending legislation on patents, as it relates to university situations. I deeply appreciate the very fine way in which you conducted the hearing; I know that the hearings on this and related bills with which you are concerned certainly must be a tremendous drain on your time and effort. Nonetheless, I do deeply appreciate the opportunity of presenting our viewpoints on this matter.

Upon my return, one other item has come to my attention which may be of some significance. I recall that you indicated that the record would remain open until August 31, and I am submitting this as perhaps an additional idea to be included in considerations of the staff with respect to researching the testimony relative to the bill that might be brought forth.

It appears to me very definitely that the patent right is really the right to exclude, and not to include. I do not see that the Government really has a need for the right to exclude on a general basis, since obviously this can be done in case of great national interest on a specific piece of pending legislation. Contrariwise, it is definitely the university, and possibly the pharmaceutical industry in the case of this bill, who need the right in order to provide the incentive to invest substantial funds—on the part of industry—in developing marketing of the drug and for the university, a source of potential revenue for the support of further research and the extension of physical facilities. I believe that this is a rather significant point, and it should be borne in mind that a patent is not like a stock certificate or a savings bond. There is no value in putting the patent into a safe deposit vault. To be of any value it must be used; the invention must be exploited, and thus made available to all who can derive value from it.

In my opinion, the mere right of patent itself will not insure use unless the right to exclude is brought into play.

I would reemphasize the fact which I made in my formal presentation to the committee that if the Government takes title to the patent and freely grants license to all comers, few industries—particularly those in the high-risk pharmaceutical industry—are likely to become interested in exploiting the invention. This could mean, for example, with regard to an important drug that the public might be deprived of the benefits of that drug. Again, this points out the importance of understanding that a patent is truly the right to exclude.

I would reemphasize the importance of this from the academic standpoint, in that unless the university by right of assignment of the patent and possible transfer for an exclusive period to an industry is so authorized, it will suffer irreparable harm in the lack of cooperation that has been evident, certainly in the last 20 years, between the academic institutions and the pharmaceutical industry.

In my formal statement I presented two or three specific instances of failure of cooperation in the last few years, based on questions regarding the impending patent policy and interpretations that were being given currently by HEW on this point. Doubtless these same facts could be elicited from hundreds—even thousands—of scientists in my particular field and those of related areas with respect to their experiences during the last few years.

I hope that consideration will be given to these points in the drafting of legislation in connection with this matter. Again, I should like to thank you for the courtesies extended me and the very fine atmosphere in which the hearings of the committee were conducted.

Sincerely yours,

LEWIS NOBLES, *Dean.*

Senator MCCLELLAN. The Chair will make this brief statement.

This concludes the public hearings that the subcommittee has scheduled to date on the pending patent policy bill.

During 7 days of hearing, we have received testimony from 38 witnesses, and a number of statements have also been submitted by others for inclusion in the record.

I am informed by the staff that over 100 individual amendments have been specifically proposed and submitted for the committee's study. The transcript of these hearings already covers over 800 pages.

I have no desire to delay action on this subject. However, if a thorough and judicious consideration is to be given to the evidence that we have heard, if the suggestions we have received are to be carefully weighed and evaluated, and if a sound and equitable bill is to be reported, it will obviously be necessary that extended and careful study be given to this entire record.

The chairman will therefore consult with the other members of the subcommittee regarding our further procedure and deliberations. How soon the subcommittee can begin meetings to consider markups of the bill and how long it will take the subcommittee to complete such markup, I just cannot say. I would not even attempt to predict at this time how soon the subcommittee can make its report.

The record, however, will remain open until August 31. If anyone desires to submit any further evidence, any statements, we will receive them and consider whether they are appropriate for the record. If they are, they will be admitted to the record; if they are not, somebody will have wasted his time.

The subcommittee will meet this afternoon at 2 p.m. to continue hearings on the copyright revision bill. The subcommittee stands in recess until 2 p.m.

(Whereupon, at 12:15 p.m., the subcommittee was adjourned.)

APPENDIX

AMERICAN COUNCIL ON EDUCATION,
COMMISSION ON FEDERAL RELATIONS,
Washington, D.C., July 20, 1965.

HON. JOHN L. MCCLELLAN,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights,
U.S. Senate, Washington, D.C.

DEAR SENATOR MCCLELLAN: Enclosed is a brief statement by the American Council on Education, indicating the position of the council on various patent bills and in particular on S. 1809.

We hope very much that this statement may be made a part of the record of the hearings held before the Subcommittee on Patents, Trademarks, and Copyrights of the Senate Judiciary Committee.

May I take this opportunity to commend you and the members of the subcommittee for devoting such careful attention to this complex problem.

Sincerely yours,

JOHN F. MORSE,
Director of the Commission.

Enclosure.

STATEMENT BY THE AMERICAN COUNCIL ON EDUCATION ON S. 1809, THE FEDERAL INVENTIONS ACT

The American Council on Education [1] wishes to commend the Subcommittee on Patents, Trademarks, and Copyrights of the Senate Judiciary Committee for the study and careful consideration it has given to S. 789, S. 1809, and S. 1899, concerning rights to inventions derived from Government-financed research and development. We believe it is desirable and should be possible to develop legislatively, as a result of these hearings, a uniform and stable Government patent policy and to eliminate specific conflicting procedures required by existing laws. In particular we wish to express our support for the Federal Inventions Act, S. 1809, and to suggest certain amendments thereto.

The Federal Government, through its sponsorship of research conducted in universities, has the objective of expanding the boundaries of existing knowledge in areas or on problems deemed in the public interest or related to national goals. The research results are generally made available to all, and the university is free to punish them. The sponsoring agency receives agreed upon reports in fulfillment of the agreement. The occurrence of an invention during the course of the reserch is above and beyond the objectives of the research agreement; in short it is a "byproduct" of the research activity, largely attributable to the personal creativity of the investigator backed by his years of professional training and experience, and to the scholarly environment provided by the university.

Even though inventions are not necessarily the objective of academic studies, patentable discoveries do arise. When they do, the equities to be recognized include those of the inventor, the university, and, very properly, the sponsors providing financial support for the particular research project most closely related to the discovery. Some of the difficult problems ordinarily involved in the assignment of patent rights as between the Federal Government and its industrial contractors are absent in the case of the colleges and universities. This is so, first, because educational institutions are not themselves organized to manufacture or produce and market the patentable invention. Rather they must

[1] The American Council on Education, a voluntary, nongovernmental body, is the principal coordinating agency for higher education in the United States. It has a membership of 1,113 colleges and universities and 230 education organizations.

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seek to interest those in the industrial world who have this capability. This is often a difficult task, since few inventions coming out of university research offer prospects of a large market or a high return on investment. These problems are absent also because of the nonprofit nature of the universities and because they exist to serve the interests not of their stockholders but of the public.

In seeking to fulfill their obligations in teaching, research, and public service, the universities and their faculties generally recognize their public responsibilities in patent development, to bring the "byproduct" inventions arising from basic research to the point of practical application in order that the general public may benefit from the discovery. There will be some exceptions. Many inventions will turn out not to have commercial potential. There will be certain inventions which, by their nature, lend themselves to Government ownership and development. There will be some universities which, for valid policy reasons, do not elect to acquire rights to inventions. As a rule, however, it will be found that the university-contractor itself is the best available instrument for carrying inventions into the economy for the public benefit.

It is our impression that the policy framework provided in S. 1809 would permit Federal agencies to establish satisfactory arrangements with colleges and universities with respect to inventions related to Government-sponsored research. The bill also provides suitable arrangements for compulsory licensing if substantial efforts are not made to bring the invention to practice.

In view of the college and university dedication to the public interest, it will generally be desirable, although not essential, to establish patent rights in the university at the time of contracting rather than at the time of identification of individual inventions. At the time of contracting, the university's established policies with regard to patent responsibilities can be reviewed so that the sponsoring agency can determine their acceptability. Such policies would usually provide, on a uniform basis, a modest share of royalties to the inventor, thus recognizing the need for some incentive to identify inventions and provide subsequently the minimum necessary assistance. Such policies would also provide for nonexclusive licensing, but would recognize the need on occasion to provide exclusive licensing, subject to reasonable conditions as to period of exclusivity, if this were necessary to call forth risk capital.

Standards and criteria for university policies on the administration of inventions, governing the above points and other relevant features, are available for comparison and review. Furthermore, the respective Federal agencies already have accumulated experience in reviewing such policies. In time of peace, and also in time of war, it has been clearly demonstrated that the colleges and universities of the Nation are a vital national resource. Placing responsibility upon the universities for the development of inventions to the point of public availability offers, we believe, the best assurance that they will be developed. When there is royalty income from inventions, this would be plowed back to further strengthen these vital educational and research resources of the Nation, but this would occur only where the royalties, under suitable controls as to reasonableness, exceeded the cost of patent administration and prosecution of the unsuccessful, as well as the economically successful, ideas.

The Federal Inventions Act (S. 1809) provides general language in section 4(a) and 4(c) which would permit the sponsoring agency to assign invention rights to the university at the time of contracting, since each of these subparagraphs provides that the contractor may acquire greater rights at the time of conracting "in exceptional circumstances." The characteristic suitability of a university as an instrument of patent development might be construed to provide the exceptional circumstances necessary to warrant greater rights at the time of contracting. It is recommended, however, that this language be strengthened and made more specific by adding the phrase "or where the contractor is an educational institution" after the word "circumstances" on page 7, line 18, of the bill.

With respect to section 4(b) there does not appear to be adequate provision for the determination of the universities' rights in inventions at the time of contracting, and for this reason it is suggested that section 4(b) should be modified to include such a provision. This modification could be accomplished, for example, by inserting, "or educational" in line 5, page 8, following the word "commercial." Lines 2 through 5, page 8, if so amended, would read as follows "and the work called for by the contract is in a field of technology in which the contractor has acquired technical competence directly relating to an area in which he had an established nongovernmental commercial or educational position, the agency" * * *."

The colleges and universities regard the broad and flexible approach proposed in S. 1809 as greatly preferable to a policy of assigning to the Government all rights to all inventions at the time of contracting. We believe that in many cases inventions would not reach the civilian economy if reliance were placed on a kind of mail-order catalog of available new product ideas. Frequently aggressive search is required to find someone willing to devote the energy and the additional capital to the task. The goals of the Government agencies and of the universities would seem to be identical—to make available to the public and to the economy the fruits of univeristy research, as quickly and inexpensively as possible. With such an identity of goals, the question would seem to be simply one of determining who best can take the initiative. We believe that, given the safeguards and controls we have suggested, the universities are best equipped to perform this function.

NICHOLS PRODUCTS CO.,
Moorestown, N.J., July 9, 1965.

Senator JOHN L. MCCLELLAN,
Chairman, Patents, Copyrights and Trademarks Subcommittee,
Senate Judiciary Committee,
Senate Office Building, Washington, D.C.

DEAR SENATOR MCCLELLAN: The action of your subcommittee in holding hearings during the past month in connection with various legislative proposals having to do with the American patent system has come to the attention of the American Society of Inventors. We feel that we have a substantial stake in the continuation of a strong and effective patent system, and would like to take this opportunity to express our views.

Much of the testimony presented before your subcommittee has been reviewed by us; and we feel that the statement presented by the national Small Business Association most nearly expresses the position of this organization. In essence, we favor the procedures prescribed by S. 1809 (McClellan bill) in determining the respective rights of the contractor and the Government in patents resulting from Government-sponsored research and development programs.

The position of the individual inventor would be substantially preserved and strengthened by the addition of various features of S. 789 (Saltonstall bill) as amendments to S. 1809. Specifically, we feel that section 9 of S. 789, which would allow the inventor whose patent has been infringed in connection with Government procurement, to obtain early and inexpensive remedy by administrative means, is urgently needed. Individual inventors cannot afford the expense and delay of seeking remedy by way of suit against the Government in the Court of Claims.

Section 11 of S. 789 would establish procedures and funds for the granting of awards to those whose inventions or discoveries were judged to be of outstanding merit. Various studies by the Department of Commerce and others have shown that the individual inventor is still a prolific source of important inventions and discoveries which contribute to the overall welfare. We believe that the recognition and rewards associated with an awards program would serve to stimulate creativity to the benefit of our national security and our society, and earnestly recommend that this provision of S. 789 be included in any overall patent legislation.

S. 1047 (Williams bill), like section 9 of S. 789, would substantially strengthen the position of the inventor patent holder in that he and/or his licensees would not find his patents infringed as a matter of normal routine by suppliers to the Government. The provisions of S. 1047, which allows for unlicensed manufacture upon certification by the Secretary of Defense, we feel, would alleviate the likelihood of unreasonable allegations and demands by patent holders. We believe that the Government of the United States has an ethical and moral responsibility to deal fairly and honestly with all its citizens; and that it should take the leadership in respecting the rights implicit in the patent grant. For these reasons we vigorously urge that the substance of S. 1047 be incorporated in any forthcoming patent legislation.

The American Society of Inventors appreciates the committee's courtesy in allowing it to submit these comments and respectfully requests that this statement is placed in the record of the hearings.

Very truly yours,

E. B. NICHOLS,
Legislative Committee, American Society of Inventors.

AMERICAN SOCIETY OF INVENTORS,
Whitefield, N.H., July 16, 1965.

DEAR MR. BRENNAN: Supplementing the statement of July 9 sent in by Mr. E. B. Nichols for our legislative committee, I am enclosing a proposed "Code of Creativity" for use by the Government agencies dealing with inventions. May I suggest that this be included in the transcript of the hearings following Mr. Nichols' statement, also the thoughts in this letter.

Our society would like to make a further suggestion that hearings be held on the problems of the inventor and creative scientist in dealing with the Government. These problems are more important than the problems of patents equities between industry and Government.

Thanking you for your cooperation in this matter, and the enclosed code will do much to improve the creativity and economic welfare of all concerned.

Respectfully submitted.

E. BURKE WILFORD, *President.*

CODE FOR CREATIVITY FOR GOVERNMENT AGENCIES

This code for creativity, designed primarily to give inventors and other creative scientists improved opportunity and incentive, will also promote progress in Government and industry. Economic growth and national defense will both benefit by revision of policies and methods for the purpose of encouraging creative workers and eliminating needless barriers in their paths.

1. The Government and industry can encourage economic growth by early recognition of inspirational ideas in the pioneering stages of development.

2. Analysis and recognition of the idea should include what is advantageous, as well as that which is not worked out and requires exploratory development. Direction of inventive thought into the right channels is very important.

3. The creator or inventor should be given a letter of status from the Government or development group about possibilities of production, so that he can develop solutions quickly and build a team or small organization. He should also not think too highly of his idea and work practically.

4. A portion of the expenses of every R. & D. contract or study should be used to have the inventor working with the development. If this is impossible, due to distance or personalities, the creative mind should make periodic visits to the development as a working consultant. Much leadtime is wasted by having the larger group in any development duplicate the work already done by the inventor and in some cases the development is spoiled by Government in-house development or a too long-haired approach.

5. If an idea is worthy of development, the inventor should be told when, how much, and at what point he can expect money from the R. & D. contract or a royalty on a test quantity. Waste of leadtime should be avoided in every stage of development.

6. Big and small industry working for the Government must be more receptive to the use of outside designs and systems, which are of a proprietary nature, and the status of the creative mind should be recognized when the development for production starts.

7. The patent and legal profession should see to it that all patent and proprietary data receive proper awards through administrative settlements, and Congress should provide a special fund out of which DOD can act quickly in these matters. Bureaucracy should treat the inventor with more personal attention, responsibility, and speed.

8. No patent legitimately issued and not assigned should be attacked by the Government lawyers on a basis of invalidity. If assigned, the inventor personally should share in the award and other solutions for blocks to inventions and adequate recognition of the inventors and creative scientists.

9. Nearly every country in the world has a more generous policy of pay for patents bearing on the national defense, and many countries have awards systems where the civilian and military personnel as well as the outstanding inventors and scientists receive reasonable sums of money to compensate them for their contributions beyond the call of duty. The U.S. Department of Defense has recommended that the Congress pass an awards bill patterned after the British system.

10. The Government should not hold any patents for contractors or Government employees except when they pay for the background work. Nonexclusive