Late in 1974 some human clinical experiments were conducted just around the corner from here by Dr. James Chan at the George Washington University Hospital. Because of prior research, most of which had been performed on chickens, rats, and dogs, Dr. Chan and his associates felt there was ample justification for small scale, tightly controlled tests on human subjects.

The experiments called for the use of a newly developed pharmaceutical agent. Naturally, in cases such as this the Hospital's Human Rights Committee must first give their official approval. Then each patient is advised of the experimental nature of his/her treatment and given an "informed consent" release to sign.

The Patients, all suffering some form of renal dysfunction (kidney disease), were experiencing varying degrees of renal osteodystrophy, a disease ~~of the bones~~ in which newly available calcium is not readily absorbed by the bones of the body. Over time this disease permits calcium to leach out of the skeletal structure leaving it brittle and weakened. Eventually, if not effectively treated, the victim of renal osteodystrophy becomes near totally handicapped, unable to walk without the assistance of prosthetic devices.

The experimental compound used by Dr. Chan was a metabolite of vitamin D-3, known as "1,25 Dihydroxycholecalciferol". This compound is identical with vitamin D-3 with the simple addition of 2 hydroxyl radicals (-OH) at the 1st and 25th carbon atom sites. One of these OH groups is added to the vitamin by action of the kidney (to be more precise the mitochondria of the renal cortex) in the normal, healthy human being. Consequently, in the patient with kidney failure, who must undergo regular hemodyalysis to escape uremic poisoning, the metabolism of vitamin D is interrupted in such a way that it can't perform the functions it must if good health is to be maintained.

To return to Dr. Chan and his associates at GWU Hospital, his patients were adolescents who had already been on the kidney machine for an extended period. The calcium was leaching out of their bones making them brittle, weak, prone to breaking. If this condition could not be corrected, they would eventually suffer permanent damage.

In the USA, there are approximately 50,000 victims of this renal osteodystrophy condition each year. Ten percent of these are children. Anyone who is kidney machine dependent for 6 months or longer is subject to the disease to some degree, but most frequently it inflicts the greatest damage on children whose bones

are in a stage of ~~normally~~ rapid growth.

Dr. Chan's patients were mostly in their teens and already owed their lives to twice weekly treatment on the GWU hemodyalysis unit, the apparatus that filters the blood of impurities that are normally excreted by the kidneys. But his patients were slowly losing their rescued existence to deteriorating bones. Beginning in April 1974, the experimental compound was administered to the patients at the same time as their machine treatments.

Over a period of months, X-Ray evidence showed conclusively that the compound performed the same way when administered orally as when produced naturally by action of the kidney and liver. In short, the calcium leaching stopped and the bone lesions healed. The treatment was dramatically successful. This would be a happy ending except for a few technicalities. If you, a relative, or close friend of yours were unfortunate enough to become one of this year's 50,000 victims, you wouldn't be able to go around the corner to GWU Hospital for treatment. No, if you needed treatment with 1,25 Dihydroxy vitamin D-3, a substance which every human body produces to maintain itself, you would have to go to France or some other country where it is licensed for general use. It's general use is illegal in the United States. A chemical which is present in the blood plasma of everyone of us here today, always has been and always will be if we are lucky enough to stay healthy, has not been sufficiently tested to be deemed safe by the U.S. Government. This state of affairs is the direct result of statutory law, passed by Congress in its wisdom and administered by FDA, the same folks who brought you the recent ban on saccaharine and the cyclamate scare of a few years ago. But before I get too deeply into the conflicts of Executive Agencies, or the far wider debate on whether our Government regulates too much or too little, or even into the realm of one of our society's paramount political issues, "centralization of power vs individual rights". before I digress to these topics, let me address the notion of ethics in public policy. — the conduct of scientific

Ethics is one of those words that can have a slippery meaning. Too often "ethical" is something we feel is right, and unethical is something our enemies feel is right. If we can just say that an ethical judgement is one based on a system of moral values governing commonly held notions of right and wrong, then that slippery essence begins to come clear.

The problem is "commonly held" notions of right and wrong." History has seldom witnessed a society as seethingly pleuralistic as our own. In such a society, plowing as it is through the surf of the 20th century's closing decades, figuring out what those commonly held notions are isn't as easy as it once was. a public law which regulates the introduction of new pharmaceutical agents onto the market and administered by FDA represents a notion, held in common by the majority of the U.S. Congress, on what is "right" for the American people. Yet in the case of individuals suffering from the disease treated by Dr. Chan, the unavailability of 1,25 Dihydroxy vitamin D-3 claarly does not seem to be right, proper, or just. To what extent, and under what circumstances should society withhold this treatment to those who critically need it, in order to protect the population at large from a possible or theoretical danger? This issue, which is, as you know, at the root of much debate in public policy issues concerning science, is fraught with many examples of well meaning government intervention that frequently results in denial of products or services for which there is a pressing need. The FDA requires on the average 4½ years to license a new pharmaceutical agent. The basic patents for the vitamin D-3 metabolites

were issued in 1968, yet today in 1977 ~~they~~ the compounds are still generally unavailable because they are not licensed. This type of delay is not uncommon. There is an anti-convulsant, Clonozapam, used for the treatment of Petit Mal seizure, licensed overseas, and especially useful in cases where the drug of choice, Dilantin, is poorly tolerated. It took 11 years from the time the license application was made until it was granted. Another pharmaceutical, chenic acid, marketed under the name Ulmenide by Hoffman La Roche in Switzerland has been demonstrated to dissolve 60% of gall stones due to the build up of cholesterol when gaulic acid is not present in bile fluid to a sufficient degree. This drug was discovered in Nutley, New Jersey, but now almost 8 years later, it is not available to Americans who must seek relief from the only other technique available, surgery. What is the social cost over the years of the pain and expense of surgery compared to the benefits of simple pharmaceutical administration?

No one can question the motives of those who call for strict regulation of pharmaceuticals by the government, yet there is a clear danger that the needs of those disease victims who must wait that space of time between innovation

and regulated application are not being paid fair heed to. After all, it is their safety that is in danger, not the safety of the general public. If there is a choice between disease and the possible ill effect of treatment, shouldn't the patient ~~have that decision~~ choose? This question becomes even more acute in the case of a drug known as Laetrile, not because of its ill effect, but because of its nil effect. Although licensed for cancer treatment overseas, it has been found to have no detectable effect on cancer. Yet, what of the psychological effect of withholding a treatment from a terminally ill person? Is the government protecting citizens from being ripped off or denying hope to the dying who know that there is something available to foreigners that they can't have? One of the "on the air" calls to President Carter on the radio last month dealt with this exact question.

There is a tragic irony in the fact that with drugs so frequently, "apparently" "ethical judgements" made to avert potential harm or injustice end up permitting very real suffering ~~which is all too real~~. In addition to the past examples, let me relate one more example, ~~and~~ perhaps the most famous. A noble gesture made by Sir Alexander Flemming in the late 1920's was a cause

for this same man's most bitter regret in subsequent years. Without filing a patent application, Dr. Flemming published his historic discovery, and in doing so voided his rights to sole ownership of the commercial possibilities of Penicillin. He did this out of a feeling that the discovery belonged to the world. He did not want the immense ~~political~~ income. Financial reward did not interest him. However, the loss of exclusive rights due to publication had an effect he hadn't counted on. Since no pharmaceutical firm could be certain of a period of proprietary rights of production, the risk of investing large sums for the necessary capital equipment ~~for production~~ could not be justified. For 11 years the miracle of Penicillin languished. It was only resurrected due to perhaps the most immoral, unethical event of the century, WWII. It has been estimated that 5 million people a year died who might have lived with administration of the wonder drug. 55 million people between 1930 and 1941 whose mortality rested on Alexander Flemming's conscience, and a short-sighted, "ethical judgement". In this case Flemming's ignorance of an economic reality, his failure to understand the market system, cost a heavy price. He might easily have used his income to support charity, education, science, medicine, or any number of worthy causes,

but by destroying the opportunity for profit itself, he put an enormous barrier between Penicillin and the public. Barriers between innovation and public availability are becoming increasingly more prevalent.

In the case of Penicillin the barrier was clearly a bad thing, but in the most obvious counterexample, the Thalidomide tragedy, a more stringent barrier might have prevented a modern nightmare. In these two premier cases of a miscalculation in ethical judgement, the barrier to innovation troubled the lives of many millions more individuals than the lack of a barrier did. Perhaps assessing human damage in so empirical or quantifiable a manner is itself unethical, yet without it we are left totally to the subjective impression. The objectivity of an empirical analysis of cost, risk, benefit, or effectiveness of one course of action compared to an alternative is almost the only defense there is against a purely partisan viewpoint. When the official in public service is confronted with a choice of assisting implementation of a new product or opening up an avenue of new research vs hindering the introduction of scientific technological effort, she/he must balance the benefits vs the costs or in the case of

research, potential risks of cost. When the results of human endeavor backfire, and there is a price to pay in human lives or misery, then there is turmoil until blame is assessed and precautions are laid to insure no similar future error. But think for a moment, what happens when a beneficial course of action, product or servide is not implemented or is greatly delayed? Lack of helpful change is somehow less galvanizing than the commission of hurtful change. Likewise, in the case of potential risks and benefits that must be envisioned when one considers basic research, it is the risk of failure or accident, and not the known or potential rewards which most preoccupy the public mind. How many people here knew the facts behind Thalidomide, but had not heard the story of Penicillin's almost none existent journey to market? How many of you realized some pharmaceuticals are cleared for use after periods of time that average 4½ years but frequently take 8,9, 10 years or even longer?

I think it is safe to say that there have been errors in ethical judgement made both through commission and by omission, yet it seems to be only the committed mistakes which enflame the passions in most people. Curiously, where

scientific innovation is concerned this phenomena has made some people work toward conservative ends that are designed to hinder or stifle scientific progress. Yet these same people will most often claim to be liberal or progressively inclined, while they work to put up barriers to innovation. In our decisions which balance (compare) costs to benefits at time 1 with other costs and benefits at time 2 we cannot afford to lose sight of either source of error. We may do something wrong, but we may also not do something right.



Daniel S. Goldin

the choice of Vice President Dan Quayle's National Space Council, Goldin has spent much of his career in the classified world of spy satellites. Even spy expert Jeffrey Richelson, author of *America's Secret Eyes in Space*, concedes: "I've never heard of him."

Goldin, 51, is a New York native and a 1962 engineering graduate from the City College of New York. He has worked as a research scientist at NASA, and since 1987 has been vice president and general manager of the TRW Space and Technology Group in Redondo Beach, California, which develops secret payloads for the military as well as robot research devices for NASA. Projects in TRW's "black" portfolio are parts of the KH-11 imaging spy satellite, the MILSTAR satellite communications system, and the Strategic Defense Initiative Organization's "Brilliant Pebbles" anti-missile package. TRW also gets credit for its work on NASA's highly successful Compton Gamma Ray Observatory, the Tracking and Data Relay Satellites, and the still unfinished Advanced X-ray Astrophysical Observatory. Although his background is in robotics, Goldin is also said to favor programs that would send humans to Mars and beyond.

There is some concern on Capitol Hill about Goldin's lack of political experience. "This guy comes from a defense world where you don't talk about what you're doing or why you're doing it," says one congressional aide, adding that "the head of NASA needs to have a political profile, to be an advocate." Still, the aide says he anticipates no "overt opposition to the nomination."

Strange Bugfellows

What do you call it when a pest-control company sponsors a museum's display of insects? Cognitive dissonance? Or maybe just financial necessity. That's what led the Smithsonian Institution to accept the sponsorship of the Orkin Pest Control Co. for their popular insect zoo. The firm, whose motto is "We destroy them all," has given $500,000 to the museum for a much-needed renovation.

The Washington Post quotes Frank Talbot, director of the National Museum of Natural History, to the effect that "what we're doing is creating a public-private partnership," which, he says, is the only way to get things done "with the current budgetary crisis." And Orkin is happy for the chance to show its eco-side—"We share the philosophy that insects are a vital part of nature," says a spokesperson.

The newly named O. Orkin Insect Zoo will re-open in September 1993 with several new exhibits, including a Florida mangrove swamp habitat, a rain forest, and a desert habitat. Those won't be the only new features of the zoo. Also on show will be the Orkin corporate logo—breaking from the Smithsonian's old policy, which barred the display of corporate emblems in permanent exhibits.

Needleman Redux

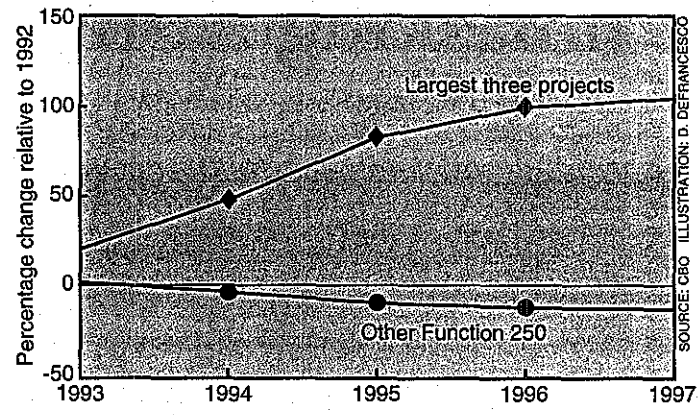
Psychiatrist Herbert Needleman of the University of Pittsburgh, widely known for work linking childhood lead exposure to lowered IQs, is back in the news. A university panel that has been looking into charges of scientific misconduct by Needleman has determined that a formal investigation is appropriate.

The charges relate to a paper by Needleman and colleagues that was published in the 29 March 1979 issue of *The New England Journal of Medicine*. Regarded as a landmark in the field, it showed that increased childhood exposure to environmental lead, as measured by lead levels in baby teeth, correlated with subsequent behavioral and intelligence deficits. Although the research results have been replicated, critics such as Claire Ernhart of Case Western Reserve University and Sandra Scarr of the University of Virginia have repeatedly raised questions about the criteria Needleman used to select his subjects and statistical methods used in the paper (*Science*, 23 August 1991, p. 253). Late last year, the NIH Office of Scientific Integrity asked the University of Pittsburgh to determine whether a formal investigation was necessary.

Needleman maintains that the allegations are purely the result of a lead industry effort to discredit his research. He has asked that Pittsburgh make public the typically confidential investigation process, and says he is confident that he will be completely cleared. While the preliminary inquiry concluded there may be methodological problems with the paper, Needleman says the inquiry determined that he did not "fabricate, falsify or plagiarize," when conducting the original research.

According to Jerome Rosenberg, research integrity officer for the university, the investigation should be completed by mid-May.

Small Science Squeeze



If practitioners of "small science" are looking for confirmation of their fear that "big science" is threatening their livelihood, they will find it in a staff memorandum prepared by the Congressional Budget Office (CBO). CBO points out that the three biggest civilian science and technology projects—the space station, the Earth Observing System, and the Superconducting Super Collider—account for two-thirds of the Administration's proposed fiscal year 1993 increase in the budget category known as Function 250, which includes the National Science Foundation, much of the National Aeronautics and Space Administration, and the general science programs of the Department of Energy. What's worse for small science devotees is that this year's proposal may be only the thin end of the wedge. CBO projects that the annual budgetary needs of the three mammoth projects will double between 1992 and 1997—yet the Administration's budget assumes flat funding for Function 250 beyond 1993. If those projections turn out to be correct—a big if—the result isn't hard to figure: Small science gets squeezed (see chart). Some relief would come from allowing Function 250 to grow. But, as CBO points out, there will be increasing pressure to cut total government spending to hold down the ballooning federal deficit, with the result that "by 1995, the cumulative cuts will be so large that Function 250 is unlikely to escape without any reduction."

Ten Commandments

OF GOOD ORGANIZATION

There are two kinds of efficiency; one kind is only apparent and is produced in organizations through the exercise of mere discipline. This is but a simulation of the second, or true, efficiency which springs, as Woodrow Wilson said, from "the spontaneous cooperation of a free people." If you are a manager, no matter how great or small your responsibility, it is your job, in the final analysis, to create and develop this voluntary cooperation among the people whom you supervise. For, no matter how powerful a combination of money, machines and materials a company may have, this is a dead and sterile thing without a team of willing, thinking and articulate people to guide it.

1. Definite and clean-cut responsibilities should be assigned to each executive.

2. Responsibility should always be coupled with corresponding authority.

3. No change should be made in the scope or responsibilities of a position without a definite understanding to that effect on the part of all persons concerned.

4. No executive or employee, occupying a single position in the organization, should be subject to definite orders from more than one source.

5. Orders should never be given to subordinates over the head of a responsible executive. Rather than do this, management should supplant the officer in question.

6. Criticisms of subordinates should, whenever possible, be made privately, and in no case should a subordinate be criticized in the presence of executives or employees of equal or lower rank.

7. No dispute or difference between executives or employees as to authority or responsibilities should be considered too trivial for prompt and careful adjudication.

8. Promotions, wage changes, and disciplinary action should always be approved by the executive immediately superior to the one directly responsible.

9. No executive or employee should ever be required, or expected, to be at the same time an assistant to, and critic of, another.

10. Any executive whose work is subject to regular inspection should, whenever practicable, be given the assistance and facilities necessary to enable him to maintain an independent check of the quality of his work.

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Wall St. Journal — July 24, 1997

ENTERPRISE

FTC Freezes Assets at Invention-Promotion Firms

By RODNEY HO
Staff Reporter of THE WALL STREET JOURNAL

The Federal Trade Commission, in its biggest crackdown ever on invention-promotion companies, announced that it froze the assets of several such concerns that it alleged engaged in deceptive marketing. The Pennsylvania attorney general's office took similar action against a separate company.

The FTC said the firms have generated at least $90 million in revenue from tens of thousands of victims.

Invention-promotion companies attempt to help inventors market their products. Unscrupulous operators in the field often promise fledgling inventors that their products will sell even if they have little commercial value. Though such operators commonly create product brochures and mass-mail them to manufacturers, the mailings typically get few responses.

The victims of the unscrupulous promoters rarely succeed in selling their inventions or products but often pay several thousand dollars up front for the promotion service. Legitimate marketing firms usually take a cut of royalties or licensing fees rather than upfront fees, advocates note.

Though the FTC has punished several invention-marketing firms over the years, this is the first time it has targeted multiple entities at once.

The FTC and the State of Pennsylvania obtained court orders from U.S. district courts in Alexandria, Va., and Pittsburgh authorizing the freezing of assets and restraining the companies from misrepresentation of their services.

The FTC is also working with the U.S. Patent and Trademark Office and the Department of Justice to pool information about law enforcement efforts and to develop an education program to inform inventors before they get hooked by unscrupulous promoters.

Robert Lougher, a consumer advocate and head of the Inventors Awareness Group Inc. in Westfield, Mass., said he has seen a "marked increase" in marketing by these companies, especially on television. "They possibly sense the end is near, and are trying to make a last-minute buck," said Mr. Lougher, who once worked for an invention-promotion company.

The FTC said Oscar Esdelle, a Jamaica, N.Y., construction worker, is a "typical victim" of the promoters. In 1995, Mr. Esdelle said he had what he thought was a great invention: a toothpaste-dispensing toothbrush. He responded to an advertisement of Invention Consultants USA Inc., Washington D.C. (The concern is no longer operating but its principals are working in similar firms named in the FTC case.)

Invention Consultants studied the invention for $500 and concluded that it was a viable idea, Mr. Esdelle said. For a further $3,950, he said he was promised services to get his product patented and marketed. But he said that once he paid the money, the firm didn't return his calls, and in the end, he received no services from it.

Mr. Esdelle received a $1,000 refund, said Arthur Salzberg, an attorney representing **Azure Communications** Inc. of Reston Va., which worked with Invention Consultants. Azure is named as a defendent in the FTC case.

Other invention promotion companies named as defendants in the FTC case include: **American Invention Associates** Inc. of Miami; **Concept Network** of Indiana, Pa., and Wexford, Pa.; **Davison & Associates** of Oakmont, Pa., and Indianola, Pa.; **Eureka Solutions International** Inc. and **OEM Communications**, both in Monroeville, Pa. Another company's investigation is still under court-ordered seal, the FTC said.

Attorneys for American Invention Associates and Davison said that the assets of those two companies have been unfrozen, although the charges remain in force.

The company that the Pennsylvania attorney general's office targeted is **International Inventors Club** Inc. of Pittsburgh.

Attorneys for American Invention Associates, Davison and OEM and Eureka all deny the charges. Attorneys for the other companies couldn't be reached.

ANHEUSER-BUSCH COS.

Net Income Declines 2.5%; Dividend Is Increased 8.3%

Anheuser-Busch Cos. said second-quarter net income fell 2.5% because the year-earlier period benefited from a one-time gain. The St. Louis-based brewer also raised its quarterly dividend 8.3% to 26 cents from 24 cents, payable Sept. 9 to stock of record Aug. 11. Net income fell to $381.2 million, or 76 cents a share, from $387.2 million, or 78 cents a share. The year-earlier quarter included a one-time gain of $33.8 million, or seven cents a share, from the sale of the St. Louis Cardinals baseball team. Sales, excluding excise taxes, rose 1% to $2.99 billion. Anheuser shares fell $2.625 to $45.25 in New York Stock Exchange composite trading amid concerns about beer-price discounting. The brewer said price-cutting that began in the first quarter spilled over into the second, and that it now expects per-share profit growth for 1997 to trail slightly its double-digit annual goal.

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DRAFT AGREEMENT C.

DRAFT Agreement B.

Collaborative Research Agreement

This Agreement, effective _____, 1986, is by and between _____ and the _____ (hereinafter referred to as _____, National Institutes of Health (NIH), a component agency of the Department of Health and Human Services (DHHS).

1. During the term of this Agreement, _____ will provide through the _____ salary and salary dependent charges for a postdoctoral research worker (the _____ postdoctoral research fellow), who will work on the project for _____ as a Guest Worker at NIH, miscellaneous supplies and expense items in the amount of $_____ for the first year and for the second year commencing October 1, 1987, $_____.

2. The Principal Investigator for the study is Dr. _____. The Principal Investigator is responsible for performing the work described in the research protocol attached at Tab A. In the event the Principal Investigator becomes unable to complete the protocol for any reason, _____ and _____ may mutually agree to a substitute Principal Investigator, in which event this Agreement shall continue in full force and effect. If _____ and _____ cannot agree on a substitute, this Agreement shall immediately terminate.

depending on the presence of five semiplates (3, 4, 5, 6, 7, fig 13) or one single plate (2) with mobile arm, the joint has the following applications: 3.a and 4.a:

3. one plate (1, fig. 28) and five semiplates (3, 4, 5, 6, 7, fig 28):
   3.a Leg extension, when one semiplate (6) with arm (6.1) is screwed to the machine, while the plate (1) with arm (1.1), featuring the central opening (9), can move.

4. two plates with arm (1,1, fig. 27), where one of them consists in the union of the five semiplates (3, 4, 5, 6, 7)
   4.a Leg Extension (fig 27), when one plate with arm is screwed to the machine, while the other plate (1) with arm (1.1, fig. 27) can move.

Regulatory Affairs all functions, authority, and responsibility of the Director under section 552a of title 5, United States Code, under Executive Order 12046 and Reorganization Plan No. 1 for telecommunications, and under section 111 of the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 759).

SEC. 4. (a) Section 400A of the General Education Provisions Act is amended by (1) striking out "and" after "institutions" in subsection (a)(1)(A) and inserting in lieu thereof "or", and (2) by amending subsection (a)(3)(B) to read as follows:

"(B) No collection of information or data acquisition activity subject to such procedures shall be subject to any other review, coordination, or approval procedure outside of the relevant Federal agency, except as required by this subsection and by the Director of the Office of Management and Budget under the rules and regulations established pursuant to chapter 35 of title 44, United States Code. If a requirement for information is submitted pursuant to this Act for review, the timetable for the Director's approval established in section 3507 of the Paperwork Reduction Act of 1980 shall commence on the date the request is submitted, and no independent submission to the Director shall be required under such Act.".

(b) Section 201(e) of the Surface Mining Control and Reclamation Act of 1977 (30 U.S.C. 1211) is repealed.

(c) Section 708(f) of the Public Health Service Act (42 U.S.C. 292h(f)) is repealed.

(d) Section 5315 of title 5, United States Code, is amended by adding at the end thereof the following:

"Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget.".

SEC. 5. This Act shall take effect on April 1, 1981.

Speaker of the House of Representatives.

Vice President of the United States and President of the Senate.

FY 1998 AUTM LICENSING SURVEY
ORDER FORM

The AUTM Licensing Survey is a national survey that provides objective information related to the field of academic technology transfer. The FY 1998 Survey report includes data for 132 U.S. universities, 26 U.S. hospitals and research institutes, 20 Canadian institutions, and 1 patent management firm, and includes information on 92% of the top 100 universities (based on research volume). The Survey is prepared as a summary report and as a comprehensive report. The comprehensive report, referred to as the *Full Report*, contains the *Survey Summary* and includes tables that present data obtained from individual respondents on an institution-by-institution basis. To purchase copies of the Survey reports, complete the Order Information below.

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have any documented information about how these regulations came about, nor do they provide insight into the meaning of the term "share".

We would appreciate your assembling a package of all documents that might be relevant to our case, and identifying others that you do not have. Copies of any papers, memoranda, letters, notes or other documentation concerning the share provision in the Institutional Patent Agreements and all subsequent related legislation would be helpful. In addition, if any of the articles or speeches cited in your vitae are in any way relevant, we would like to obtain copies.

If you have any questions, please contact me. We look forward to meeting you in the near future and we look forward to working with you.

Very truly yours,

Minna F. Felig

Minna F. Felig

MFF:as
Enclosure

FAR APPORTIONMENT

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2	Definitions of Words and Terms
52	Solicitation Provisions and Contract Clauses
53	Forms

This list is subject to modification by agreement of both Councils.

* These parts have a shared community of interest and a case will be established on a case-by-case basis in accordance with procedures established in this Memorandum of Agreement.

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where the Government has determined to provide the continued funding to industry for development of such findings has been left to random and haphazard execution.

From the viewpoint of the Government and the public, the stake in closing this gap is very high. The sheer magnitude of Government support of research and development at universities demands evidence of useful results if it is to be continued in the prevailing competition for the Federal dollar. In fiscal year 1972, approximately $3.1 billion of the $12 billion; or over one quarter spent by the Government on research and development outside its own laboratories went in the form of grants and contracts to universities. Of the $3.1 billion the Department of Health, Education, and Welfare was responsible for administering $1.2 billion.

On September 23, 1975, the Federal Council on Science and Technology's Committee on Government Patent Policy recommended that all agencies of the Executive Branch provide to universities a first option to substantially all future inventions generated with Federal support, provided that the inventing organization is found to have an identified technology transfer function and subject to ~~strengthened march-in pro-~~ a number of conditions deemed necessary to protect the public interest. Some of the ~~visions.~~ In addition, the Committee also directed that an interagency committee be formed for the purpose of joint agency identification of universities having a satisfactory technology transfer function. more important conditions are,

(1) a royalty-free license permitting the Government and those functioning under Government direction to practice the invention,
(2) a limit on the term of any exclusive license granted,
(3) Department authority to withdraw specified ~~grants~~ from the agreement, ~~and~~ contracts or grants
(4) the right of the Department to regain ownership due to public interest considerations or the institution's failure to take effective steps to commercialize the invention.
(5) and a requirement that all royalties be used for research or educational purposes w/ the exception that 15 percent may be retained by the inventor

~~A more detailed outline of such conditions is enclosed.~~

this chapter, including but not necessarily limited to the following:

(1) section 10(a) of the Act of June 29, 1935, as added by title I of the Act of August 14, 1946 (7 U.S.C. 427i(a); 60 Stat. 1085);

(2) section 205(a) of the Act of August 14, 1946 (7 U.S.C. 1624(a); 60 Stat. 1090);

(3) section 501(c) of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951(c); 83 Stat. 742);

(4) section 106(c) of the National Traffic and Motor Vehicle Safety Act of 1966 (15 U.S.C. 1395(c); 80 Stat. 721);

(5) section 12 of the National Science Foundation Act of 1950 (42 U.S.C. 1871(a); 82 Stat. 360);

(6) section 152 of the Atomic Energy Act of 1954 (42 U.S.C. 2182; 68 Stat. 943);

(7) section 305 of the National Aeronautics and Space Act of 1958 (42 U.S.C. 2457);

(8) section 6 of the Coal Research Development Act of 1960 (30 U.S.C. 666; 74 Stat. 337);

(9) section 4 of the Helium Act Amendments of 1960 (50 U.S.C. 167b; 74 Stat. 920);

(10) section 32 of the Arms Control and Disarmament Act of 1961 (22 U.S.C. 2572; 75 Stat. 634);

(11) subsection (e) of section 302 of the Appalachian Regional Development Act of 1965 (40 U.S.C. App. 302(e); 79 Stat. 5);

(12) section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974 (42 U.S.C. 5901; 88 Stat. 1878);

(13) section 5(d) of the Consumer Product Safety Act (15 U.S.C. 2054(d); 86 Stat. 1211);

(14) section 3 of the Act of April 5, 1944 (30 U.S.C. 323; 58 Stat. 191);

(15) section 8001(c)(3) of the Solid Waste Disposal Act (42 U.S.C. 6981(c); 90 Stat. 2829);

(16) section 219 of the Foreign Assistance Act of 1961 (22 U.S.C. 2179; 83 Stat. 806);

(17) section 427(b) of the Federal Mine Health and Safety Act of 1977 (30 U.S.C. 937(b); 86 Stat. 155);

(18) section 306(d) of the Surface Mining and Reclamation Act of 1977 (30 U.S.C. 1226(d); 91 Stat. 455);

(19) section 21(d) of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2218(d); 88 Stat. 1548);

(20) section 6(b) of the Solar Photovoltaic Energy Research Development and Demonstration Act of 1978 (42 U.S.C. 5585(b); 92 Stat. 2516);

(21) section 12 of the Native Latex Commercialization and Economic Development Act of 1978 (7 U.S.C. 178(j); 92 Stat. 2533); and

(22) section 408 of the Water Resources and Development Act of 1978 (42 U.S.C. 7879; 92 Stat. 1360).

The Act creating this chapter shall be construed to take precedence over any future Act unless that Act specifically cites this Act and provides that it shall take precedence over this Act.

(b) Nothing in this chapter is intended to alter the effect of the laws cited in paragraph (a) of this section or any other laws with respect to the disposition of rights in inventions made in the performance of funding agreements with persons other than nonprofit organizations or small business firms.

(c) Nothing in this chapter is intended to limit the authority of agencies to agree to the disposition of rights in inventions made in the performance of work under funding agreements with persons other than nonprofit organizations or small business firms in accordance with the Statement of Government Patent Policy issued on ~~August 23, 1971, (36 Fed. Reg. 16887)~~ February 18, 1983, agency regulations, or other applicable regulations or to otherwise limit the authority of agencies to allow such persons to retain ownership of inventions. Any disposition of rights in inventions made in accordance with the Statement or implementing regulations, including any disposition occurring before enactment of this section, are hereby authorized, or

except that all funding agreements, including those with oth than small business firms and nonprofit organizations, sh include the requirements established in paragraph 202(c)(4) a section 203 of this title."

(d) Nothing in this chapter shall be construed to require the disclosure of intelligence sources or methods or to otherwise affect the authority granted to the Director of Central Intelligence by statute or Executive order for the protection of intelligence sources or methods.

§ 211. Relationship to antitrust laws

Nothing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law.

§ 212. Disposition of rights in educational awards

"No scholarship, fellowship, training grant, or other fund agreement made by a Federal agency primarily to an awardee educational purposes will contain any provision giving the Fed agency any rights to inventions made by the awardee.

dations submitted by the Office of Science and Technology Policy, may prescribe.

(b) AWARD.—The President shall periodically award the medal, on the basis of recommendations received from the Secretary or on the basis of such other information and evidence as he deems appropriate, to individuals or companies, which in his judgment are deserving of special recognition by reason of their outstanding contributions to the promotion of technology or technological manpower for the improvement of the economic, environmental, or social well-being of the United States.

(c) PRESENTATION.—The presentation of the award shall be made by the President with such ceremonies as he may deem proper.

Section 13 of that Act

SEC. [13] *15.* PERSONNEL EXCHANGES.

The Secretary and the National Science Foundation, jointly, shall establish a program to foster the exchange of scientific and technical personnel among academia, industry, and Federal laboratories. Such program shall include both (1) federally supported exchanges and (2) efforts to stimulate exchanges without Federal funding.

Section 14 of that Act

SEC. [14] *16.* AUTHORIZATION OF APPROPRIATIONS.

(a) There is authorized to be appropriated to the Secretary for purposes of carrying out section 6, not to exceed $19,000,000 for the fiscal year ending September 30, 1981, $40,000,000 for the fiscal year ending September 30, 1982, $50,000,000 for the fiscal year ending September 30, 1983, and $60,000,000 for each of the fiscal years ending September 30, 1984, and 1985.

(b) In addition to authorizations of appropriations under subsection (a) there is authorized to be appropriated to the Secretary for purposes of carrying out the provisions of this Act, not to exceed $5,000,000 for the fiscal year ending September 30, 1982, and $14,000,000 for each of the fiscal years ending September 30, 1983, 1984, and 1985.

(c) Such sums as may be appropriated under subsections (a) and (b) shall remain available until expended.

(d) To enable the National Science Foundation to carry out its powers and duties under this Act only such sums may be appropriated as the Congress may authorize by law.

Section 15 of that Act

SEC. [15] *17.* SPENDING AUTHORITY.

No payments shall be made or contracts shall be entered into pursuant to this Act except to such extent or in such amounts as are provided in advance in appropriation Acts.

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Counsel/designee (785.1(b)(1)); the contractor is required to commercialize any elected invention within a three year period (or a two year extension period(s) thereto (785.1(b)(2) and (c)(1)) from disclosure to DOE; and DOE certification of the applicability of the waiver provision (785.1(b)(3) and (c)(4). These restrictions are not only burdensome on domestic large businesses, they also vest too much discretion in DOE in their application to a given factual situation. In addition, they are contrary to the intent of the President's February 18, 1983 Patent Policy Memorandum and the clear instructions on page two in the fact sheet attached thereto referring to the Department of Energy. This sheet recognizes that DOE will continue to operate under statutes which are inconsistent with the Memorandum and states DOE is "to make maximum use of the flexibility available to them to comply with the provisions and spirit of the Memorandum." (underscoring supplied). Putting unnecessary restrictions on DOE contractors not specifically required by statute are, in our opinion, contrary to the spirit and intent of the President's Patent Policy Memorandum. Where are these same or similar restrictions found in the guiding provisions of 35 USC 202 for a contractor to be allowed to elect to retain title?

For the above reasons, we must reaffirm our objection to the issuance of the proposed DOE Patent Waiver Regulation. It is our recommendation that this regulation not be issued until a further review is made under the new Administration.

Attachments (2)

(2) Description of the Related Art: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(f) Brief Summary of the Invention: A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(g) Brief Description of the Several Views of the Drawing(s): A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(h) Detailed Description of the Invention: A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. This item may also be titled "Best Mode for Carrying Out the Invention." Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(I) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet. (37 CFR 1.52(b)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps.

inventors and small businesses. Once open, we intend that no conditions which impede commercial application of results be imposed. In that regard all background rights of these grantees must be honored and all inventions made retained by the grantee. Only in this way will we be able to assure that SBIC will consider second and third tier investment in bringing grant results to the marketplace. Establishing these conditions will in most part make current grant programs comparable to ONR's program of the 50's and 60's.