

A. Organization:

- Present the key management roles and responsibilities in the company.
- Discuss the individuals who will fill each position.
- If it is not possible to fill each executive role with a full-time person without adding excessive overhead, indicate how these functions will be performed (e.g., using part-time specialists or consultants to perform some functions), who will perform them, and when they will be replaced by a full-time staff member.
- If any key individuals will not be on board at the start, indicate when they will join the company.
- Discuss any current or past situations where key management people have worked together that could indicate how their skills complement each other and result in an effective management team.

B. Key Management Personnel:

- For each key person, describe career highlights, particularly relevant know-how, skills, and track record of accomplishments that demonstrate his or her ability to perform the assigned role. Include in your description sales and profitability achievements (budget size, numbers of subordinates, new product introductions, etc.) and other prior entrepreneurial or general management results.
- Describe the exact duties and responsibilities of each of the key members of the management team.
- Complete resumes for each key management member need to be included here or as an exhibit and need to stress relevant training, experience, any concrete accomplishments, such as profit and sales improvement, labor management success, manufacturing or technical achievements, and meeting of budgets & schedules.

C. Management Compensation and Ownership:

- State the salary to be paid, the stock ownership planned, and the amount of their equity investment (if any) of each key member of the management team.

D. Other Current Investors:

- Describe here any other investors in your venture, the number and percentage of outstanding shares they own, when they were acquired, and at what price.

E. Employment and Other Agreements, Stock Options and Bonus Plans:

- Describe any existing or contemplated employment or other agreements with key members.
- Indicate any restrictions on stock and vesting that affect ownership and disposition of stock.
- Summarize any incentive stock option or other stock ownership plans planned or in effect for key people and employees.

F. Board of Directors:

- Discuss the company's philosophy about the size and composition of the board.
- Identify any proposed board members and include a one or two sentence statement of the member's background that shows what he or she can bring to the company.

G. Other Shareholders, Rights, and Restrictions:

- Indicate any other shareholders in your company and any rights and restrictions or obligations, such as notes or guarantees, associated with these. (If they have all been accounted for above, simply note that there are no others.)

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H. Supporting Professional Advisors and Services:

- Indicate the names and affiliations of the legal, accounting, advertising, consulting, and banking advisors selected for your venture and the services each will provide.

SECTION IX: OVERALL SCHEDULE

A graphical schedule that shows the timing and interrelationship of the major events necessary to launch the venture and realize its objectives is an essential part of a business plan. The underlying cash conversion and operating cycle of the business will provide key inputs for the schedule. In addition to being a planning aid by showing deadlines critical to a venture's success, a well-presented schedule can be extremely valuable in convincing potential investors that the management team is able to plan for venture growth in a way that recognizes obstacles and minimizes investor risk. Since the time necessary to do things tends to be underestimated in most business plans, it is important to demonstrate that you have correctly estimated these amounts in determining the schedule.

Create your schedule as follows:

Step 1: Prepare a month-by-month schedule that shows the timing of such activities as product development, market planning, sales programs, production, and operations, and that includes sufficient detail to show the timing of the primary tasks required to accomplish an activity.

Step 2: Show on the schedule the deadlines or milestones critical to the venture's success, such as:

- Incorporation of the venture.
- Completion of design and development.
- Completion of prototypes.
- Rental of facilities.
- Obtaining of sales representatives.
- Obtaining product display at trade shows.
- Hiring of key managers.
- Obtaining critical financing.
- Initiating marketing activities and in what order.
- Signing up of distributors and dealers.
- Ordering of materials in production quantities.
- Starting of production or operation.
- Receipt of first orders.
- Delivery on first sale.
- Receiving the first payment on accounts receivable.

Step 3: Show on the schedule the "ramp up" of the number of management personnel, the number of production and operations personnel, and plant or equipment and their relation to the development of the business.

Step 4: Discuss in a general way the activities most likely to cause a schedule slippage, what steps will be taken to correct such slippages, and the impact of schedule slippages of the venture's operation, especially its potential viability and capital needs.

Note: You want to be fairly detailed for the first six months to a year, and then just hit key developments or benchmarks for years two and three. A three-year schedule is adequate

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SECTION X: CRITICAL RISKS, PROBLEMS AND ASSUMPTIONS

The development of a business has risks and problems, and the business plan invariably contains some implicit assumptions about these issues. You need to include a description of the risks and the consequences of adverse outcomes relating to your industry, your company and its personnel, your product's market appeal, and the timing and financing of your startup. Be sure to discuss assumptions concerning sales projections, customer orders, and so forth. If the venture has anything that could be considered a fatal flaw, discuss why you do not see it as a problem or how you intend to overcome it. The discovery of any unstated negative factors by potential investors can undermine the credibility of the venture and endanger its financing. Be aware that most investors will read the section describing the management team first and then this section. It is therefore recommended that you not omit this section. If you do, the reader will most likely come to one or more of the following conclusions:

1. You think he or she is incredibly naïve or stupid, or both.
2. You hope to pull the wool over his or her eyes.
3. You do not have enough objectivity to recognize and deal with assumptions and problems.

Identifying and discussing the risks in your venture demonstrate your skills as a manager and increase credibility of you and your venture with a venture capital investor or a private investor. Taking the initiative on the identification and discussion of risks helps you to demonstrate to the investor that you have thought about them and can handle them. Risks then tend not to loom as large black clouds in the investor's thinking about your venture.

1. Discuss assumptions implicit in your plan. Examples of key assumptions might include:

- Revenue forecasts (price, volumes, discounts, margins).
- Development expenses (number of people, key salaries, sub-contracts)
- Average cost of a unit.
- COGS (material, etc.).
- Working capital (accounts receivable, inventory, payables)
- Capital expenditures (major items)
- Ability to obtain key distribution channel.
- Getting a patent licenses or permit.
- Rate of growth in sales.
- Obtaining a particular site or facility that is key to the business.
- Hiring of key staff members with experience in a critical area.
- Approval of critical financing.
- Overcoming key obstacles in product design.

2. Identify and discuss any major problems and other risks, such as:

- Running out of cash before orders are secured.
- Competitor risks e.g. you are pre-empted in the market by a competitor
- Technological risks i.e. cannot make the product work
- Potential price-cutting by competitors.
- Any potential unfavorable industry-wide trends.
- Design or manufacturing costs in excess of estimates.
- Sales projections not achieved.
- Difficulties or long lead times encountered in the procurement of parts or raw materials.
- Difficulties encountered in obtaining needed bank credit.
- Larger-than-expected innovation and development costs.

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- Running out of cash after orders pour in.
3. Indicate what assumptions or potential problems and risks are most critical to the success of the venture, and describe your plans for minimizing the impact of unfavorable developments in each case. What is the worst-case scenario and how will you respond? Focus on risks that are important and critical to your business, not the ordinary operating risks faced by any business.

SECTION XI: FINANCIAL PLAN

A. Highlights of the Financial Statements:

In the write up of this section, discuss the highlights of your financial statements. The section lays out a picture of the financial performance of the firm as it is started, stabilizes and grows. The financial plan is basic to the evaluation of an investment opportunity and needs to represent your best estimates of financial requirements. The purpose of the financial plan is to indicate the venture's potential and to present a timetable for financial viability. It also can serve as an operating plan for financial management using financial benchmarks. In preparing the financial plan, look creatively at the venture and think about bootstrapping techniques, especially in the early days.

Highlight the important conclusions, such as what is the maximum amount of cash required is and when it will be required, the amount of debt and equity needed, how fast any debts can be repaid, etc., start up costs, etc. Given the earlier discussed strategies and assumptions, show when the venture will attain a positive cash flow. Show if and when you will run out of cash. Note any significant stepwise changes in cash flow that will occur as you grow and add capacity. Given your entry strategy, marketing plan, and proposed financing, how long it will take to reach a unit breakeven sales level. How many months to breakeven? Highlight sales and profit performance patterns over time.

To help validate your financials compare critical financial ratios from your plan with those of your industry. Explain and justify significant differences.

Pro forma income statements are the plan-for-profit part of financial management and can indicate the potential financial feasibility of a new venture. Usually the level of profits, particularly during the start-up years of a venture, will not be sufficient to finance operating asset needs, and since actual cash inflows do not always match the actual cash outflows on a short-term basis, a cash flow forecast that will indicate these conditions and enable management to plan cash needs is recommended. Further, pro forma balance sheets are used to detail the assets required to support the projected level of operations and through liabilities, to show how these assets are to be financed. The projected balance sheets can indicate if debt-to-equity ratios, working capital, current ratios, inventory turnover and the like are within the acceptable limits required to justify future financing that are projected for the venture.

B. Cost Controls:

Describe how you will obtain information about report costs and how often, who will be responsible for the control of various cost elements, and how you will take action on budget overruns. Explain any unusual items not identified in the financial statement.

C. Documents to be Developed for this Section (Put Financial Statements in Appendix)

As part of the financial plan, financial exhibits need to be prepared. Be sure to give the investors the columns and rows that they want to see. The more detail you give them, the more difficult it will be for them to challenge your assumptions. You need to prepare: i) Pro forma income statements (3-5 years, done monthly for at least the first 1-2 years); ii) Pro forma balance sheets (3-5 years), and iii) Pro forma cash flow analysis (3-5 years, done monthly for at least the first 1-2 years). To estimate cash flow needs, use cash-based, rather than an accrual-based, accounting (i.e., use a real-time cash flow analysis of expected receipts and disbursements).

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On the appropriate exhibits, or in an attachment, assumptions behind such items as sales levels and growth, collections and payables periods, inventory requirements, cash balances, cost of goods, and so forth, need to be specified. Your analysis of the operating and cash conversion cycle in the business will enable you to identify these critical assumptions.

Pro Forma Income Statements:

- YR1 - Monthly
YR2 - Quarterly
YR3-5 - Annually
- Using sales forecasts and the accompanying operating costs, prepare pro forma income statements for at least the first three years. Be sure these numbers are consistent with what is being proposed in all the earlier sections of the plan (marketing, operations, management team, etc.)
 - Fully discuss assumptions (e.g., the amount allowed for bad debts and discounts, or any assumptions made with respect to sales expenses or general and administrative costs being a fixed percentage of costs or sales) made in preparing the pro forma income statement and document them.
 - Draw on Section X of the business plan and highlight any major risks, such as the effect of a 20% reduction in sales from those projected or the adverse impact of having to climb a learning curve on the level of productivity over time, that could prevent the venture's sales and profit goals from being attained, plus the sensitivity of profits to these risks.

Pro Forma Balance Sheets:

YR1-5 - Annually

Prepare pro forma balance sheets semi-annually in the first year and at the end of each of the first three years.

Pro Forma Cash Flow Analysis:

- YR1 - Quarterly
YR2-5 - Annually
- Project cash flows monthly for the first year of operation and quarterly for at least the next two years, detailing the amount and timing of expected cash inflows and outflows; determine the need for and timing of additional financing and indicate peak requirements for working capital; and indicate how needed additional financing is to be obtained, such as through equity financing, bank loans, or short-term lines of credit from banks, on what terms, and how it is to be repaid. Remember they are based on cash, not accrual, accounting. Explain how much money you will need. For debt funding, what will you use as collateral? How will the money be used for working capital, R&D, marketing, capital acquisitions? This dictates the level of risk of the investment. Investors generally feel that expenditures for R&D and marketing are riskier than are expenditures for capital acquisitions.
 - Discuss assumptions, such as those made on the timing of collection of receivables, trade discounts given, terms of payments to vendors, planned salary and wage increases, anticipated increases in any operating expenses, seasonality characteristics of the business as they affect inventory requirements, inventory turnovers per year, capital equipment purchases, and so forth. Again, these are real time (i.e., cash), not accrual.
 - Discuss cash flow sensitivity to a variety of assumptions about business factors (e.g., possible changes in such crucial assumptions as an increase in the receivable collection period or a sales level lower than that forecasted).

SECTION XII: PROPOSED COMPANY OFFERING

The purpose of this section of the plan is to indicate the amount of any money that is being sought, the nature and amount of the securities offered to the investor, a brief description of the uses that will be made of the capital revised, and a summary of how the investor is expected to achieve its targeted rate of return.

It is important to realize the terms for financing your company that you propose here are only the first step in the negotiation process with those interested in investing, and it is very possible that your financing will involve different kinds of securities than originally proposed.

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A. Desired Financing:

- Review the monthly real-time cash flow projections and your estimate of how much money is required over the next three years to carry out the development and/or expansion of your business as described.
- Determine the amount and timing of cash infusions required to prevent cash balances from going negative. Add a cash safety cushion (~25% as a good "guesstimate") to the anticipated cash needs to protect against unexpected expenses or delayed income.
- Determine the type of funding that will suit your business: debt/equity or non-traditional financing. Indicate how this capital requirement will be obtained -- from whom and how much will be obtained via term loans or lines of credit.

B. Offering (this is the deal structure – your pitch for money):

- If you have decided to seek equity capital, then you need to describe the type of security being offered (e.g., common stock, convertible debentures, debt with warrants, debt plus stock), the unit price, and the total amount of securities to be sold in this offering. If securities are not just common stock, indicate by type, interest, maturity, and conversion conditions.
- Show the percentage of the company that the investor in this offering will hold after it is completed or after exercise of any stock conversion or purchase rights in the case of convertible debentures or warrants i.e. what share of your company does the investor get for a specified investment.
- Securities sold through a private placement (and therefore exempt from SEC registration) should include the following statement in this section: "The shares being sold pursuant to this offering are restricted securities and may not be resold readily. The prospective investor should recognize that such securities might be restricted as to resale for indefinite period of time. Each purchaser will be required to execute a Non-Distribution Agreement satisfactory in form to corporate counsel".
- If you are seeking a loan, then you need to indicate to the potential lender how the loan will be repaid and what the interest rate is. What is the collateral for the loan?

C. Capitalization:

- Present in tabular form the current and proposed (post-offering) number of outstanding shares of common stock. Indicate any shares offered by key management people and show the number of shares that they will hold after completion of the proposed financing.
- Indicate how many shares of your company's common stock will remain authorized but un-issued after the offering and how many of these will be reserved for stock options for future key employees.
- Identify any other terms that you are willing to negotiate as part of the deal e.g. right of first refusal, seat on board, voting rights, and other rights and preferences.

D. Use of Funds:

- Investors like to know how their money is going to be spent. Provide a brief description of how the capital raised will be used. Summarize as specifically as possible what amount will be used for such things as product design and development, capital equipment, marketing, and general working capital needs.

E. Investors' Return (Exit Strategy):

- What is the value of your company? How did you calculate this value?
- Indicate how your valuation and proposed ownership shares will result in the desired rate of return for the investors you have targeted. What will be the likely harvest or exit mechanism (IPO, outright sale, merger, MBO, operate and grow, etc.)?
- What is the exit strategy for the investors and founders?

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COVERING YOUR BASES: FORTY ISSUES TO DIE FOR

As the Nuts and Bolts booklet makes clear, there is much that goes into a great business plan. Below is a checklist of things you might want to ensure appear somewhere in your plan. While this is not a comprehensive list, it covers the primary issues.

1. Define the industry and characterize it in terms of size and the life cycle and draw implications. If it has an SIC or NAICS industry code, indicate so.
2. Develop a diagram of the value-added chain and the approximate number of firms at each level, and indicate the proportion that are large firms or chains.
3. Evaluate the attractiveness of the industry in terms of Porter's 5-factor model.
4. Identify at least three ways that companies are differentiating themselves in this industry.
5. Specify other leading trends in the industry (e.g., in costs, prices, marketing approaches, new products or services, use of technology, etc.) and identify the three most critical success factors in this industry.
6. Summarize key industry financial norms for companies in this industry.
7. Identify the principal components of the business concept. Be sure you are defining the concept in terms of customer value and customer benefits. Apply the five key criteria for a good business concept.
8. What is the need that the business exists to satisfy? How well satisfied is that need already? How high are the customer's switching costs from whatever they are currently using or doing?
9. What is the set of forces creating the opportunity? What is the likely window of opportunity?
10. How is the market defined? What is the size of the market opportunity in dollars, units or both? Distinguish current market size from market potential and estimate the size of the primary and selective demand gaps. What is the growth rate of the market?
11. How are you segmenting the market? Are the key segments homogenous, sizeable, reachable, and responsive? Provide descriptors of the customers who make up the key segments. Which segments will you be targeting (provide a prioritization)? Who will be your early adopters? Are their segments with different price elasticities?
12. Develop a simple model of customer buying behavior for this product or service. How long is the buying process? Who is the decision-maker? Why do they buy? It is a high or low involvement purchase? How loyal are customers to existing vendors/products?
13. What are the key factors affecting sales in the market? Will there be patterns to the company's sales. Is seasonality an issue? Is the business cyclical? Do interest rates have an impact?
14. Who are the direct competitors? Identify the strengths and weaknesses of each. How is each differentiating itself? Who are the indirect competitors? As a group, how much of a threat are they and why?
15. Be sure that you have developed a price list. Do prices adequately reflect: a) overall marketing strategy, b) costs, c) competition, d) customer demand, and e) legal issues?
16. Explain whether the company will be set up as a sole proprietorship, a partnership, an S corporation, a C corporation, or a limited liability company.
17. Describe the economics of the business. What is your average price, average cost per unit and average margin? How much of your cost structure is fixed versus variable? How much operating leverage do you have, and what are the implications of this? Calculate your contribution margin and breakeven levels in dollars and units. Make it clear where you will be making your money (for instance, in a bar, how much of profit will come from drinks versus food, in a copier business how much will come from selling machines versus selling service?)
18. Have you formulated measurable objectives? Are you certain you've established objectives in all the appropriate performance areas?

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19. How will you ensure that the company has a strong market-orientation?
20. What will be the principal or core competencies of the company? Is strategy built around these competencies.
21. Separate from the business concept, define the company's product mix. Assess the company's principal offering to customers in terms of the core, tangible and augmented product. Be sure to include such product-related issues as hours, facility layout, parking, etc.
22. How will the company's products be positioned?
23. If it is a service business, develop a diagram of the visible and non-visible aspects of the service delivery system.
24. How will operations be organized? If it is a manufacturing or assembly operation, what is the overall layout. Provide a schematic as well as a diagram of the workflow. If it's a service business, again describe the operational layout, and then how the service will be delivered.
25. Are any product policies needed (warrantees, returns policies)? If so, what will they be.
26. What is the company's unique selling proposition?
27. Have you developed an integrated communications mix that matches the customer's buying process. Summarize the company's complete mix of customer communications, including personal selling, advertising, sales promotion and publicity. Explain how they will be coordinated and managed as a mix.
28. What will the distribution channel look like? How much market coverage will this give you? What key approaches will be used to achieve cooperation among channel members?
29. How is customer service to be defined, measured and managed? What are the key components of customer service? Construct a comprehensive list of the points of customer contact involving any personnel, paperwork or facilities of the company.
30. What is the current stage of product development? Is a prototype completed? What further R&D work is needed and by when will it be completed? What's the ongoing plan for R&D?
31. Provide a detailed cash flow statement for each of the first 3-5 years of operation. Provide pro forma income statements and balance sheets for the first three years.
32. Have you identified all of the resources (human, financial, channels, customer base, information) the company will require to start up and achieve success over the first 3 years?
33. Identify the major direct competitors and assess the strengths, weaknesses, strategy and source of differentiation relied upon by each of them.
34. How will the firm's logistical arrangements work (inventory policies, physically getting products to customers, warehousing/storage)? What is the intended order cycle time?
35. Who will be the key members of the management team? Provide a resume of each of these individuals in an appendix. Briefly describe the role of each in the firm and how it fits their background and experience. Also, will there be a board of directors or advisors?
36. What are your staffing needs beyond the management team? What kind of people are you looking for and what is your plan for getting them?
37. Identify the major technology, legal/regulatory, economic and social developments that are likely to impact on this business in the next two years, and indicate the likely impact.
38. How much money are you asking for, from which sources, how will investors earn their return, and when? Will funding come in stages?
39. Identify the five major downside risks or things that could go wrong, and indicate your contingencies for dealing with each of them.
40. Is there internal consistency in your plan? For example, can one see the logical fit and consistency between you target market, the product/service you are selling, your marketing approach, and the budget you have put together?

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Judge's Rating Sheet
Business Plan Evaluation: WRITTEN
Syracuse Panasci Competition
April 2007

Name of Team/Venture _____

Judge Name: _____

Please provide a rigorous evaluation of this final draft of the team's written plan. Could you rate the written plan first on each of the ten content areas listed in Part I below, and then rate the written document in the five areas noted in Part II. Parts I and II involve rating on 5-point scales. Finally, provide a separate overall score out of 100 on the plan. Your written comments are also very much appreciated and will be shared with the team. It is critical that we give them tangible help on how to improve.

I. Coverage of Key Components (please rate each area below on a 5-point scale where 1 = poor, 5 = excellent)

- | | |
|---|-------|
| a. The Opportunity (how well-identified, how significant of an opportunity, forces creating the opportunity) | _____ |
| b. The Business Concept and Product(s) (core concept for the business, value proposition, product/service mix) | _____ |
| c. The Market (definition, size, market potential, target audience, purchase decision maker & process) | _____ |
| d. Economics of the Business (margins, breakeven, cost structure, how we will make our money) | _____ |
| e. Marketing (pricing, promotion, selling, distribution, customer service) | _____ |
| f. Operations (staffing requirements, how product/service will be produced, delivered, supported, logistics, inventory) | _____ |
| g. Non-financial resource requirements (people, facilities, location, etc) | _____ |
| h. Management Team (players, roles, experience/credibility, compensation, board of directors, key advisors) | _____ |
| i. Venture Financing (money needed, from where, how investors will receive their return, rate of return to them) | _____ |
| j. Financials (projected cash flow, income statement, balance sheet) | _____ |

II. Written Document Mechanics (again, please rate each area below on a 5-point scale where 1 = poor, 5 = excellent)

- | | |
|------------------------------------|-------|
| a. Pragmatism/Realism | _____ |
| b. Completeness/Comprehensiveness | _____ |
| c. Internal Consistency | _____ |
| d. Writing Style | _____ |
| e. Professionalism of the Document | _____ |

III. Separate Overall Recommended Score (out of 100 points, where 100 = outstanding and you absolutely want to invest; note that this score is separate from the scores above---it is an overall assessment) _____

IV. Particular Feedback on the Written Business Plan (Please provide detailed suggestions to the team on how they can improve the plan):

(use reverse of form or attach comment sheets)

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Judge's Rating Sheet
Business Plan Evaluation: ORAL
Syracuse Panasci Competition
April 2007

Name of Team/Venture _____

Judge Name _____

Please rate the presentation of the business plan first on each of the seven content areas listed in Part I below, and then rate the presentation itself in Part II. In Part III, please give the presentation an overall rating from 0 to 100. Your written comments are very much appreciated and will be shared with the team.

I. Coverage of Key Components (please rate each area below on a 5-point scale where 1 = poor, 5 = excellent)

- a. The Opportunity (forces creating the opportunity, size of the opportunity, market need) _____
- k. The Business Concept (core concept for capitalizing on the opportunity, products/services, benefits) _____
- l. The Market (definition, size, market potential, target audience, purchase decision process) _____
- m. Operations (staffing requirements, how product or service will be produced/delivered/supported, logistics) _____
- n. Marketing (pricing, promotion, selling, distribution, how an actual sale will be accomplished) _____
- o. Economics of the Business (margins, breakeven, cost structure, how we will make our money) _____
- p. Financials (projected cash flow, income statement, balance sheet, how much money we need, how we will get it, how financiers will get their return) _____

II. Professional Assessment of Oral Presentation (again, please rate each area below on a 5-point scale where 1 = poor, 5 = excellent)

- a. Powerpoint or other audiovisuals _____
- b. Ability to capture audience attention _____
- c. Completeness of the presentation _____
- d. Mastery of facts and material related to venture _____
- e. Professionalism of the presentation _____
- f. Handling of questions _____

III. Separate Overall Recommended Score (100 = Outstanding, I want to invest!) _____

Written Comments on the Presentation of the Venture (Continue on reverse side if you need more space):

TO NORM LATNER

FROM JOE ALLEN

NOTE TO SHARON HOLSTON

1/20/88

Subject: Delegation of Authority Under the Federal Technology Transfer Act
(FTTA)

Attached are the latest versions of the transmittal memorandum to the PMS Agency Heads and the instrument of delegation under FTFA. They incorporate the modifications requested by Bruce Artin and have been sent to ASH for signature. Please note the changes in the delegation of Section 11(c)(3) (B). You may want to start work on the redelegation of authority.

Eileen Wormser

Attachments

From: Assistant Secretary for Health

Subject: Delegation of Authority Under the Stevenson-Wydler Technology Innovation Act of 1980 as Amended by the Federal Technology Transfer Act (FTTA) of 1986, P.L. 99-502

To: PHS Agency Heads

The attached delegation instrument of the above authority supersedes the October 14 delegation of authority under the FTFA. The new delegation of authority clearly fixes responsibility in the PHS Agency Heads for the implementation of the FTFA. The November 24 delegation under 37 CFR Part 401 is rescinded.

In general, the new delegation gives to the Agency Heads and to the directors of second echelon components the same authorities as in the October 14 document. The essential differences are:

1. All of the delegated authorities will now flow through the Agency Heads.
2. I am retaining the following authorities:
 - a. Section 11(a)(2) - The authority to approve agreements and contracts with invention management organizations.

Pending the full implementation of the Act and an assessment of its impact, I have decided to retain the above authority. I have, however, signed a Memorandum of Understanding between PHS and the National Technical Information Service (NTIS) (attached) to carry out these responsibilities, so that licensing and foreign patent activities can continue. All invention management activities are to be carried out with NTIS under the above Memorandum of Understanding unless otherwise approved by me.

- b. Section 11(c)(3)(B) - The authority to propose necessary statutory changes to employee standards of conduct to be forwarded to the authorizing committees.

Should your review of employee standards of conduct under Section 11(c)(3)(A) indicate that potential conflicts of interest require legislative changes, I am requesting that you prepare the necessary documentation of my review.

3. The authority to disapprove or require the modification of cooperative research and development agreements and licensing agreements, previously delegated under Sections 11(c)(5)(A) and (B), should remain within the Office of the Agency Head, although because of the volume of agreements to be considered, the Agency Head may wish to redelegate it to a senior official within his/her office. I expect Agency Heads to establish a mechanism for reviewing all agreements (within the time limitations set forth in the law) to ensure consistency with their program mission.

4. Agency Heads will not be allowed to redelegate to second echelon components the following authorities previously delegated to centers and institutes:

- a. Section 11(b)(3) - The authority to waive Federal Government ownership to any invention made by employees of the collaborating organizations under such agreements.

Section 11(b)(4) - The authority to permit current and former employees to participate in the commercialization of inventions they made while they were employed in the agency.

These authorities should be exercised by the Agency Heads to ensure that a high-level management review has been carried out before such decisions are made.

- b. Section 11(c)(3)(A) - The authority to review employee standards of conduct and establish new guidelines in accordance with the NBS Instruction which supplements Chapter 735-1 of the Federal Personnel Manual.

This authority should be exercised by the Agency Heads to ensure uniform policy and guidelines regarding standards of conduct throughout each agency. I plan to oversee your exercise of this authority through the FHS Technology Transfer Policy Board.

5. I have clarified that those authorities which will be delegated to officials reporting directly to the Agency Head may not be further redelegated.

I want to make it clear that I intend to exercise oversight over the management of activities under this Act. I have included in the delegation a section providing for my exercising some of the authorities I have delegated to you. I expect each of you to advise me of significant pending cooperative agreements, waivers of government rights, or standards of conduct problems in sufficient time (within the limitations set forth in the law) for me to take action should I so desire.

I am also directing each of you to implement immediately a policy requiring all collaborative agreements to be in writing. This includes formalizing currently informal agreements, except for those cases where, for example, scientific information is exchanged, with no expectation of an invention resulting.

I shall be communicating with you further concerning the FHS Technology Management Advisory Board. Over the next few weeks I shall be considering how I wish to manage the overall implementation of the FTTA. In the meantime, I urge each of you to take immediate action to redelegate, where appropriate, the pertinent authorities to the proper officials.

Robert E. Windom, M.D.

Attachments



DEPARTMENT OF THE TREASURY
WASHINGTON

FEB 10 1987

ASSISTANT SECRETARY

MEMORANDUM FOR MEMBERS OF THE EPC WORKING GROUP ON R&D

FROM: Stephen J. Entin *SE*
Acting Assistant Secretary
for Economic Policy

SUBJECT: Copyright of Technical Data

In January 1986, the Economic Policy Council adopted the R&D Working Group recommendation that OMB develop a policy that would permit government contractors to copyright technical data developed in conjunction with the performance of contracts. The Working Group's recommendation and background notes are attached.

A draft policy statement has been developed by OMB and has been forwarded to me for comment by the Working Group (copy attached, together with an OMB prepared analysis). In addition, an amendment to the Federal Acquisition Regulations dealing with copyright of technical data has been proposed by the Federal Acquisition Regulations (FAR) Council.

Please review OMB's proposed policy statement and the draft FAR regulations to determine whether they are consistent with the Working Group's recommendation. I would appreciate receiving your written comments by c.o.b. March 4. If you have any questions concerning this matter, please call Ed Murphy (566-5755) or Maynard Comiez (566-5808).

Attachments

DEC 19 1985

MEMORANDUM FOR THE ECONOMIC POLICY COUNCIL

FROM: Working Group on Research and Development
SUBJECT: Recommendations to Encourage R&D

Executive Summary

Background

There has long been an awareness in the United States that increased research and development (R&D) and innovation produces significant benefits to the economy. More rapid rates of innovation increase productivity and economic growth, reduce the rate of inflation, create new jobs, and strengthen the competitiveness of U.S. goods and services.

The R&D and innovation process is complex and frequently involves a relatively high degree risk. Generally, the market mechanism provides adequate incentives for private firms to fund the R&D needed to sustain rapid rates of innovation. In certain instances, however, all of the benefits from some types of R&D, particularly basic research, may not accrue to private investors although they would be available to society as a whole. In such cases there may be underinvestment of private resources in R&D, and society is the loser. The presence of these externalities has long been viewed as justifying government intervention in the R&D process, particularly basic research.

The Government has both a direct and indirect role in R&D and innovation. Government policies, including tax incentives, antitrust, procurement practices, and patent and copyright laws, indirectly influence, but to a significant degree, R&D and innovation. Strong, sustained economic growth is also very beneficial.

Government R&D spending generally has a more direct impact on R&D. The current budgetary situation may require that Federal R&D programs share with other programs the need to scale back the growth of spending. There are ways, however, in which the Federal Government can encourage increased R&D efforts by the private sector without adding to the budget deficit.

The Working Group on R&D reviewed a number of proposals for encouraging R&D and improving the effectiveness of our overall R&D effort. The following are four unanimous recommendations and one exploratory proposal for EPC consideration.

Recommendations

1. The existing R&D tax credit is intended to provide companies incentives to increase their R&D efforts. However, the three-year "creeping-base" provision of the credit may provide less incentive for increases in R&D than an alternative base because the additional R&D performed in the current year will increase the base in each of the three succeeding years, thus reducing the credit the company could claim in subsequent years.

The Working Group recommends that Treasury consider an amendment that would replace the present 3-year moving base for the credit by a fixed three-year period, indexed annually for inflation. The rate of credit would be adjusted to maintain revenue neutrality equivalent to present law.

2. Many types of commercially valuable information such as computer software, engineering drawings and other technical data are generated under Federal grants and contracts or in conjunction with them. This information often has great commercial importance to the private sector, but private sector participation in Government-funded research projects may be discouraged because of the uncertainty created by the fact that agencies have a multiplicity of policies governing copyright ownership of this information.

The Working Group recommends that a uniform Federal copyright policy be developed by OMB allowing all contractors (including those medium and large size businesses not now explicitly covered by a February 1983 Presidential memo) ownership of software, engineering drawings and other technical data in exchange for royalty-free use by the Government.

3. Federal laboratories perform more than \$17 billion in R&D annually, of which about two-thirds goes to government-operated institutions and one-third to contractor-operated institutions. At present, both kinds of laboratories have authority to grant exclusive licenses for their inventions to the private sector but only contractor-operated labs and their employees may receive a share of the royalties. Thus, there is no incentive for researchers in government-operated laboratories to transfer technology to the private sector for commercialization and to contribute to U.S. industrial competitiveness. Legislation is now pending in the Congress that could improve this situation.

The Working Group recommends that the Administration should take administrative action or propose or endorse legislation that would:

- incorporate contribution to U.S. industrial competitiveness as an explicit laboratory mission wherever that has not already been done and is not inconsistent with the primary laboratory mission;

Recommendation 2. Ownership of Software and other Technical Data Produced Under Contract to the Federal Government

Problem/Issue

Many types of commercially valuable information such as computer software, engineering drawings, etc. are generated under Federal grants and contracts or in conjunction with them. Agencies now have a multiplicity of policies governing copyright ownership of this information. Such information often has great commercial importance to the private sector. However, the threat that the Government will hold all copyrights that derive in any way from work produced under contract can have a chilling effect on private sector participation in Government funded research projects. Copyrightable information developed in Government funded research projects does not receive the same protection afforded patentable products or processes developed under the same circumstances. This threat is especially great to researchers seeking to commercialize valuable copyrights such as software programs.

Background/Analysis

Passage of the Bayh-Dole Act (Public Law 96-517) in 1980 marked a turning point in Federal policy on patent rights to inventions. Congress sought to increase technology transfer from Federal research and development to the private sector by allowing universities and small business contractors to manage patentable inventions they made under Government grants and contracts. Subsequently, a number of university and private contractors have established technology licensing programs. The President's Memorandum on Government Patent Policy, February 18, 1983, extended the principals of the 1980 Bayh-Dole Act to all businesses, consistent with existing law; some medium and large business contractors still do not receive the benefits of this policy because of preexisting laws that were not affected by the 1980 Act. In 1984, PL 98-620 extended the 1980 Act to include most contractors who operate Federal laboratories. However, the patent protection afforded to these contractors and grantees does not extend to copyrightable software and other technical information. The absence of a uniform Federal policy allowing contractor ownership of copyrights that may be generated under grants and contracts in exchange for royalty-free use by the Government inhibits contractors working in fields where such protection is needed for commercialization. This slows the transfer of new ideas to the commercial sector.

Recommendation

A uniform Federal copyright policy should be developed by OMB allowing all contractors (including medium and large size businesses) ownership of software, engineering drawings and other

technical data in exchange for royalty-free use by the Government; it could be modeled on the President's memorandum of February 18, 1983. Such a policy would be consistent with the Administration's technology transfer goals by encouraging commercialization of copyrightable products by the private sector. This policy would also encourage the most innovative small, medium and large companies and universities to participate in Federally sponsored R&D projects, thereby benefiting the Federal agencies and the public.

and im...

DRAFT

GOVERNMENT POLICY ON THE OWNERSHIP OF TECHNICAL INFORMATION

1 To the extent permitted by law, agency policy with
2 respect to the ownership of technical information that
3 has been developed wholly or partially at government
4 expense shall provide for contractor, sub-contractor, or
5 grantee ownership. Such ownership of technical
6 information shall be subject to the government's right
7 to use it on a non-exclusive, royalty-free basis. For
8 purposes of this policy, technical information means
9 engineering drawings or other data relating to products
10 or processes, semi-conductor mask works, computer
11 software, and software documentation.

12 An agency shall expand its rights to use technical
13 information beyond the specific application for which
14 the information was developed only to the extent
15 required to perform agency missions. In such cases, the
16 agency shall specify these additional rights narrowly
17 and require separate pricing for their acquisition. For
18 example, a purchasing agency may need to acquire the
19 rights to disseminate technical information for the
20 purpose of promoting competition in related follow-on
21 procurements.

22 Nothing in this policy is intended to preclude placing
23 limitations on the access to, or on the use of,
24 technical information classified for reasons of national
25 security or under other authorities.

GOVERNMENT POLICY ON THE OWNERSHIP OF TECHNICAL INFORMATION

Background Paper

In January 1986 the Economic Policy Council (EPC) asked OMB to develop a uniform policy allowing all contractors ownership of technical information in exchange for royalty-free use by the government. The EPC meeting was devoted to improving protection for intellectual property rights and increasing U.S. international competitiveness. The attached draft policy statement answers the EPC request. It is expressly designed to stimulate discussion and comment, and to encourage the submission of hard evidence that substantiates the alleged budgetary and economic impacts of various policy alternatives. Following EPC agreement on a final policy, the Federal Acquisition Regulation will require revision to implement the policy.

Technical information or technical data includes engineering drawings or other data related to products or processes, semiconductor mask works, computer software and software documentation. Ownership of technical information can affect procurement costs, participation in bids for sales, the ability to protect sensitive technology, the commercial exploitation of new technology, and the climate for scientific innovation. While many issues in technical data policy are similar to those faced in making government patent policy, there are two significant differences. First, timely access to previously unreleased proprietary technical information can be much more valuable in the short run than a patent or patent license. Second, government rights in technical data are essential to promote competition in procurements.

Policy History

Existing policy has evolved piecemeal. Since at least 1972, the Executive Branch has attempted without success to develop a uniform data rights policy. Meanwhile, Congress has enacted several policy-creating statutes. Public Law 98-577 (41 U.S.C. 418a), the Small Business and Federal Competition Enhancement Act of 1984, and, most recently, Public Law 99-661 (10 U.S.C. 2320), the National Defense Authorization Act for FY 1987, define policies to be followed in the government-wide Federal Acquisition Regulation (FAR). Although the FAR contains a brief statement of policy (48 CFR 27.401), current practice is defined in a multiplicity of agency regulations which reflect years of agency procurement and grant-making experience. Civilian agency regulations generally favor contractor ownership of technical information in exchange for a license for use within the

government. At the time they were written, however, ownership of information was not the issue that rapid advances in computers and biotechnology have made of it.

In late 1983, because of concerns about patents, proposed FAR patent and data rights rules were withdrawn at the request of the Vice President. The action reflected OMB's urging and Congressional concern that the rules were inconsistent with the February 1983 Presidential Memorandum on Government Patent Policy. Proposed revisions to civilian agency (FAR) and Defense FAR Supplement (DFARS) technical data rules were again published in the fall of 1985. Private sector critics charged that, while procurement reform statutes were written to encourage the use of technical data to enhance competition in government procurements, the 1985 proposed implementing rules went beyond Congressional intent in acquiring rights for the government. Echoing this criticism, the FY 1987 Defense authorization provisions attempt to restore "the delicate balancing of interests between the government's need to acquire the right to release technical data to ensure competition and the contractor's interest in preserving valuable property rights in data on products that they develop at their own expense."

The final report of the President's Blue Ribbon Commission on Defense Management (Packard Commission) suggests, and the 1987 Defense authorization requires special provisions for ownership and use based on the source of funding. These provisions:

- permit the government to exercise unlimited rights in data developed entirely at government expense, suggest cases where more limited rights are appropriate, and, in the statute, allow the Secretary of Defense discretion to define the extent of the government's license;
- permit a contractor to limit the government's rights in data developed exclusively at private expense; and
- require that rights be negotiated in data developed with mixed funding.

Extensively revised versions of last fall's technical data provisions are nearing completion in the Civilian and Defense Acquisition Councils. The Defense provisions will incorporate these distinctions.

Draft Policy Statement

Vigorous scientific research and technology development are fundamental to U.S. economic and military security. In addition to providing almost half of the money spent annually on U.S. research and development, the Federal Government has supported innovation in the recent past by guaranteeing to inventing organizations the titles to inventions made with Federal support,

subject to license rights in the government.

The statement extends policies contained in the Presidential Memorandum on Government Patent Policy of February 18, 1983, to software and other technical information. At the same time it recognizes the legitimate requirements of agencies to obtain the rights to the taxpayer-funded technical information they need to perform their missions and to lower procurement costs.

The statement is consistent with OMB Circular No. A-130, "Management of Federal Information Resources." It recognizes that government information is a valuable national resource, and cautions agencies to limit their collection and dissemination of information to that necessary for proper performance of agency functions.

Finally, the policy statement requires that encouraging contractor ownership of technical information be done in a way that is consistent with the proper and appropriate administration of existing national security classification systems, and with other authorities for restricting access to technical information for reasons of national security.

Issues

The draft policy statement allows private ownership of technical information developed wholly or partially at government expense, subject to royalty free use by the government. This section of the background paper addresses several issues regarding the extent of the government's rights in technical data. We expect that agency staffs will raise additional issues to the Working Group and that these comments will be discussed and forwarded to OMB to be worked into a final policy.

1. Extent of the government's royalty-free license.

The conditions under which the government may use, modify, or disseminate technical information for public purposes beyond the specific application for which the information was developed is the key issue in formulating a technical data policy. There are five main consequences to retaining in the government broad rights in technical data. Broad government rights:

- o enhance the government's ability to obtain competitive procurements;
- o may cost more to acquire initially, but save the government money downstream;
- o encourage the free flow of scientific information;
- o decrease private incentives to fund innovation;

- o decrease private incentives to fund commercial development.

Formulation of a uniform, government-wide policy that balances increased incentives for innovation with efficient procurement practice is further complicated by differing civilian and defense-related data environments. Civilian agency-sponsored R&D often results in products or processes for which there is a substantial potential commercial market (e.g., biotechnology), and for which the government has little interest in large-scale later procurements. Defense R&D also produces commercial spin-offs, but Defense data requirements grow out of the need to obtain competitive procurements of products initially developed with substantial government sponsorship.

As drafted, the policy statement reflects OMB's position that the most cost-effective way to manage the government's use of technical data is to favor the automatic acquisition of only the most limited rights. Additional rights, and their costs, are to be specified separately as required. At present the government routinely and automatically acquires rights to modify technical data and to disseminate them outside the government. Thus the price the government pays for technical data reflects contractor hedging against the risk that the government will modify for its own use, and/or disseminate, the data to its competitors. Such modification or dissemination will reduce the contractor's return on the data to less than that possible had it retained exclusive ability to develop and market the data.

On the other hand, the government has a limited ability to make full use of the broad rights it routinely requires. The government's inability even to catalog, much less exploit, the vast amount of technical data in its possession is probably reflected in discounted prices for data rights. The highly competitive nature of R&D contracting serves further to lower the price of retaining broad rights in the government. Furthermore, proponents of retaining broad rights to disseminate technical data for the purpose of promoting competition in government procurement argue that contracting officers will rarely be able to predict all the rights the government may need in the future.

The draft policy statement reflects OMB's preliminary position that automatic retention of rights in the government creates disincentives both to the efficient management of the government's technical data and to energetic innovation from and commercialization of the results of efforts funded in whole or in part with public funds.

2. "wholly or partially at Government expense" - line 3

As noted above, the Packard Commission and recent Defense-related legislation contain provisions permitting the government unlimited rights in data developed wholly at government expense.

OMB recognizes that its identical treatment of wholly and partially funded data in the draft policy is potentially a contentious issue. The draft is expressly designed to generate comments, and hard evidence to support those comments, on the budgetary and economic effect of limits on the government's rights in data. The market mechanisms outlined in the previous discussion will operate however the government participates in funding the data's development. In addition, the paperwork burden on contractors resulting from the reporting and recordkeeping required to substantiate the data's funding history can be reduced by uniform treatment. Finally, as noted above, the draft policy allows agencies to specify and acquire the rights they actually need to perform their missions.

3. "computer software" - line 10

Software is different from much of the other technical information the government acquires to support its maintenance, quality assurance, and competition requirements. While most data are incidental to or supportive of the use of an end item, software is itself a tool, an end item that is procured for its value to do work. Furthermore, it is readily copyable, and a copy has the potential to serve as an equally effective tool for someone else.

Under existing practice the government typically acquires unlimited rights to copy and modify computer software that is developed wholly or partially at government expense. (Commercial products developed wholly at private expense, such as Lotus 1-2-3, are outside the scope of the draft policy.) While the National Technical Information Service (NTIS) operates a software exchange program to facilitate inter-agency sharing, agencies only occasionally use this program, often because the software available has been custom designed for a very specific application. NTIS makes federally-funded software available to the public as well. As drafted, the policy would allow routine sharing of such software within the government and routine public distribution only if the software development contract specifically provides for it.

Even more than with other types of data, the present policy of acquiring the rights to copy and use software within the government may increase the cost of software developed for a single application. This increase will depend on the contractor's perception of the software's commercial potential. At a minimum, the contractor will be more likely to invest the private funds necessary to turn an agency-funded software design into a generic package with wider usefulness if the software has not already been disseminated throughout the government.

4. Should the policy specifically address the rights of foreign contractors to data produced under U.S. government grants or contracts?



Memorandum

Date **NOV 24 1987**

From Assistant Secretary for Health

Subject Implementation of the Technology Transfer Act

To Heads of PHS Agencies, Center and Institutes
(Delegates of Technology Transfer Act of 1986)

In followup to the first meeting of the PHS Technology Management Advisory Board, I am providing additional information and guidance to be followed in implementing the Act. This memorandum contains:

- (1) Additional information on actions that may be taken under the delegation of October 14, 1987 memorandum and points to be addressed in cooperative research and development agreements (Attachment I Part A and B).
- (2) Attachment II presents Draft Model Agreements for cooperative/collaborative research and development agreements and Draft License Agreements:
 - o Agreement A--Department of Commerce Model R&D Agreement;
 - o Agreement B--PHS Model R&D Agreement;
 - o Agreement C--Department of Commerce License Agreement; and
 - o Agreement D--PHS License Agreement.

These documents provide a basic guidance that institutes or centers can utilize to shape precise agreements to accomplish the specific tasks of collaboration with other organizations or in licensing of technologies.

- (3) Identification of three working groups to support the work of the PHS Technology Management Advisory Board.
 - A. Implementation Group. This group is to assist, review and facilitate the PHS agencies, centers and institutes in their development of implementation plans required by ASH's October 14 delegation. Further, the group is to establish

appropriate guidelines and procedures for carrying out the Act which includes developing reports, information and data needs and other operational procedures pertinent to the Advisory Board. This group will be chaired by Dr. Ronald Hart, Director NCTR.

- B. Operations Group. This group will develop collaborative R/D, licensing and other instruments for carrying out the purposes of the Act. It will provide descriptions of, and access to, tools available to the institutes and centers. As a first agenda item, this group will be responsible for reviewing cooperative research and development and licensing agreement for use by the institutes and centers (see Attachment II above). This group is to be chaired by Dr. Vince DeVita, Director, NCI.
- C. Legal Support Group. This group is responsible for assisting the Implementation and Operations Group and in providing legal assistance of issues related to conflict of interest, confidentiality, patent and license agreements, and other support material as requested. It is to be chaired by Mr. Robert Lanman, NIH General Counsel.

Full consideration of other cross-cutting issues shall be folded into the work of each group on a best-fit or case-by-case basis as they arise. I will leave selection of the membership of the three working groups to the Chairperson. Further, I would request that those of you who have interest in one or more of these areas contact Chairperson and indicate that interest.

- (4) For you information, I am attaching a memo entitled "Preparation of Materials Explaining the Application of the Employee Standards of Conduct to Activities Under the Technology Transfer Act of 1986" by Robert Ortner, Under Secretary for Economic Affairs at Department of Commerce, see Attachment III.


Robert E. Windom, M.D. -

ATTACHMENT I PART A

ACTIONS THAT HEADS OF PHS AGENCIES, CENTERS, AND INSTITUTES
MAY TAKE UNDER THE OCTOBER 14, 1987 DELEGATION OF AUTHORITY
UNDER THE FEDERAL TECHNOLOGY TRANSFER ACT

The Head of a PHS Agency, Center or Institute may:

- o Negotiate licensing agreements for Government-owned inventions made within the respective Center, Institute or PHS Agency, or other inventions of Federal employees that may be voluntarily assigned to the government.
- o Negotiate and enter into, subject to the approval of the appropriate PHS Agency Head, cooperative research and development agreements, under which the PHS components may accept, retain and use funds, personnel, services, and property and, in exchange, provide personnel, services and property, but not funds.

Under these agreements, the Institute, Center or Agency may waive the Federal Government's right of ownership to any invention made under the agreement by collaborating party or employee of a collaborating party, subject to reservation by the Government of a nonexclusive, irrevocable, paid-up license to practice the invention, or have the invention practiced throughout the world by or on behalf of the Government.

In addition, a collaborating party may be granted a patent license (exclusive or nonexclusive) or assignment, or option thereto, in any invention made in whole or in part by a Federal employee under the agreement, retaining for the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government.

- o Identify, evaluate and file patent applications on inventions made by employees of the respective Agency, Center or Institute. These activities may be undertaken through the use of distributed royalties or other income.
- o Subject to approval by the Assistant Secretary for Health, enter into agreements for the services of other agencies, persons or organizations for invention management and licensing services. The purpose of these services is to facilitate direct support to carry out the work of the institute and center in transferring technology to bring the result of research to the marketplace and patient.

- o Use royalty income distributed to the PHS component to reward scientific, engineering and technical employees of the laboratory, for payment of expenses incidental to the administration and licensing of inventions, to further scientific exchange among the Government-operated laboratories, and for education and training of employees consistent with the research and development mission of the Agency, and for other activities that increase the potential for transfer of technology.
- o Heads of the PHS agencies shall receive all royalty or other income produced under cooperative research and development and license agreements for distribution to their respective Centers and Institutes. After paying the inventor's share, the majority share of royalties and income shall be returned and utilized by the Center or Institute where the invention occurred. Any remaining amount shall be used as directed by the Agency, either at the Agency or at the Agency's other Centers and Institutes, in accordance with the requirements of the Act.
- o Institutes and Centers may enter into Cooperative Research and Development Agreements negotiated by the Centers and Institutes. Part B of Attachment I identifies points to be considered in negotiating and finalizing such agreements. It should be noted that the PHS Agency Head has thirty (30) days to review and disapprove in writing to the Institute or Center Director.

Topics to be Addressed in Cooperative Research and
Development Agreements

A Cooperative Research and Development Agreement should contain provisions addressing the following subjects:

1. The effective date.
2. Principal investigator(s) for the Government and for the collaborating party.
3. Funds, personnel, services and property to be provided by the collaborating party.
4. Personnel, services and property to be provided by the Government.
5. Retention and ownership of property in the event of termination.
6. Delineation of the research encompassed by the agreement.
7. Procedures for interaction between the collaborating parties.
8. Provisions protecting the Government's right to publish research results while giving the collaborating party an opportunity to protect its proprietary information.
9. Provisions for the protection of proprietary information, including appropriate references to the Freedom of Information Act. Such provisions should reference 35 U.S.C. which authorizes federal agencies to withhold from disclosure to the public information disclosing any invention in which the Federal Government owns or may own a right, title or interest (including a nonexclusive license) for a reasonable time in order for a patent application to be filed.
10. Patent rights clauses, which may include the granting to the collaborating party of an exclusive or nonexclusive license to inventions made in whole or impart by a Federal employee and a waiver of any Government rights to an invention made in whole or impart by a collaborating party or an employee of a collaborating party. Both of the foregoing are subject

to retention by the government of a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the government.

11. A disputes resolution clause, providing that disputes which cannot be resolved by the parties are to be resolved by the Head of the Agency.
12. A clause addressing identification. The Government cannot agree to identify the collaborating party for damages, nor may the Government agree to pay attorney's fees or waive any of its rights in litigation that might arise regarding the agreement but may permit a collaborating party to assume responsibility to pursue of patents licensed by government.
13. The term of the agreement.
14. Procedures for termination of the agreement and a statement of what rights survive termination.
15. A statement as to what law governs the validity and effect of the agreement. Federal law must control, but in the absence of any conflicting Federal law, State law may control.

ATTACHMENT II

DRAFT AGREEMENT D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

This Agreement, made and entered into this _____ day of _____, 19__ , by and between the United States of America, as represented by the Assistant Secretary for Health of the Department of Health and Human Services, hereinafter referred to as the DEPARTMENT, and _____

hereinafter referred to as the LICENSEE,

WITNESSETH: That whereas the Department is the owner of the entire right, title, and interest in and to United States Patent Number _____, issued _____, and entitled _____

and

WHEREAS, the Regulations of the Department covering licenses to practice inventions covered by patents and pending patent applications owned by the United States Government, as represented by the Department, provide in 45 C.F.R., Section 6.3 that where it appears that the public interest will be served, the Assistant Secretary for Health may issue licenses providing for limited exclusivity and the payment of royalties to the Department; and

WHEREAS, the Licensee is desirous of obtaining an exclusive license under said patent for the manufacture, use, and sale of the inventions depicted therein throughout the United States, its territories, possessions and dependencies, and the issuance of such a license has been determined to be in the public interest, in order to more adequately and quickly develop the aforesaid invention of the patent for the widest use by the general public; and

WHEREAS, the Licensee has tendered the required sum of two hundred and fifty dollars (\$250.00) to the Government to partially reimburse the Government for administrative costs incurred in the issuance of this license and the further processing required during its term;

WHEREAS, the Assistant Secretary for Health has reviewed the request for this license submitted by the Licensee and has determined that extensive development and testing requiring substantial investment of private risk capital in the invention covered by the above patent is needed to bring this invention to the point of practical application, and that the granting of this license is consistent with Section 6.3 of the Department patent regulations.

NOW, THEREFORE, in consideration of the foregoing premises and in consideration of the public interest, and for other good and valuable considerations, the parties hereto agree as follows:

1. DEFINITIONS

Patent Rights - "Patent Rights" means said United States Patent Number _____ and any reissue of such patent, and the invention described therein.

Improvements - "Improvements" means betterment of the processes, intermediates, or the products which are defined by the claims of the above-cited United States patent developed by the Department or party obligated to assign such developments to the Department.

Product - "Product" means any device, material, or substance which is within the scope of Patent Rights, or which is synthesized by a process within the scope of Patent Rights or employing an intermediate within the scope of Patent Rights.

2. LICENSE

The Department hereby grants and Licensee hereby accepts an exclusive and revocable license under the Patent Rights to make, have made, use, and vend Products, and to use processes coming within the scope of the Patent Rights in the United States of America, its territories, dependencies and possessions, subject to the conditions and limitations hereinafter set forth until _____ years after the first commercial sale of Product by Licensee, or _____ years from the date of this license, whichever occurs first, provided that Licensee shall use all reasonable effort to effect introduction into the commercial market as soon as practicable, consistent with sound and reasonable business practices and judgment. Any extension of the maximum period of exclusivity shall be subject to the approval of the Department. Any request for such an extension shall be considered on its merits upon written request and justification, it being understood that upon expiration of the period of exclusivity or any extension thereof, the Licensee thereafter for the remaining life of the patent shall have a nonexclusive license. The Licensee shall have the privilege of granting sublicenses with respect to all Patent Rights, or assigning such rights, subject to all the conditions of this Agreement, after

furnishing the Department with a copy of the proposed sublicense or assignment thirty (30) days prior to its execution and receiving no reasonable objection thereto. Such sublicense or assignment shall not be revoked by the Department except under the terms of Paragraph 11 hereof.

3. RESERVATION OF RIGHTS

The license granted in Paragraph 2 above is subject to the reservation by the Department of an irrevocable, nonexclusive, nontransferable, 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 existing or future treaty.

4. OPTION ON IMPROVEMENTS

The Department will disclose each Improvement to Licensee pursuant to Paragraph 8 hereof. The Licensee may elect, by written notice to the Department within three (3) months after being notified of an Improvement, to file a United States patent application and have said Improvement included as a part of Patent Rights under this Agreement at no increase in royalty. If Licensee does not elect to have an Improvement included as a part of Patent Rights, Licensee and the Department shall have no further obligations hereunder, each to the other, with respect to said Improvement.

5. GOVERNMENT FUNCTIONS - PERFORMANCE

a. The Licensee agrees that development and testing of the invention disclosed in the aforesaid patent or application and marketing of all products under this license will be in accordance with all laws and regulations applicable thereto. This license shall not be construed as restricting any of the rights or powers of the United States to exercise its normal governmental functions in the control of the manufacture, sale, distribution, or consumption of any product within the scope of this license under all pertinent Federal laws or regulations which may now or hereafter be in force.

b. In the event of the exploitation of the Patent Rights outside the United States, Licensee shall comply with all applicable laws and regulations of the United States, including particularly the export control regulations, foreign assets control regulations and transaction control regulations. The license granted herein shall not be construed as exempting Licensee from any of such laws or regulations of the United States.

6. PATENT FILING, PROSECUTION AND MAINTENANCE

The Licensee shall bear the expense of all prosecution of any United States patent applications on Improvements which Licensee has elected to include as part of Patent Rights.

Licensee shall not abandon any patent application on an Improvement, without first offering to transfer prosecution of such application to the Department not less than forty-five (45) days prior to the date a reply to a Patent Office action is due. If the Government does not request a power of attorney to continue prosecution within thirty (30) days of receipt of this offer, the Licensee may permit the application to go abandoned. The Licensee shall, upon request, grant a power of attorney authorizing the Department to inspect and make copies of any documents in the Patent Office pertaining to the prosecution of United States patent applications on any Improvements.

7. DISCLOSURE

The Department shall, upon execution of this Agreement, disclose to Licensee all information, know-how and data relating to Patent Rights, Products, methods for manufacturing Products and formulations containing Products in its possession or under its control, and the Department shall from time to time disclose to Licensee such additional information, know-how and data as it shall acquire or control, all to the extent the Department shall have the right to disclose such information, know-how and data for use by Licensee hereunder without restriction or obligation other than as set forth in this Agreement. The Department shall have the right to publish and make disclosure of any information relating to any subject matter or invention pertaining to the Patent Rights or Improvements, whenever deemed to be in the public interest, provided compliance with Article 4 above of this Agreement has been effected.

8. REPORTS

Licensee shall provide written annual reports to the Department commencing one year from the date of this Agreement regarding the development and commercial use that is being made and is intended to be made of the invention, including the amount of money expended in such development and such other non-proprietary data and information as the Department may

specify. No further annual reports will be required after notification of the first commercial sale of any product embodying the invention unless otherwise requested by the Department.

9. PATENT MARKING

Licensee agrees that it will take all reasonable steps to assure that all packages or containers in which Products are sold by it pursuant to the license herein granted will bear an appropriate legal notice with respect to the patent included in Patent Rights, under which patent the Product is sold. The Department will from time to time supply Licensee the necessary information to be contained in such notices.

10. DEPARTMENT REPRESENTATION OR WARRANTY

a. Warranty - The Department does not warrant that this Product is capable of commercial exploitation, or that the practice by the Licensee of the invention licenses hereunder will be free from any infringement or charges of infringement of any patent or patents. The Department assumes no liability whatsoever that may result from the exercise of the license. The Department, in granting this license, does not represent or warrant the validity of any patent, nor does the Department undertake to prosecute or defend any suit brought by or against the Licensee, or indemnify it for the infringement or enforcement of any patent, nor do the parties hereto waive any rights they may have under the anti-trust laws.

b. Non-Use of Names - This license shall not be construed or in any way be represented as constituting the endorsement by the Government of any product manufactured by the Licensee within the scope of this license, or of the therapeutic utility or safety of any such product.

Licensee shall not use the name of the Government, nor any adaptation of the name of the Government, in any advertising, promotional or sales literature without prior written consent obtained from the Government (as represented by the Assistant Secretary for Health, Department of Health and Human Services) in each case.

11. REVOCATION OF EXCLUSIVE LICENSE

a. The Department reserves the right to revoke the exclusive license granted under Paragraph 2 of this Agreement and/or grant licenses to an applicant on a nonexclusive basis, royalty-free or on terms that are

reasonable under the circumstances if (1) the Licensee or its sublicensees fail to comply with any of the provisions of this Agreement, (2) the Department determines that the public health, safety or welfare requires such action, or (3) within three years after the issue date of this license agreement, the Licensee or its sublicensees have not only failed to bring the invention to the point of practical application, but have also failed to make the invention available for licensing royalty-free or on terms that are reasonable in the circumstances.

Licensee shall be given written notice of any proposed determination pursuant to the provisions of this paragraph not less than thirty (30) days prior to the effective date of such determination and, if it requests, shall be granted a hearing before any such determination is put into effect.

In the event the written notice proposes to revoke the exclusive license on the ground that the Licensee or its sublicensees have failed to comply with any of the provisions of this Agreement (pursuant to clause (1) of this subparagraph), such notice shall not be effective unless, within a period of ninety (90) days (or such longer period as the officer executing this Agreement on behalf of the Department, or his successor, may authorize in writing) from its receipt, the Licensee or its sublicensees shall have failed to cure the asserted noncompliance.

b. If the exclusive license is revoked pursuant to the provisions of subparagraph "a(2)" or "a(3)" above, the Licensee shall have a nonexclusive license under the Patent Rights until expiration thereof. A nonexclusive license obtained pursuant to the terms of this subparagraph shall be revocable if the Licensee, three years after a patent issues on the invention, has failed to bring the invention to the point of practical application.

12. OTHER LICENSEES

In the event that this license becomes nonexclusive, the Department agrees that with respect to licenses to others, if the Department should during the period of this License Agreement grant a license to any person, firm or corporation under more favorable terms, except as to the royalty paid, than those hereby granted to Licensee, the Department will promptly notify Licensee and advise Licensee concerning the differences, in terms between such more favorable license and this License Agreement. Licensee

shall, at Licensee's election, be entitled to the benefit of such more favorable terms as of the date upon which such more favorable license shall become effective.

13. TERMINATION OF AGREEMENT

Licensee shall have the right to terminate this Agreement at any time by giving six (6) months prior written notice to the Department to that effect. From and after the effective date of any termination of this Agreement, neither the Licensee nor the Department shall have further rights, powers, privileges, licenses, obligations or liabilities under any of the provisions of this Agreement.

14. DISPUTES

All disputes concerning the interpretation or application of this License Agreement which are not disposed of by mutual agreement shall be decided by the officer executing this license on behalf of the Government, or his successor, who shall reduce his decision to writing and mail or otherwise furnish a copy thereof to the Licensee. His decision shall be final and conclusive, except on questions of law, unless within thirty (30) days from the date of receipt of such copy the Licensee mails or otherwise furnishes to him a written appeal addressed to the Secretary, Department of Health and Human Services. The decision of the Secretary, or his duly authorized representative for the determination of such appeals, shall be final and conclusive, except on questions of law, unless determined by a court of competent jurisdiction to have been fraudulent, or capricious, or arbitrary, or so grossly erroneous as necessarily to imply bad faith, or not supported by substantial evidence. In connection with appeals under this clause, the Licensee shall be afforded an opportunity to be heard and to offer evidence in support of its appeal.

15. NOTICES

Any report or notice to be given hereunder shall be sent to the following respective addressees:

For the Department:

Assistant Secretary for Health
Department of Health and Human Services
Washington, D. C. 20201

For the Licensee:

16. COVENANT AGAINST CONTINGENT FEES

The Licensee warrants that no person or selling agency has been employed or retained to solicit or secure this license upon an agreement or understanding for a commission, percentage, brokerage, or contingent fee, excepting bona fide employees or bona fide established commercial or selling agencies maintained by the Licensee for the purpose of securing business. For breach or violation of this warrant, the Department shall have the right to annul this license without liability.

17. OFFICIAL NOT TO BENEFIT

No member of or delegate to Congress, or resident commissioner, shall be admitted to any share or part of this license or to any benefit that may arise therefrom, but this provision shall not be considered to extend to this license if granted to a corporation for its general benefit.

18. COMPLETE AGREEMENT

This Agreement sets forth the entire understanding between the parties as to the subject matter, and the provisions cannot be modified or changed without the written consent of both parties.

IN WITNESS WHEREOF, the parties hereto have executed this instrument in triplicate by proper persons thereunto duly authorized of the day and year hereinabove written.

UNITED STATES OF AMERICA

By: _____

Date: _____

Title: Assistant Secretary for Health,
Department of Health and Human Services

By: _____

Date: _____

Type Name: _____

Title: _____

ATTACHMENT III



UNITED STATES DEPARTMENT OF COMMERCE
The Under Secretary for Economic Affairs
Washington, D.C. 20230

2 NOV 1987

MEMORANDUM FOR Douglas A. Riggs
General Counsel

FROM: Robert Ortner *RO*
Under Secretary for Economic Affairs

SUBJECT: Preparation of Materials Explaining the
Application of the Employee Standards of Conduct
to Activities Under the Technology Transfer Act
of 1986

In your memorandum of February 11, 1987, you reviewed this Department's Employee Standards of Conduct for the purposes of the Federal Technology Transfer Act of 1986, and concluded that "our regulations establish adequate guidelines to cover situations under the law and do not require changes at this time." My office is now beginning to prepare materials for use in the Department's laboratories that will establish guidelines for employees in situations likely to arise under the Act. The purpose of this memorandum is to ask you to assign a member of your staff to work with Norm Latker, Director, Office of Federal Technology Management, in the preparation of these guidelines.

These guidelines would address problems that might arise in the course of this Department's implementation of the Act. Some examples of specific questions that should be discussed include:

- o Could a Federal employee/inventor accept compensation as a consultant from a firm which is licensing that employee's invention from the Federal government?
- o Could a Federal employee/inventor or co-inventor accept compensation for giving technical advice to a private firm on developing an invention that these employees made under a cooperative agreement with the laboratory?
- o Could a Federal employee/inventor invest or become a stockholder in a firm which is licensing that employee's invention from the Federal government?
- o Could a Federal employee/inventor become an officer in a firm which is licensing that employee's invention from the Federal government?

- o Could a Federal employee/inventor remain an employee and become an officer in a firm which, as a result of a cooperative agreement, has been granted in advance a patent license for all that employee's inventions arising under the agreement?
- o Would a Federal employee/inventor who obtains a license from the government to use his or her own invention receive 15 percent of the royalties back from the government that he or she paid to the government for the right to use the invention?
- o What restrictions are there on a former employee of a Federal laboratory negotiating a cooperative R&D agreement with that Federal laboratory?
- o Under what circumstances can an employee of a laboratory leave the laboratory and become an employee of a company which has a cooperative agreement with the laboratory?



UNITED STATES DEPARTMENT OF COMMERCE
The Assistant Secretary for Productivity,
Technology and Innovation
Washington, D.C. 20230

(202) 377-1984

Mr. Lawrence J. Rizzi
Director, GSA FAR Project
General Services Administration
4040 North Fairfax Drive, Suite 700
Arlington, Virginia 22203

Re: CAAC Case 85-49 Rights in Data and Copyrights,
DAR Case 85-87, FAR Case 85-39 (MM)

Dear Larry,

This is to amplify the Commerce comments presented at the April 9, 1986, Civilian Agency Acquisition Council (CAAC) meeting on the subject case. As we noted, the draft technical data regulations do not permit contractors, other than participants in the Small Business Innovation Research (SBIR) Program and educational institutions (under specified conditions), to copyright data first produced under a contract unless: a. it is a scientific journal article based on or containing such data or; b. the contracting officer approves.

The restriction and contractor rights is stated on page 44 in the basic data clause as follows:

"The prior, express written permission of the contracting officer is required to establish claim to copyright subsisting in all other data first produced in the performance of this contract."

We consider this to be an unauthorized departure from the practice of most agencies and object to its implementation without statutory or express Administration policy guidance. The Department of Defense (DOD) regulations which permit all contractors to copyright data subject to an appropriate license in the Government illustrates the conventional treatment.

At the April 9, CAAC meeting the chairman of the drafting committee made clear that the driving force for this departure is to provide publication materials for dissemination by the National Aeronautics and Space Administration and the Department of Energy contractors hired for this purpose. We believe you should note the following:

a. This objective is inconsistent with OMB Circular A-130, which requires an agency to ascertain whether the private sector is able to undertake contemplated agency information and

dissemination activities prior to undertaking them itself. (See sections 7e, 8a(1), 8a(9)(b), and 8a(11)(b)). The draft regulations are the reverse of this requirement and presume agency dissemination unless persuaded otherwise by the contractor who originated the information;

b. The draft regulations are diametrically opposed to the January 8, Economic Policy Council recommendation that the Office of Management and Budget develop a technical data policy permitting contractors to retain ownership of all technical data generated in performance of contract subject to appropriate license rights in the Government to enable it to utilize the data for the purpose it was generated. The Economic Policy Council recommendation is consistent with the President's Memorandum on Government patent policy which requires that all contractors, to the extent not otherwise provided by law, be permitted the first right of ownership to the patentable results of their research;

c. The draft regulations are the opposite of DOD treatment of copyright in their Defense Federal Acquisition Regulations (DFARs). As noted, the DFARs permit all contractors to copyright data subject to appropriate license in the Government. This has been the traditional treatment of copyright for over 40 years rather than the proposed case-by-case petition procedure;

d. The draft regulations are inconsistent with special provisions that have been provided to educational institutions and small businesses engaged in the SBIR programs. These provisions permit contractors to copyright data resulting in performance of their contracts. There are no compelling reasons for this dichotomy of treatment.

In light of the foregoing, we believe it is important to revise the basic data clause to permit contractor ownership of copyrightable data subject to an appropriate license in the Government. This would provide for all Government needs for procurement of goods and services, while being consistent with evolving policies related to the private sector. To do otherwise would destroy the incentive to disseminate and further develop copyrightable data. For example, computer programs must be continuously managed and debugged to make them useful in the commercial marketplace. Government ownership acts as a disincentive to the critical involvement of the originating contractor or marketing distributor if their market position cannot be protected.

In addition to the above, we take strong issue with the draft subcommittee chairman's attempt to modify the draft regulations to permit agencies that believe they have established dissemination functions to withhold copyright rights from educational institutions. Virtually every university comment protested the reversal of traditional policy as discussed above. This protest led to the special provision drafted for universities. The chairman's proposed language, which was not

developed or discussed in subcommittee, substantially modifies the subcommittee's recommendation to the council and ignores the overwhelming preponderance of the proposed comments. Further, the proposed language directly conflicts with the sections of OMB Circular A-130 cited above.

D. Bruce Merrifield

cc: Honorable Wendy Lee Gramm, Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget

Honorable Stephen J. Entin, Acting Assistant
Secretary, Economic Policy
U. S. Department of the Treasury

Honorable John P. McTague, Acting Director
Office of Science and Technology Policy

In Order (2)
Per 4838

ABSTRACT OF SECRETARIAL CORRESPONDENCE

TO: The Secretary The Deputy Secretary

Date: FEB 20 1987

BRIEFING MEMORANDUM

From: Under Secretary for Economic Affairs RO

Prepared by: Norman J. Latker/EA/OPTI/377-0659

SUBJECT: Federal Acquisition Regulation on Technical Data and Copyrights

GSA has proposed a regulation defining Government and contractor rights to technical data used or produced in procurement contracts. In its current form, the regulation (appended) is inconsistent with Administration policy and should not be approved.

BACKGROUND

The President's Competitiveness Initiative commits the Administration to helping commercialize nonpatentable results of Federally-funded research. The initiative would permit Federal contractors to own software, engineering drawings and other technical data generated by Federal contracts in exchange for royalty-free use by the Government. This provision on technical data follows logically from the President's memorandum of February 18, 1983, leaving the title to inventions resulting from Federally-funded research with the contractor.

GSA's proposed rule would provide unlimited discretion to agencies to retain ownership of technical data rather than giving the data to the contractor.

The appended draft letter to Jim Miller recommends that OMB not approve the GSA regulation. You urge OMB to return the regulation to GSA for revision to conform with the President's Initiative.

Control No. 701395

(SIGNED)
MAR 11 1987

PREPARED BY	CLEARED BY	CLEARED BY	CLEARED BY	CLEARED BY	CLEARED BY
DBMerrifield A/S, PTI	REllert Ch.C./EA	ES			
<i>JW</i> 2/17/87	Robert B. Ellert FEB 18 1987				



THE SECRETARY OF COMMERCE
Washington, D.C. 20230

MAR 0 4 1987

Honorable James C. Miller, III
Director, Office of Management
and Budget
Washington, D. C. 20503

Dear Jim,

OMB's Office of Information and Regulatory Affairs is reviewing a set of GSA regulations involving civilian-agency ownership of technical data. In their current form, these regulations are inconsistent with Administration policy.

Item 21 of "The President's Competitiveness Initiative" commits the Administration to helping commercialize nonpatentable results of Federally-funded research. Specifically, the item would permit Federal contractors to own software and other technical data in exchange for royalty-free use by the Government.

Item 21 is a logical outgrowth of the policy established for Government patents by the President's memorandum of February 18, 1983. This memorandum leaves title to inventions resulting from Federally-funded research with the contractor.

The proposed GSA regulations move in the opposite direction, providing unlimited discretion to agencies to retain ownership of technical data rather than giving it to the contractor.

The regulations also ignore the recommendation on contractor ownership of technical data by the White House Conference on Small Business and Section 21(b)(2) of the Federal Procurement Policy Act.

I urge that you return the regulations to GSA and request that they be revised to give contractors the first option to ownership of Federally-funded technical data as intended by Item 21.

Sincerely,

A stylized signature of the Secretary of Commerce, appearing to read "C. V. ...".

Secretary of Commerce

EA/OPTI/FTMP/Norman Latker/rh 2/17/87
bc: Dr. Ortner (2)
Dr. Merrifield
Dr. Williams
Norm Latker
ES (4)
Chron
Read