THE DEMISE OF TECHNOLOGY TRANSFER IN DHEW

Barry Leshowitz, Ph.D.
Arizona State University

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In what some have called an unparalleled display of bureaucratic tyranny, HEW fired its Patent Counsel, Norman J. Latker on Dec. 13, 1978, after 22 years of uninterrupted government service. He was given no notice, no written explanation of the charges and no severance pay. Now accused by the HEW General Counsel of being "disloyal" to the Department, Latker has been credited with having helped bring to the public more than 100 HEW-supported medical inventions. The rubella vaccine, anti-tumor agents, silver sulfadiazine for treatment of burns and rechargeable cardiac pacemakers are only a sample of the revolutionary medical discoveries introduced through the efforts of the HEW Patent Counsel.

Latker's difficulties stem from testimony he provided at Senate hearings on federal patent policy held by the Senate Small Business Committee last spring. Representing DHEW, Latker testified that for almost a year all requests by scientists and their universities for patent rights to their inventions had been "frozen" by the HEW General Counsel. The net effect of the HEW decision was, according to Latker, resulting in bottling-up of potentially life-saving technology from this country's major medical laboratories.

The outcry from the biomedical research community was so intense that it attracted the attention of two prominent Senators, Dole (R-Kansas) and Bayh (D-Indiana). They, together with 14 co-sponsors in the Senate, introduced legislation in September 1978 that mandated HEW to end its curtailment of medical technology. HEW's response to the Dole-Bayh Bill was almost immediate - - within hours, it released for development the more than 30 inventions it had held for more than a year.

Now in an act of pure retaliation, HEW has chosen to punish Latker for having drawn attention to the HEW patent situation.

HEW's cut-off of development of medical technology through the patent system is not another instance of an unavoidable bureaucratic delay, as it has claimed, but a continuing effort to withhold from the public biomedical inventions it has had a hand in funding. The Department's demonstrated anti-medical-technology, anti-business attitude is clearly apparent not only in the firing of its Patent Counsel, but also in an internal HEW memorandum on patent policy discussed later.

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[1] Barry Leshowitz is an Associate Professor of Psychology at Arizona State University, Tempe, Arizona 85281. Dr. Leshowitz was a Congressional Science Fellow from September 1977 to September 1978 and served as an aide to Senator Robert Dole. Many of the issues discussed in the article were raised at a round-table discussion entitled "Transfer of Medical Technology from the Laboratory to the Market place," chaired by Dr. Leshowitz at the 13th Annual Meeting of AAMI in April, 1978.

Biomedical Research in HEW

Biomedical research programs conducted at this country's prominent universities, medical schools and research institutes and supported by the National Instittues of Health of the Department of Health, Education and Welfare are acknowledged as the best in the world. Not only are these programs dedicated to pushing back the frontiers of knowledge, they are also seeking to discover diagnostic techniques and cures for cancer, arthritis, diabetes, heart and lung disease, and other dreaded diseases. While much important work still remains to be done, the achievements of HEW's biomedical programs include an outstanding list of accomplishments in both basic and applied areas. Over the past ten years, for example, as shown in Table 1, more than 63 HEW-supported medical inventions have reached the public. In addition to the obvious benefits to the nation's health, these discoveries have attracted hundreds of millions of dollars in captial investment and have added importantly to our international trade. Biomedical research is clearly one area where there is an abundance of tangible evidence of a return on the federal research investment.

In August of 1977, suddenly and with no explanation, HEW ended its program of transfering biomedical technology to the public by freezing all patent rights to inventions discovered under HEW grant and contract support.

Patents Underlie Technology Transfer

To understand why patents play such a pivotal role in the transfer-of-technology process, it need only be pointed out that unless patent (ownership) rights are available to the inventor, there is little incentive to the University, by inventor to report an invention nor will ~~is no possible way~~ a private firm will be willing to commercialize an invention, no matter how bright its prospects appear to be. The cost of the development, testing and marketing phases that precede introduction of a product to the market are extremely high, perhaps ten times as expensive as the cost of the initial research, and cannot be assumed by the government agency that sponsored the initial research. Private firms interested in ultimately marketing the invention consititue the only currently available mechanism by which a laboratory discovery can be made available to the public. Patent rights provide the basis for collaboration between a private firm and the university-based inventor. Patent protection provides the incentive, the glue if you like, needed to cement the relationship between the inventor and the private firm. HEW's decision in August 1977 to deny to its grantees ownership rights, then, forclosed any possibilities of the inventions reaching the public.

Patent Policy in HEW

In HEW, the focal point for technology transfer is the HEW Patent Counsel, who has the responsibility for bringing together scientist-inventors supported with public funds and private organizations interested in developing and commercializing medical inventions. Over the past 15 years, the Patent Branch of HEW, under the supervision of Mr. Norman Latker, has amassed a record of transfering government-supported inventions to the market that has been truly outstanding.

Prior to Latker's assumption of the supervisory position of the HEW Patent Branch, HEW's record in technology transfer was dismal. According to an official government report issued by the General Accounting Office in 1968 on pharmaceutical research in NIH, not a single invention on the market could be traced to an NIH program. The report documented that the hundreds of millions of dollars of annual federal outlay for pharmaceutical research failed to yeild a single useful medical breakthrough. The GAO report attributed NIH's nonexistant output to its policy of refusing to relinquish ownership of all inventions it had funded.

In 1968, following publication of the GAO report, a new HEW patent policy was developed. Through a contractual relationship called the "Institutional Patent Agreement," universities and their scientists were promised in advance, ownership rights to inventions funded by HEW for a limited period of time under the restriction that the inventions be commercialized. These

agreements between HEW and more than 70 of this country's major non-profit research institutes created the conditions of certainty and the spirit of cooperation between public and private sectors so important for the steady flow of technology to the market. The list of inventions shown in Table 1 is testimony to the success of HEW's patent policy. In fact, the HEW policy has worked so well that it has become the model for other federal R & D agencies, including the National Science Foundation, the Department of Agriculture, and the Veterans Administration.

Rarely in public service can an individual who has "made the difference" for a particular program be identified so clearly. Norman Latker is one such person. Through his efforts and those of his dedicated staff, consisting of two attorneys and two secretaries, he has been able to accomplish what literally hundreds of patent attorneys in other federal agencies have been unable to accomplish. The list of inventions in Table 1 cannot be matched anywhere in government.

Beginning in August of 1977, when HEW decided to freeze all patent rights, transfer of technology deteriorated to the point where commercial firms began to abandon their collaborative relationships at a number of major research centers. The uncertainty as to the disposition of the patents was inconsistent with accepted business practices and was an intolerable obstacle to the continuation of joint ventures. HEW's public position was that all patent matters were under study by the Department and therefore, all patent decisions were pending. The circumstances

prompting the Department's review and why it was necessary to shut down the system during the review was never made clear. More importantly, HEW would not offer any estimate as to when the review would be completed.

The Dole-Bayh Patent Bill

In June of 1978, the problem had become so critical that the Senate Small Business Committee investigating federal patent policy requested that HEW testify as to its patent policy. Mr. Latker, representing HEW, reviewed the delays being encountered in processing patent requests and informed the Committee that patent rights for more than 30 inventions had been approved by the appropriate sponsoring institute of NIH months ago and now awaited administrative approval by the HEW General Counsel. He requested the Committee direct any policy questions to the Office of the HEW General Counsel.

In cooperation with various university officials, a complete list of the inventions held by HEW since August of 1977 was compiled by the staff of Senator Bob Dole who had become concerned about the situation in HEW. As Table 2 reveals, potential diagnoses of cancer, including a revolutionary blood test, pharmaceutical therapies for cancer, and treatments for hepatitis and arthritis, amongst other important discoveries, were being held by the HEW General Counsel.

Convinced of the urgency of the HEW impasse, Senators Dole and Bayh instructed their staffs to draft patent legislation that would mandate that patent rights of government supported inventions be provided to inventors for purposes of commercialization. On September 13, 1978, Senators Dole and Bayh held a joint press conference to announce introduction of the bill (S3496) and to fully aprise the American public of the deteriorating patent situation in HEW. Eminent biomedical scientists, many of whom had had first-hand experience with the HEW patent system before and after August of 1977, attended the news conference and urged the Senators to go forward with this badly needed legislation.

HEW's Response

On the day of the news conference, General Counsel, Mr. Peter Lebasy, as well as the Secretary of HEW, Joseph Califano, expressed concern about the patent situation. Perhaps in response to the attention brought by the press, perhaps because of the concern of 16 U.S. Senators who co-sponsored the Dole-Bayh Bill, the very next day, Secretary Califano instructed his Department to release all of the cases. After more than a year of delay, he ordered that all of the ownership rights were to be released to the inventors. Almost immediately, twenty of the thirty cases were mailed out from the Department. In hind sight, the public clamor and outcry were undoubtedly pivotal. The invention, I am certain, would still be stuck in the General Counsel's office were it not for the galvanizing of public opinion.

The Future of HEW Patent Policy

Although all of us who played a role in the release of the thirty inventions naturally take some satisfaction, I am not optimistic about the future of biomedical transfer efforts in HEW. There is, what I consider, an uninformed attitude in HEW and other federal agencies that views the private sector as an adversary. HEW fails to understand that isolating the private sector is counterproductive and out of step with most thinking about how to solve societal problems.

Underlying the present administration's patent policy in HEW also is the pervasive view that introduction of new medical technology is responsible for the increasing costs of health care and therefore must be tightly controlled. Quoting from an internal HEW Memorandum prepared by the Office of HEW General Counsel on HEW Patent Policy, this view is succinctly expressed as follows:

> "Historically, the objectives of our patent policies have been to make inventions developed with government funding available to the public as rapidly and as cheaply as possible, goals which are sometimes incompatible.
>
> While these objectives are basically sound, recent experiences with the high cost of proliferating health care technology suggests that there may be circumstances in which the Department would wish to restrain or regulate the availability of a new invention. Recognizing this objective requires a broader statement of purpose -- to influence the availability and cost of inventions made with HEW support, sometimes encouraging rapid, low cost availability, at other times restraining or regulating availability."

The statement is so transparent, so inappropriate, so ludicrous it hardly requires comment.

The Firing of the HEW Patent Counsel

HEW's opinions about new medical technology provide an explanation not only for its bottling-up of patents for more than a year, but also for its recent decision to fire its supervisory patent counsel, Norman Latker.

With essentially no notice and with no written explanation, on December 13, 1978, Norman Latker was summarily dismissed by his supervisor, Associate General Counsel, Richard Beattie. The dismissal of Mr. Latker, for reasons known only to his immediate supervisor and with no opportunity for a fair hearing, constitutes, in my opinion, a bureaucratic "horror story." Mr. Latker, who only last June was asked by HEW to represent the Department at Congressional hearings, and, who, for the past 22 years, has been acknowledged as a leading authority on federal patent policy suddenly, without cause, is fired and given no severance pay.

What indiscretion did Latker commit in the last six months that could provide grounds for termination? I can't help but speculate that it was Latker's testimony to the Small Business Committee last June and information about the patent freeze he provided members of Congress upon their request that prompted the job action by HEW. Indeed, his supervisor, Richard Beattie, who just recently was promoted to Executive Assistant to the

Secretary of HEW, stated at Latker's termination interview that he should have refused to provide Congress with information about the patent situation. How Beattie, who is now in such a high administrative position in government, could make the suggestion that a public official be less than forthright with Congress is frightening. Does Beattie mean to suggest that Latker should have stonewalled Congress, in effect cover-up the entire patent debacle?

What person of conscience could possibly have followed HEW instructions to ignore Congressional requests for information? Faced with the realization that as many as 30 potentially life-saving inventions were languishing on the shelves of the HEW bureaucracy, one could hardly have expected Latker to remain silent. Having helped bring to fruition more than 100 life-saving inventions over the past 10 years. Latker could not ignore requests for status reports from the various NIH programs and medical scientists from across the nation with whom he had worked so closely in the past.

Where Do We Go From Here?

As matters stand today, Norman Latker's reputation has been besmerched by unspecific charges brought by some faceless bureaucrat. Rather than rewarded he is shunned as a public servant who has been disloyal to the "team." Because he puts loyalty to the highest moral principles above loyalty to a Government department, he is without gainful employment, seeking redress of his grievance through the courts.

There is little to add to the story except to comment on what is reputed to be HEW's explanation of the grounds for Mr. Latker's termination. According to HEW, Norman Latker had discussions with the American Association of Medical Colleges (AAMC) regarding a legal brief AAMC was preparing for submission to the Supreme Court on the system of closed peer review of federal grants. Mr. Latker, it is charged by HEW, provided information that was "contrary to the position of HEW."

The extent to which HEW is willing to go to undo Latker is now painfully obvious. Does HEW also plan action against the President of the National Academy of Sciences, the Director of the National Institutes of Health, and other prominent educators and scientists who also were consulted by the AAMC on this matter? Does HEW contend that in its 180-billion-dollar bureaucracy, employing tens of thousands of people, there exists a "party line" on all the sundry issues of education, welfare and health? If so, where is "big brother" located? Where does an employee go to check out his information before addressing issues of concern to his profession? We are all familiar with the shortcomings of the giant bureaucracy, but never could one have anticipated that mind-control of its employees was a function it would attempt to assert.

Summing up, the events of the last year have provided an opportunity to raise the issues of federal patent policy for consideration by a public larger than the patent bar. With the

release of the patents by HEW, inventions that were delayed for more than a year now have a reasonable chance of being developed. A patent bill mandating a progressive patent policy that will set the stage for transfer of federally supported technology is now before Congress and has a good chance for passage in the next session. In the process, unfortunatley, a good man has been sacrificed simply because he provided to Congress information it felt it needed to have.

Because of the testimony and information given to the Congress, which appears to have resulted in the Department reversing its position on patent policy, Norman Latker has been hounded out of a position he has had for more than 22 years. Rather than admit, or at least tacitly acknowledge, its poor judgment, HEW has chosen to extract its pound of flesh from the individual it deems responsible for its emabrrassment, in a display of pure revenge.

If HEW's job action against Norman Latker goes unchallenged, a pall will hang over the entire federal bureaucracy. If the country's civil service is to work effectively, its employees must not be intimidated by the capricious acts of a few bureaucrats. The public response to a bureaucracy that looses sight of its function, is unresponsive to the needs of the people it serves, insists upon total fealty from its employees, is vindictive, will, I predict, pale in comparison to what Proposition 13 has recently evoked.

The abuses of the bureaucracy attributed to the federal government by its critics are often too complex to comprehend and to fragmented to illustrate. Only on rare occasions when the bureaucracy insists that a loyal public servant be sacrificed because he dared speak out can we begin to understand the seriousness of this uncontrolled arm of government. Norman Latker deserves our support, not only because it is the right thing to do, but also because our system of government just cannot tolerate tyranny by the bureaucracy.

TABLE 1

HEW-SUPPORTED INVENTIONS (1968-1977)

Inventor	University	Invention	Private Firm
Walser	John Hopkins U.	Keto-Acid Analogs of Amino Acids for treatment of uremia	Pfrimmer of Germany & Syntex of USA
Wiktor	Wistar Institute	Rabies Vaccine	Wyeth Laboratories
Kamen et al	Case Western Reserve	Methotrexate Assay during Cancer Chemotherapy	Diamond Shamrock Corporation
Lillehei/Kaster	U. of Minnesota	Pivoting Disc Heart Valve	Medical, Inc.
Blackshear et al	U. of Minnesota	Implantable Infusion Pump (Constant Infusion of Drugs for Treatment of Cancer, Diabetes, Pain, Morphine-addiction, etc.)	Metal Bellows Co.
DeLuca	U. of Wisconsin	25-Hydroxycholecalciferol for treatment of Osteodystrophy with liver dysfunction	Rousel-Uclaf (Hoechst) & Upjohn
DeLuca	U. of Wisconsin	1-Alpha Hydroxycholecalciferol for treatment of Osteodystrophy with Kidney Dysfunction	Leo Pharmaceuticals
DeLuca et al	U. of Wisconsin	1, 25-Dehydroxy~~ergocalciferol~~ cholecalciferol for treatment of Osteodystrophy with Kidney and Liver dysfunction and Senile Osteodystrophy	Hoffman-LaRoche Inc.
Fox	Columbia U.	Silver Sulfadiazine used in treatment of burns	Marion Labs Kansas City, MO
Heidelberger	U. of Wisconsin	Use of F_3TDR for Herpes Infection of the Eyes	Burroughs Wellcome Co., Research Triangle Park, NC

Table 1 cont.

Fischell	Johns Hopkins U.	Rechargeable Cardiac Pacemaker	Pacesetter Systems Sylmar, CA
Holland	Tulane U.	Method of Reducing Intraocular Pressure in the Human Eyes (Glaucoma Treatment)	Cooper Labs Bedford Hills, NY
Pressman	U. of Miami	Application of X-537A in the Cardiovascular System (for stimulation of cardiogenic shock, congestive heart failure, etc.)	Hoffman-LaRoche Nutley, NJ
Higley	National Institute of Scientific Research	Polycarbonate Dialysis Membranes (kidney dialysis)	C.R. Bard Inc. Murray Hill, NJ
Talbot/Harrison	Johns Hopkins U.	Ballistocardiograph Apparatus	Royal Medical Corp Hunstville. ALA.
Plotkin	Wistar Institute	Rubella Vaccine	Wellcome Foundation L'Institute Merieus Swiss Serum & Vaccine Institute,etc.
Schaffner/Mechlinski	Rutgers U.	Derivatives of Polyene Macrolide Antibiotics	E.R. Squibb, USA Dumex, Denmark
Zweig	Syracuse U.	Apparatus for Measuring and controlling cell population density in a Liquid Medium	New Brunswick Scientific Co., NJ
Lovelock	Yale U.	Gas Analysis method and device for the qualitative and quantitative analysis of classes of organic vapors	Varian Associates Palo Alto, CA
Fried	U. of Chicago	Prostoglandins for possible treatment of bronchial asthma, duodenal ulcers, inflammatory conditions, etc.	Richardson-Merrell NY.

Table 1 cont.

Leininger/Grotta et al	Battelle Memorial Inst	Preparation of nonthrombogenic surfaces and materials	C.R. Bard, Inc, MASS Sherwood Medical Ind American Hospital Supply Corp, CA
Merrifield	Rockefeller U.	Apparatus for the Automated Synthesis of Peptides	Beckman Instruments Fullerton, CA
Smith/Kozoman	Duke U.	Apparatus & method for rapid harvesting of Roller Culture Supernatant Fluid	Bellco Glass, Inc. Vineland, NJ
Zweng	Stanford U.	Laser Photocaugulator	Coherent Radiation,CA
Sweet et al	Stanford U.	Cell Sorter	Becton-Dickinson, NJ
Boyd/Macovski	Stanford U.	Computerized Axial Tomography	SAI, Cupertino, CA
Saxena	Cornell U.	Method for testing pregnancy	Carter-Wallace
Calneck/Hitchner	Cornell U.	Cell-free virus preparation	Merck
Carlson	Iowa State	Respiratory Augmentor with Electronic monitor and control	Bourns, Inc.
Leake/Rappoport	Harbor General Hospital	Bone Induction in an Alloplastic Tray	American Hospital Sup.
Bradford/Williams	U. of Georgia	Protein Assay Reagent & method	Bio-Rad Labs, Inc. Quantimetric Corp.
Tenckhoff	U. of Washington	Catheter Insertion Trocar	Sweden Freezer Mfg Cobe Labs Psysio-Control Corp.
Leonard et al	U. of Illinois	Fluorescent Derivatives of Cytosine-Containing compounds	PL Biochemicals
Secrist et al	U. of Illinois	Fluorescent Derivatives of Adenine-Containing compounds	PL Biochemicals

Table 1 cont.

Asgar	U. of Michigan	Partial Denture Alloy	
Carlson/Ward	U. of Washington	Coherent Biological Cell Analyzer	3M Company
Charlson/Alhquist	U. of Washington	Integrating Nephelometer and Photon-counting Integrating Nephelometer	Battelle Development
Thomas	U. of Washington	Artery-Vein Shunt Applique	Battelle Development
Holcomb	Yale U.	Method & Apparatus for Stimulation of Body Tissue	Avery Labs, Inc.
Dugan	Temple U.	Novel Compositions for Radiotracer Localization of Deep Vein Thrombi	Rand Research & Devlp
Roelofs	Cornell U.	Codling Moth Pheromone	Zoecon Corp
Whitby	U. of Minnesota	Particle Counter	
Backaner	U. of Minnesota	Method for suppressing Ventricular Fibrillation	Burroughs, Wellcome
Whitby	U. of Minnesota	Aerosol Sampler	
Bradley	U. of Minnesota	Apparatus to Stimulate the Bladder	
Butler	Purdue Research Found	Hydrophobic Noncovalent Binding of Proteins to Support Naterials	Regis Chemical
Rosenberg	Michigan State U.	Platinum Compounds as Anti-Tumor Agents	Possibly Adria, Bristol or Miles Labs
Coller	Institute for Cancer Research	Process of Viral Diagnosis and Reagent (Radioimmuno-assay)	Abbot Labs
Kosikowski	Cornell U.	Antibiotic Test Kit	Bacto Strip
Kosikowski	Cornell U.	Process for Milk Sterilization	De Laval,Alpha Laval

Table 1 cont.

McLafferty	Cornell U.	Pregnancy Test	Carter-Wallace
Kattwinkel et al	Case Western Reserve	Device for administering pressure via nasal route	Sherwood Medical
Neckers et al	U. of New Mexico Wayne State U.	Polymer-based Photosensitizers	Natl. Patent Devl Corp
Keith/Snipes	Penn. State U.	BHT Antiviral Agent	Key Pharmaceuticals
Najjar	Tufts U.	Therapeutically useful polypeptides	Calbiochem
Story et al	U. of Georgia	Macrocyclic Compounds	Chemical Samples Co Albany International
Mielke	Institutes of Medical Sciences	Template for Ivy Bleeding Time	Hemakit, Inc.
Murray/Somerset	State Univ of NY	Knee Joint Prosthesis	Howmedica, Inc.
Volz/Brownlee/Tyers	Penn State U.	Rechargeable Cardiac Pacemaker	Intermedics, Inc.
Volz et al	Penn State U.	Rechargeable Cardiac Pacemaker	Intermedics, Inc.
Travis/Pannell	U. of Georgia	Albumin Recovery Method	Calbiochem
Schaffner et al	Rutgers	Derivatives of Polyene Macrolide Antibiotics	E.R. Squibb
Kupchan et al	U. of Virginia	Ansa Macrolide Tumor Inhibitor	Bristol-Myers

TABLE 2

INVENTIONS "FROZEN" BY HEW (8/1977 to 9/1978)

Sponsoring Institute (NIH)	Inventor & University	Invention
Employee - Bureau of Standards	Cetas - Univ of Arizona	-Birefringement crystal thermometer for measuring heat of cancerous tissue during electromagnetic-wave treatment.
National Institute of Allergy and Infectious Diseases (NIAID).	Remers/Kumar - Univ of Arizona	-New mitomycin anticancer agents.
National Institute of General Medical Science (NIGMS).	Powers - Georgia Institute of Technology	-Compounds to treat emphysema and arthritis
National Heart, Lung, and Blood Institute (NIHLBI):		
NIGMS	Fox - Columbia University	-Aqueous hypertonic solution for treatment of burns.
NIGMS	Everett - Univ of Houston	-Apparatus and synthesis of film transfer characteristics.
National Cancer Institute (NCI)	Sela/Arnon - Weizmann Inst	-Test for diagnosing cancer.
NHLBI	Normann - Baylor University	-Remote monitoring of blood pumps.
NCI	Goldstein - Univ of Texas	-Hormone (thymosin) treatment of immune system diseases
NCI	Salmon/Hamburger - Univ of AZ	-Bioassay for treatment of cancer
NCI	Townsend/Earl - Univ of Utah	-Synthesis of anti-cancer compounds
NCI	Pogell/McCann - Saint Louis U.	-Pamamycin - new broad spectrum antibiotic.
National Institute of Dental Research (NIDR) Division of Research Resources	Latham/Georgiade - Univ of NC	-Appliance to be placed in the mouth of infants to correct bilateral cleft of the lip and palate.
NIAID, NHLBI	Goetzel/Austin - Harvard Univ	-Synthetic therapeutic agents for anaphylaxis, asthema,etc.
NHLBI	Mahoney - Univ of Colorado	-Device to examine hemoglobin to detect abnormalities.

cont.

Table 2 cont.

National Institute of Arthritis Metabolism, & Digestive Diseases (NIAMDD).	Walser - Johns Hopkins Univ	-Salts of Keto acids for alleviating hyperammonemia due to liver damage caused by cirrhosis, hepatitis or genetic liver damage.
Employee	Vurek - NIH	-Measurement of carbon dioxide in blood plasama for diagnosis
Employee	Walker - NIH	-Needle valve detent attachment for controlling cuff deflation during the taking of blook pressure.
NCI	Apple/Formica - Univ of CA	-Anticancer drug - Azetomicins
NCI	Splegelman - Columbia Univ	-Method for detecting cancer
NIGMS	Marshall/Rabinowitz - Univ of Miami	-Synthetic carbohydrate - Protein conjugates for extending conditions under which enzyme can be used in biochemical processes.
NCI	Farnsworth- Univ of Illinois	-Anticancer drug - Jacaranone.
NCI	Turcotte - Univ of Rhode Island	-Anticancer drug.
National Institute of Neurological and Communicative Disorders & Stroke	Jobis - Duke University	- Method for noninvasive monitoring of oxygen sufficiency in human tissues & organs by infra-red radiation.
NIGMS	Montalvo - Gulf S. Research Inst	-An invention to selectively measure substances in the blood to diagnose blood disorders
NCI	Petit/Ode - Arizona State Univ	-Anticancer drug
Employee	Leighton - NIH	-Intracranial pressure gauge.
NCI	Kuehne - Univ of Vermont	-Method for synthetically preparing a useful naturally occuring substance to be used in making a drug for treatment of high blood pressure
NICHD	Gray - Illinois Inst of Tech	-Prolong release of anti-fertility drugs
NCI	Gosalvez - Univ of Madrid	-Novel anti-cancer compounds - Analogs of adriamycin.

Taken from Statement of Norman J. Latker, Patent Counsel, Department of Health, Education, and Welfare, at Hearings Before the Subcommittee on Monopoly and Anticompetitive Activities of the Select Committee on Small Business, United States Senate, 95th Congress, Second Session on Government Patent Policies, May 22, 1978.

Mr. LATKER. I am sorry, I did not check that out. Three months prior to September 30 we send out a reminder to IPA holders that their reports will be due September 30. Most of the universities are very prompt and do report. But, as indicated, whether this includes the entire listing I am not quite sure because I did not check that.

Twelve: Also, please supply a copy of your information item No. 59 pertaining to the subcommittee's December hearings on patent policy, plus any subsequent items in the series dealing with the subcommittee's study of Government Patent Policy of these hearings.

Response: We understand that Mr. Sturges has copies of these items. [See appendix, p. 1563.]

Thirteen: Please address the question on intellectual property rights—and the degree of protection they do receive or should receive in the peer review process.

Response: While the establishment of policies on the peer review process is outside my domain, it is the current policy of the Department generally to close meetings of peer review groups among other reasons to protect against disclosure of research designs and protocols submitted with grant applications to the extent that such disclosure would affect future patent or other valuable commercial rights. Attached as items 8 and 9 are the reports of the National Commission for the Protection of the Human Subjects of Biomedical and Behavioral Research and the President's Biomedical Research Panel on this subject.

These advisory groups were directed by Congress in title III of the Health Research and Health Services Amendments of 1976, Public Law 94–278, to investigate and study the implications of public disclosure of information contained in research protocols, hypotheses and designs submitted to the Secretary of Health, Education, and Welfare in connection with applications or proposals for grants, fellowships or contracts under the Public Health Service Act.

I would add that the National Commission requested public statements through a Federal Register notice, to which they received approximately 250 letters on that subject, and their report is a distillation of the 250 responses.

Mr. STURGES. Mr. Latker, can you tell us about the processing of deferred determinations, that is, requests for retention of patent rights by universities coming to HEW after the invention had been made, from schools not holding IPAs.

It is our understanding that processing stopped sometime ago, and we would be interested in the details.

Mr. LATKER. Well, there is a delay, and backlog of case-by-case reviews in the Department. Which would be conjecture on my part, although there is a study on department patent policy being conducted.

Mr. STURGES. There is a what?

Mr. LATKER. A study of our patent policy of the Department going on, so one could assume that the delay is part of the study or caused by the study.

Mr. STURGES. At what level within the Department?

Mr. LATKER. General Counsel.

Mr. STURGES. Can you tell us how many applications for rights might be involved?

Mr. LATKER. There is a backlog, in the General Counsel's office, of between 25 and 30 cases.

Mr. STURGES. Between 25 and 30?
Mr. LATKER. Yes.
Mr. STURGES. When did the processing stop?
Mr. LATKER. August 1977.
Mr. STURGES. August of 1977?
Mr. LATKER. Yes.
Mr. STURGES. So we are 9 months into a period of delay on processing these determinations?
Mr. LATKER. Yes.
Mr. STURGES. Has there been any comparable restraint imposed on IPA holders?
Mr. LATKER. No.
Mr. STURGES. Mr. Latker, in May of 1977 you testified in the House before the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology. You attached some examples of inventions licensed by universities which reached or were reaching the marketplace, and in your prepared statement you said:

> As you will note, there are a number of pharmaceutical products on this list. We knew of no comparable situations at the time of the GAO report in 1968. I would conjecture this number will increase in subsequent years due to the opportunity of the pharmaceutical industry to capitalize on positive leads from the non-profit sector which could result in reduction of the industry's escalating R&D costs by eliminating a number of blind leads.
>
> The rise in successful development of university generated inventions is also considered significant when noting the steady decline in introduction of new drug entities from 65 in 1959 to 15 in 1975. This slide might also be attributed to the increased cost of drug development. In this context it is apparent that the existence of a licensable patent right is probably a primary factor in the successful transfer of the university innovation to industry and the marketplace, and failure to protect such right may affect the transfer of a major health innovation.

That is the end of the quotation. That seems to be a prediction or suggestion that the cost of developing deadend drugs, or those that do not make it to the marketplace, should be transferred from the private to the public sector.

Is that what you had in mind?

Mr. LATKER. No, not at all. In fact, it is just the opposite. The ability of the universities to license and there are many examples of this with a comparison to an inability at one time to license indicates in the latter situation that potential drugs lie dormant for many years until the Government perceives some pressure to involve itself in the development of the drug. In most such situations, Federal funds never become available.

Mr. STURGES. I am sorry, but I am not following your answer. The statement seems to say, or at least to imply, that as of May 1977 you felt campus discoveries are playing a larger role.

Mr. LATKER. Right, as long as there are licensing rights available.
Mr. STURGES. As long as the rights are available?
Mr. LATKER. Yes.
Mr. STURGES. Well, does the current Institutional Patent Agreement facilitate the development of new drugs that are transferred to the marketplace?
Mr. LATKER. Yes.
Mr. STURGES. Do you see more of this occurring?
Mr. LATKER. Yes.