LEGISLATIVE RESEARCH COMMISSION

BIOTECHNOLOGY DEVELOPMENT

REPORT TO THE 1985 GENERAL ASSEMBLY OF NORTH CAROLINA

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Introduction

The Legislative Research Commission, originally created in 1965 and authorized by Article 6B of Chapter 120 of the General Statutes, has the authority, pursuant to the direction of the General Assembly, "to make or cause to be made such studies of and investigations into governmental agencies and institutions and matters of public policy as will aid the General Assembly in performing its duties in the most efficient and effective manner" and "to report to the General Assembly the result of the studies made," which reports "may be accompanied by the recommendations of the Commission and bills suggested to effectuate the recommendations." G.S. 120-30.17. The Commission is chaired by the Speaker of the House and the President Pro Tempore of the Senate, and consists of five Representatives and five Senators who are appointed respectively by the Cochairmen. G.S. 120-130.10(a).

Chapter 905 of the 1983 Session Laws (House Bill 1142) authorized the Legislative Research Commission to study, among other subjects, biotechnology development as outlined in Senate Joint Resolution 620 (Appendix B, pages 42-45) and House Joint Resolution 1282 (Appendix C, pages 45-49), and as specified in Chapter 899 of the 1983 Session Laws (House Bill 1122), which created the New Technology Jobs Act (Appendix D, pages 50-54). Section 6 of Chapter 905 authorizes a report to the 1984 or 1985 Sessions of the General

Assembly, or in the alternative permits an interim report to the 1984 Session and a final report to the 1985 Session. The Biotechnology Study Committee did make an interim report.

The Joint Resolutions referred to above called for the study committee to review the projections that biotechnology will have a pervasive impact on various industries, as well as other areas; to review the steps being taken by other states to strengthen their positions in biotechnology; to review the present status of and further plans for biotechnology programs in the state's universities, the North Carolina Biotechnology Center, the Department of Commerce, the state's business community, and other organizations concerned with the development of biotechnology in the state; to review the development of the federal guidelines for safe conduct of research and development in this area, as well as the experiences of other states that have addressed that issue; and, finally, to "determine the short term and long term needs for North Carolina to be at the forefront of the technological and economic developments in the rapidly advancing field of biotechnology."

The study committee has looked at each of these issues and has addressed them, either in its interim report or in this final report, and in some cases in both. The recommendations in the interim report, which were intended to fulfill the mandate to the study committee to determine the state's short term needs, were adopted by the General

Assembly in the 1984 Session, although the amounts funded were different than those recommended. This final report expands on some of the information provided in the interim report, providing complete answers to all of the questions outlined above, and specifically lays out the "long term needs for North Carolina to be at the forefront of the technological and economic developments in the rapidly advancing field of biotechnology."

Findings of the Study Committee

The Biotechnology Study Committee makes the following findings based upon the testimony of witnesses that have appeared before it, the report of its Economic Advisory Panel, and other information supplied to it by its staff:

I. After further study following its interim report, the committee feels even more strongly that biotechnology will have a pervasive economic impact on agriculture, forestry, marine biology and aquaculture, pharmaceuticals, chemicals, medical care, pollution control, and many other industrial and commercial areas. Furthermore, biotechnology-related developments in many of these areas will have positive effects on human health and the environment. (For a more complete explanation of biotechnology, see Biotechnology: What Is It and Why Is It So Important?, Appendix E, pages 55-60.)

II. A carefully planned major state effort in biotechnology can bring substantial benefits to every area of the state through industrial expansion, increased employment, and increased agriculture productivity. This effort can also maintain and improve the academic excellence of our public and private universities and colleges in science and engineering.

III. As stated in the interim report of the committee, many other states are keenly aware of the economic significance of biotechnology and have undertaken programs to strengthen their positions in this area. This competition from other states necessitates immediate action on the part of our state to maintain our existing competitive edge and to achieve a position of national leadership in biotechnology.

IV. A successful biotechnology development program must recognize the need for targeted economic development and that economic development in biotechnology depends on our having strong academic resources. Commercial applications of biotechnology depend on basic research efforts to supply knowledge which can be applied to produce solutions to "real world" problems and to take advantage of commercial opportunities. Applied technology cannot exist very long if it is not backed up by basic research. These needs are complementary, but the program must be designed in such a way that there is also flexibility and independence for the academic and commercial sectors so that each is able to respond to its own needs as they relate to the goals particular to its efforts.

Such a program must include substantial financial support for basic research and teaching, as well as focused efforts in applied technology, agriculture, forestry, and other commercial activities (using the term in its broadest sense) related to North Carolina problems and opportunities.

It must also include specific components to promote the diffusion of biotechnology advances and to spread economic development across the state. This combination will form the underpinning of our efforts to promote the state as a center of excellence in biotechnology, resulting in the maintenance of our existing industries, recruitment of new ones, and the strengthening of our agricultural base. It will also help maintain the strength of our educational system.

This program must also include a cooperative effort to frame strategies for economic development that will focus on opportunities and problems unique to North Carolina and the southeast region. This effort should be led by the North Carolina Biotechnology Center (NCBC) in consultation with appropriate groups, such as the universities, the Department of Commerce, the Department of Agriculture, and the commercial and agricultural sectors of our state.

A biotechnology development effort must get underway immediately and must be highly visible around the world. It should include recruitment of world-class researchers and the putting in place of other components of research, together with the strengthening of NCBC and additional focus on biotechnology in the Department of Commerce and the Agricultural Extension Service. It should include the construction of bioprocess engineering facilities, if the need is shown by the study described in Recommendation VI., page 13.

V. Significant investments in facilities and equipment should include, whenever possible, funding from industry and other non-state sources.

VI. The biotechnology program must include requirements for the accountability of all recipients of state funds so that the results of the investment can be measured by the General Assembly, the Governor, and the people of North Carolina.

VII. The Department of Community Colleges is in a position to provide training for the technicians needed for biotechnology-related industries and will maintain its flexibility and responsiveness by continuing to work with the North Carolina Biotechnology Center, as it has in the past.

VIII. The Department of Public Instruction is aware of activity in biotechnology in the state and will be taking it into consideration as it plans for science and mathematics education. It is already in communication with the North Carolina Biotechnology Center and will continue to work with NCBC so that education of elementary and secondary school students will keep pace with biotechnology advances as they occur.

IX. The federal government is presently involved in a comprehensive multi-agency review of the federal regulatory

structure as it applies to biotechnology with an expected completion date of January, 1985. This would be in sufficient time for the legislature to assess the adequacy of the federal regulations and take action in the 1985 Session if it appears necessary to do so.

Recommendations for the 1985 Legislature

The Biotechnology Study Committee recommends that the actions which follow be taken by the Legislature, the appropriate administrative departments, and the other entities mentioned below:

I. North Carolina should undertake a program to support and promote biotechnology development in the state which will result in strengthening the state's public and private universities and colleges, as well as producing positive economic benefits which can be spread across the state. The components and funding of these efforts are outlined in the recommendations which follow. The complete program will cover a five year period, but the specific activities for the 1985-87 biennium are also indicated. The total cost of the five year program is $70.085 million. The cost for the 1985-87 biennium is $40.235 million, with $18.949 million required in FY 1985-86, and $21.286 million in 1986-87.

II. State funding for activities of the North Carolina Biotechnology Center (NCBC), not including construction of facilities, should be increased by appropriating additional funds of $4.8 million per year for five years, for a total of $24 million of additional money. This would be an increase of $9.6 million for the 1985-87 biennium for support of the NCBC's activities which would include

determining areas of focus involving opportunities and problems unique to North Carolina, enhancing and promoting the economic impact of biotechnology research, and promoting biotechnology-related economic development throughout the state. In cooperation with the Department of Commerce, NCBC would expand its activities in areas of direct promotion of the state as a center of excellence in biotechnology and, with the additional cooperation of the Agricultural Extension Service, promote the spread of biotechnology-related economic development across the entire state. NCBC would expand its programs of competitive basic and applied research grants to private and public institutions in the state, and occasionally to private research scientist entrepreneurs. It could also use its funds for faculty salary supplements for private and public universities and colleges; grants to private and public universities to aid in recruiting world-class scientists and engineers; grants to develop new university and college courses; grants for special equipment in private and public universities and colleges; support for limited in-house research; entrepreneurial support; conferences and symposia; coordination and mobilization of all biotechnology resources in the state; and for the acquisition and maintenance of specialized computer software which would be available to the private and public universities and colleges and to the private sector working in the area of biotechnology.

III. The Legislature should appropriate $1.12 million for use by NCBC to construct a facility to carry on its functions at the new recommended level. Of this amount, $.112 million should be allocated for FY 85-86 for planning, site acquisition and site preparation, and the balance, $1.008 million should be allocated for FY 86-87. The total cost of the facility is estimated to be $2.24 million, with NCBC being required to obtain commitments for the additional funding from outside sources before any state funds are expended. These commitments must be obtained by June 30, 1986. It is expected that the facility would be approximately 20,000 square feet.

IV. Funding for the University of North Carolina system should be increased by appropriating an additional $4.8 million per year over five years for a total commitment of $24 million of additional funds over current levels, not including funding for construction of facilities. This would be an increase of $9.6 million for the 1985-87 biennium. These funds would be used to develop a world-class program in biotechnology research and teaching, with the focus being on the recruitment of world-class scientists and engineers, supported by younger excellent researchers. While a portion of these funds would be used for the salaries of the newly recruited scientists and engineers working in the field of biotechnology, these funds would also be used for the other components of such a

program, examples of which would be support of post-doctoral students and graduate students; employment of technical personnel; start-up research money for newly recruited researchers; new course development; equipment; and any other components deemed necessary by the Board of Governors to recruit and set up world-class researchers and support personnel and for the development of first-rate biotechnology teaching and research programs in the university system.

These funds should be specifically designated for biotechnology and should be appropriated to the Office of State Budget and Management, where they would be held in a nonreverting reserve to be disbursed as needed by the Governor, with the advice of the Advisory Budget Commission, and after notification to the Joint Legislative Commission on Governmental Operations, provided that the conditions for release of the funds specified in Recommendation X. are complied with.

No portion of the new money recommended for the five year period could be used for maintenance of efforts funded prior to FY 85-86. These new funds would, however, be used to maintain any efforts begun with them during this five year period.

V. In order to provide space for the new programs implemented under Recommendation IV, the Legislature should appropriate to the Office of State Budget and Management

for the 1985-87 biennium the sum of $17.155 million, evenly divided between the two fiscal years, to be disbursed by the Governor, with the advice of the Advisory Budget Commission, and after notification to the Joint Legislative Commission on Governmental Operations, provided that the requirements of Recommendation X. have been complied with. These funds could be used for renovation of existing space or construction of new space. They could not be used for other capital expenditures, such as equipment, which would be funded from the appropriations in Recommendation IV., or from other sources.

VI. NCBC should complete a study to determine the merits, cost, type and location or locations of partially state funded bioprocess engineering facilities in sufficient time to present it to the Legislature during the 1985 Session. (The formation of the study group, which will include university and industry members and employ outside consultants as needed, has already begun.)

VII. Depending upon the outcome of the study discussed in Recommendation VI above, the Legislature should appropriate up to a total of $2.66 million during FY 85-86 and FY 86-87 for the construction of bioprocess engineering facilities, provided that commitments for this purpose equal to twice the amount of state funds are obtained from non-state sources by June 30, 1986. Funds for FY 85-86 should be $.66

million for planning, acquisition of a site or sites, and commencement of construction. The balance of state funds, $2 million, should be budgeted for FY 86-87. Furthermore, when such facilities are in operation, most probably during FY 87-88, the Legislature should appropriate up to $250,000 of state funds per year for their operation. This would amount to approximately 25 percent of operating costs, with the balance coming from user fees.

VIII. The Legislature should provide funding for the Department of Commerce to train personnel in biotechnology subjects, and for specific targeting of industrial applications of biotechnology, for promotion of the state as a biotechnology center, for recruitment of new industries related to biotechnology, and for programs designed to promote biotechnology among existing commercial entities in the state. During the five years proposed for this developmental effort, a total of $200,000 should be allocated to the Department of Commerce. Specifically, the Legislature should appropriate $50,000 for use of the Department of Commerce during FY 86-87, and a similar amount for each fiscal year following through FY 89-90.

IX. Funding for the Agricultural Extension Service should also be increased during this promotional effort because the rate at which biotechnology developments related to agriculture and forestry are disseminated to the agricultural and

forestry interests in the state and put to use by them will have a direct effect on the economic payback of the state's overall investment in biotechnology. Therefore, a total of $200,000 should be allocated to the Agricultural Extension Service for this purpose at the rate of $50,000 per fiscal year with the first appropriation being for FY 86-87. This money would be used to educate farmers about biotechnology and to speed the dissemination of biotechnology-related agricultural improvements as they become available.

X. Due to the size of the monetary commitment involved, it is necessary to have procedures for accountability and the reporting of efforts of all recipients of funding under this proposal.

NCBC, prior to receiving the first funds under this proposal, and thereafter on a biennial basis, prior to receiving funds appropriated for the succeeding biennia, should be required to produce an action plan detailing its activities over the coming two years. This action plan would be distributed to the General Assembly, the Governor, the Advisory Budget Commission, the Department of Commerce, the Commissioner of Agriculture, the Secretary of Natural Resources and Community Development, the Board of Science and Technology, the University of North Carolina Board of Governors, the administrations of the Department of Community Colleges and the Department of Public Instruction, and

the general administrations of the private universities and colleges in the state.

NCBC should require annual reports of the activities of its funding grantees and the economic impact or potential economic significance of their work. These reports should also include the grantees' efforts at disseminating the results of their work, where applicable. This information should be included in an annual report by NCBC to the General Assembly, with a copy being sent to the Governor, which details all of NCBC's efforts during the preceding fiscal year, assesses the over-all economic impact of those efforts, and describes the dissemination of developments related to biotechnology. This report must be made by January 1 each year.

NCBC should prepare a cost-benefit analysis of its activities for FY 85-86 through FY 88-89 so that the economic benefit from the state's investment can be quantified. This analysis would also be sent to the General Assembly, with a copy to the Governor, not later than January 1, 1990.

As a condition to the release of the funds appropriated for the UNC system, the UNC system should be required to submit a report outlining the present status of biotechnology efforts within its constituent universities so that there will be a baseline from which it can later be determined how the money has been used. At the same time and as a further condition of receiving any of these funds, UNC should submit a five-year plan defining its

biotechnology development program, as best it can based upon current perceptions of its needs and expected state and other funding, with the understanding that this plan will change from time to time. In any event, the report and five-year plan should be submitted not later than January 1, 1986. Thereafter, UNC would be required to update the five year plan on January 1, 1987 and on January 1, 1989. In preparing the original five-year plan, and in updating it, UNC would consult with NCBC, though NCBC's approval of the plan is not required. The baseline report, the five year plan and its updates, would be sent to the General Assembly, with copies going to the Governor and NCBC.

The Board of Governors would also provide, by January 1 of each year, a report of the specific activities carried out during the preceding fiscal year with the funds provided in this plan, as well as the specific activities carried out with other funds regardless of the source, and which would also include the economic impact of these activities, and what efforts have been made at dissemination of the results, where appropriate. This report would also be provided to the General Assembly, with copies going to the Governor and NCBC.

Both the Department of Commerce and the Agricultural Extension Service would also be required to report to the General Assembly, with copies to the Governor and NCBC, on January 1 of each year, outlining their activities in the field of biotechnology during the preceding fiscal year, the

economic impact of their efforts, and, where appropriate, their efforts at dissemination of biotechnology-related information.

XI. The study committee urges the commercial financial institutions of the state to be sure they keep pace with high technology oriented business efforts in our state by maintaining staffs which are attuned to the special needs of these businesses.

XII. The study committee also recommends that the Legislature remain cognizant of the link between economic growth and programs which provide for start-up and growth financing for small businesses, as well as programs that are nurturing during the beginning years of these businesses, and that it be prepared to respond to these needs as development efforts in biotechnology and other high technology areas create more and more small businesses.

XIII. The study committee recommends that the Department of Community Colleges and the Department of Public Instruction continue to work closely with NCBC so that their respective programs will keep pace with the developments in biotechnology.

XIV. The study committee does not recommend any state action at this time to regulate the research, development or

production aspects of biotechnology because the federal government is presently involved in a comprehensive multi-agency review of the federal regulatory structure as it applies to biotechnology. It is expected that the results of this review will be published during January, 1985. It is the feeling of the study committee that additional layers of regulation should not be added unless efforts on the federal level appear to be inadequate.

XV. The study committee recommends the adoption of the legislation included as Appendix H of this report, beginning on page 99.

XVI. The study committee recommends the continuation of the study committee for the 1985-87 biennium for the purpose of continuing the General Assembly's inquiry into the subject of biotechnology in North Carolina, and recommends adoption of the legislation included as Appendix I of this report, beginning on page 108.

Summary of Report and Recommendations

The Biotechnology Study Committee has met nine times during the twelve months it has been at work, and has received extensive information concerning all of the areas it was requested to study. The committee has reached the conclusion that a comprehensive biotechnology development effort supported by state funds can produce significant tangible economic results across the entire state, and at the same time ensure that the public and private universities and colleges in the state maintain their academic excellence.

Testimony before the committee has shown that the effects of what has been termed the "biotechnology revolution" will be pervasive on a worldwide basis. North Carolina is in a unique position to take advantage of the positive effect of the developments in biotechnology because many of these developments pertain directly to areas already of economic importance to the state. These include agriculture, forestry, pharmaceutical research and production, marine biology, food processing and pollution control. In addition, there are emerging commercial areas unique to biotechnology development, such as bioprocess instrumentation and control, where North Carolina is in a good position to capture a significant market share.

There has been agreement by virtually everyone who has testified before the study committee, and by the committee's

Economic Advisory Panel, that North Carolina is in a uniquely favorable position to stimulate biotechnology-related development, both academically and commercially, because of the strengths of its universities, the existence of businesses and industries which can benefit from biotechnology and are likely to exploit it, the state's desirable business climate, and even its desirability as a place to live. Agriculture and forestry, two of the most important and geographically well-spread economic forces in our state could benefit greatly from focused advances related to them. Appropriate skills exist in our work force which can be used in areas of commercial development such as biomedical manufacturing and bioprocess instrumentation and controls, and where new skills are needed, we have the ability to teach them in our colleges, universities, and community colleges.

There is competition in other states, and, indeed, in other countries. The window of opportunity which exists for North Carolina in this area is limited in size and will close in a relatively short period of time due to this already existing competition. The most significant benefits will go to those states which have acted aggressively. Therefore, if North Carolina is to take advantage of this emerging opportunity, it must act now, and its commitment must be visible. The program proposed is for a five year period because in testimony before the committee it has been estimated that this is the period during which we must

capture our share of this market or lose out to other states.

The investment of state funds aimed at biotechnology-related objectives should be for the attraction and support of world-class researchers and for promoting interaction between universities and industry, bridging any gaps between them, so that, where appropriate, the results of basic research can quickly benefit industrial and agricultural development. In addition, there needs to be aggressive promotion of the state as an international center of excellence for biotechnology, both academically and commercially.

This two-pronged approach, which recognizes both economic and academic development in the area of biotechnology, exploits the linkages between them. As one of the committee members, Dr. Roy Morse, who heads R. J. Reynolds, Inc.'s research and development efforts, pointed out, applied technology, no matter how strongly we support it, will wither if there is not a strong basic research effort as well. On the other hand, applied technology and economic development efforts can stimulate academic growth because they heighten the interest of the business community in contributing financially and intellectually to that effort, and create an environment which is attractive to world-class researchers as well.

The program outlined in this report includes substantial monetary support for basic research and teaching, as

well as components for focused efforts in applied technology, agriculture, forestry and other commercial activities (used in the broadest sense of the word). It also provides the means to promote the diffusion of biotechnology advances and to otherwise spread economic development across the state. The combination of these components will form the underpinning of our efforts to promote the state as a center of excellence in biotechnology, maintaining and enhancing our existing industries, and recruiting new ones.

In addition to supporting the spectrum of efforts outlined above, the program is designed to show the rest of the world that North Carolina has made a commitment to biotechnology development because the program is laid out with particularity. This is important in attracting both industry and world-class researchers.

This program also provides the means for a cooperative effort to frame strategies for economic development which will focus on opportunities and problems unique to North Carolina and the southeast region. It is contemplated that this focus will be provided by the North Carolina Biotechnology Center (NCBC) in consultation with appropriate groups, such as the universities, the Department of Commerce, the Department of Agriculture, and the commercial sector.

In addition to the recruitment of world-class researchers, the program includes the putting in place of other

components of research such as younger, but excellent, researchers and teachers, equipment, startup research money ("people and related items" in the table which follows), facilities, a strengthening of NCBC, and additional focus on biotechnology in the Department of Commerce and the Agricultural Extension Service.

There is also a recommendation for the construction of bioprocess engineering facilities as part of the development program, provided the need is borne out by the study now being performed by NCBC. The uses for such facilities include the research involved in determining the feasibility and methodology of scaling-up from producing a product in the laboratory to producing it for consumption, as well as other aspects of production technology. A recent report prepared for the United States Congress pointed out that the United States was comparatively weak in this segment of biotechnology development compared to its international biotechnology competitors, most notably Japan. That report further stated:

> In the next decade, competitive advantage in areas related to biotechnology may depend as much on developments in bioprocess engineering as on innovations in genetics, immunology, and other areas of basic science.

See Commercial Biotechnology: An International Analysis (United States Congress, Office of Technology Assessment, January 1984) pages 5, 7-8. The study of such facilities and the probable construction of them was also recommended by the committee's Economic Advisory Panel. See Appendix F

of this report, pages 63-64. The existence of such facilities could be extremely attractive to biotechnology-related industries seeking to locate production facilities.

Wherever possible, the programs proposed contemplate leveraging of additional non-state funds as suggested in the Economic Advisory Panel report.

Finally, there are extensive provisions for accountability by all recipients of funds under the program so that the results of this investment can be followed as the program proceeds.

The investment of state funds over the five year period contemplated in this report is outlined in the following table:

Biotechnology Program

New State Funds Over 5 Years

(millions)

FY	85-86	86-87	87-88	88-89	89-90	5 yr. Total
UNC System						
People and related items	4.80	4.80	4.80	4.80	4.80	24.00
Construction of facilities	8.577	8.578				17.155
Total	13.377	13.378	4.80	4.80	4.80	41.155
NCBC						
All activities and administration	4.80	4.80	4.80	4.80	4.80	24.00
Construction of facilities	.112	1.008				1.12
Total	4.912	5.808	4.80	4.80	4.80	25.12
Bioprocess Engineering Facilities						
Construction and equipment	.66	2.00				2.66
Operation			.25	.25	.25	.75
Total	.66	2.00	.25	.25	.25	3.41
Dept. of Commerce		.05	.05	.05	.05	.20
Ag. Ext. Serv.		.05	.05	.05	.05	.20
Total	0.00	.10	.10	.10	.10	.40
Grand Total	18.949	21.286	9.95	9.95	9.95	70.085

In reviewing this program it is important to keep in mind that the actual funds invested in the state's biotechnology program over the five year period would be much higher than shown on the preceding table because of the leveraging effect contemplated, and in several instances required. With regard to the funding for the UNC system, one estimate provided to the study committee was that a UNC system program comprised of twenty world-class scientists and engineers could result, over a five year period, in outside research grants alone totalling $81.85 million. And the contemplated leverage effect would not be limited only to research grants. There are other areas where outside funds would augment the program, such as in monetary support of postdoctoral students, grants for acquisition of specialized equipment, and so on.

It is also important to note that NCBC already has a track record of leveraging its state funds with outside funds on a dollar-for-dollar basis. It has been estimated that the additional $24 million of state funds over the five year period would produce more than $20 million in additional non-state funds. In order to construct the facilities proposed for NCBC, there is a specific requirement in the committee's proposal that NCBC must match state construction funds with non-state funds on a dollar-for-dollar basis.

The bioprocess engineering facilities suggested by the committee are another example of leveraging state funds. The estimated overall cost of such facilities is $8 million. The

recommendation of the committee provides specifically that the $2.66 million of state funds must be matched on a two for one basis with non-state funds to produce the total of $8 million. Furthermore, it has been estimated that in the operation of such facilities, 75 percent of operational expenses would come from user fees, with state support amounting to only 25 percent.

This proposal contains funding for the training of Department of Commerce personnel in biotechnology subjects and for specific targeting of industrial applications in biotechnology, for promotion of the state as a biotechnology center, for recruitment of industries related to biotechnology, and for programs designed to promote biotechnology among existing commercial entities in the state. This component of the program is important for the same reason a sales force is important to any business. You can have the best product in the world, but competent and aggressive people have to get out and sell it. The study committee contemplates Department of Commerce personnel who are well versed in the subject area, will use the existence of this program to help sell the state as a place for biotechnology-related businesses to locate, and who will also help promote biotechnology advances among existing businesses in the state. The study committee expects the Department of Commerce to work closely with NCBC in these efforts. This component of a state program was also

recommended by the study committee's Economic Advisory Panel. See Appendix F of this report, pages 64-65.

The funds proposed for the Agricultural Extension Service are important because the economic payback of the state's investment related to agriculture and forestry is directly tied to the speed with which new developments are adopted by the agricultural and forestry interests in the state. This was documented by the Economic Advisory Panel, which specifically recommended funding for this purpose. See Appendix F of this report, pages 64-65, 66-82. The proposed funding would be used initially to educate farmers and foresters about the coming advances related to biotechnology, and as these advances were developed, to ensure that they were rapidly put to use.

The biotechnology study committee believes that the program it has proposed strikes a balance between the needs of the academic community and the need to produce tangible, economic results that will spread across the entire state in a relatively short period of time. However, it is important to remember that this is a comprehensive program, carefully worked out by the study committee, and it is the linkages between the various components of the plan which will result in a successful state effort.

Proceedings of the Study Committee

The Biotechnology Study Committee met a total of four additional times after delivering its interim report to the 1984 Session of the 1983 General Assembly. These meetings occurred on September 26, October 15, November 9, and December 4, 1984. Altogether, the committee met a total of nine times during its total term.

During the May 15, 1984 meeting of the committee, it authorized the committee cochairmen to appoint a panel to assist the committee in determining whether or not there would be sufficient economic returns to justify the cost associated with a comprehensive state funded program for biotechnology development. If such a program was justified, the committee also wanted advice on how the economic benefits could be spread across the entire state. Finally, the committee wanted the panel to examine the proposals which had been put before the committee, as outlined in Appendix F of the committee's report to the 1984 Session of the 1983 General Assembly, to determine if these proposals would result in economic development or whether they should be modified. This panel, which came to be known as the Economic Advisory Panel, was appointed by the cochairmen in June, 1984. The members of the panel were Herbert L. Schuette, Professor of Business at Duke University, who served as chairman; James E. Holmes, a principal of an investment banking firm in Winston-Salem and a member of the University of North Carolina Board of Governors; Thomas

Johnson, Professor of Business at North Carolina State University; Francis X. Russell, an economist and commercial banker in Charlotte; Curtis P. McLaughlin, Professor of Business at the University of North Carolina at Chapel Hill; Samuel J. Wornom, III, the chief executive officer of a large business enterprise with headquarters in Sanford. The members of the panel served without compensation.

The Economic Advisory Panel was assisted by two research assistants who were funded by the Biotechnology Study Committee and the North Carolina Biotechnology Center. Quentin Lindsey, the Governor's Science Advisor, Laura Meagher, then Acting Administrator of the North Carolina Biotechnology Center, and Steven Rose, Counsel to the Biotechnology Study Committee, provided additional assistance to the panel.

The panel met during the months of July and August and issued its report entitled Economic Effects of a North Carolina Biotechnology Initiative: A Preliminary Study in September of 1984. The report was presented to the study committee at its meeting on September 26, 1984 at the Fuqua School of Business at Duke University.

Selected portions of the panel's report, including the Summary of Findings and Recommendations and some of its analyses of selected economic sectors of North Carolina and quantitative assessments of the likely effects of a biotechnology initiative on those sectors, are included in the Appendix to this report (Appendix F, pages 61-95). The panel concluded that a significant state funded effort in

biotechnology could result in a substantial economic payback to the state in a relatively short period of time provided there was a focus on state specific problems, such as those in agriculture and forestry and provided further, that efforts were targeted toward specific opportunities that the state could take advantage of. For example, one of the computer models created by the panel for purposes of its study showed that a breakthrough in agriculture biotechnology in even a single area, such as corn, could return approximately $42 million in incremental farming profits over a 15 year period, in discounted 1985 dollars. (Appendix F, page 74.) Using an industrial example, in the bioprocess instrumentation sector, the panel found that the state could realize an added payroll of $200 million in 1985 dollars over a fifteen year period, provided it focused a significant effort on this particular technology. (Appendix F, page 95.)

These examples are significant because they also address the question of whether the economic benefits can be spread across the state. That is, a North Carolina specific breakthrough in corn production would have economic impact for farmers all across the state. A field such as bioprocess instrumentation is one where production could be located in many areas across the state because the skills needed for this type of production either already exist in our work force, or could be provided by the community college system.

At the request of the study committee, some additional examples of potential economic benefits were developed after

the panel's report was made. These concern forestry production and an example pertaining to the biomedical sector, a diagnostic kit for Rocky Mountain spotted fever. A summary of these, prepared by Professor Schuette, is included in the Appendix to this report (Appendix G, pages 96-98).

The specific recommendations of the panel, in addition to the recommendation that a North Carolina biotechnology development strategy be targeted, included the admonition that the degree of success in a biotechnology initiative also depended on creating and supporting centers of basic and applied research in science and engineering which would be seen as sources of excellence in the field of biotechnology.

Further specific recommendations included the suggestion that the costs and merits of a partially state funded bioprocess facility be examined, and if justified that it be built; that significant investments in plant and equipment by the state should, wherever possible, be made jointly with industry and other non-state funds; that NCBC should acquire and maintain computer software for use by universities and industry in biotechnology research and development; that NCBC should lead a cooperative effort with appropriate groups, including the state's universities, to frame a North Carolina biotechnology industry strategy so that specific industry segments could be targeted; that the efforts of the Department of Commerce, the Agriculture Extension Service, and the Agricultural Research Service should be strengthened, and that

the ability to train production workers and technicians should keep pace with the developments in biotechnology industries.

Perhaps the most significant recommendation of the Economic Advisory Panel was that there should be a major increase in the funding support for NCBC over that which had been discussed by the study committee up to that time, since NCBC would be the vehicle for focusing the state's efforts in biotechnology, and, in the opinion of the panel, such a focus was necessary in order to obtain a substantial economic payback for the state's investment, in a reasonable period of time. Recommendation #1 of the Economic Advisory Panel suggested that the funding for NCBC be increased by $24 million over a five year period, and that $6 million be allocated to the state university system over that same period for support of faculty positions in focused areas of biotechnology. On this recommendation, the panel was evenly split. (The panel was unanimous on all other aspects of the report.) While all members of the panel agreed that the level of funding for NCBC should be increased to $24 million as shown in the report, there was disagreement on the allocation of funds to the state university system. From the testimony of panel members at the September 26, 1984 meeting, it appeared that the split had to do with the failure of the report to identify the full scope of the state university system's funds. Although the report does not say that the university system should be limited to $6 million over the five year period, and testimony at the study committee meeting showed that the panel members who favored the

recommendation felt that the university system would seek additional funds from the Legislature on its own, the wording of the report did create this perception. Unfortunately, the extremely tight schedule of the panel in order to produce the report in time for the September study committee meeting lead to the printing of the final draft of the report with only a telephone review by panel members. It was apparent from listening to the discussion at the September 26th study committee meeting that the differences raised by some panel members could probably have been resolved had more time been allowed.

Nevertheless, the Economic Advisory Panel had performed the task which the study committee asked it to do and the bottom line was that, in the opinion of the panel, a significant state effort in biotechnology development was justified and that the benefits could be spread across the state, but that such an effort required not only significant support of the state's academic institutions, but a substantially funded economically oriented entity to focus and drive the economic segment of the development effort.

The next meeting of the study committee took place on October 15, 1984. The focus of that meeting was to attempt to pull together once again all of the information the study committee had received and to see if there was a basis for agreement on the kind of development effort the state should make. The committee concluded that when all of the information was put together, it was apparent that a two-pronged approach

to biotechnology development was needed. That is, the state needed to make a significant commitment in academic and economic development, producing programs that were complementary in a desirable way, but which also had flexibility and independence so that they could accomplish their particular goals. A comprehensive state program must show its support of academic and economic development with sufficient particularity so that it appears to the rest of the world that North Carolina has made a firm commitment to biotechnology development. This would aid in commercial recruitment and also create an atmosphere that was attractive for recruiting world-class researchers.

At that meeting,the study committee reviewed a comprehensive staff proposal embodying academic and economic development which, for the most part, resulted in the recommendations in this report.

The North Carolina Biotechnology Center, which by now had become an independent non-profit corporation, was supportive of this comprehensive approach. The committee then requested that the other parties effected by the proposal, including the public and private universities, the Department of Commerce, the Agricultural Extension Service, the Department of Agriculture, the Department of Community Colleges, and the Department of Public Instruction, be asked to respond to the proposal.

The November 9, 1984 meeting of the study committee involved a review of all of the responses which the committee had requested at its October 15 meeting. All of the responses

of the effected parties were positive and supportive of the proposal. There were some suggestions for minor changes in the proposal, which the committee adopted. These involved deleting funds which had been proposed for the Department of Community Colleges to provide coordination for technical training of biotechnology workers. The department had informed the committee that it felt it could meet these needs out of its normal operating budget. In addition, the Agricultural Extension Service had proposed beginning its funding for dissemination of biotechnology-related developments to farmers two years earlier than was originally proposed. It was their feeling that if they began to educate farmers about the coming advances in biotechnology prior to their actual availability, the dissemination of those advances when they were ready for use would be much quicker, thereby enhancing the payback to the state and promoting further the spread of the economic benefits across the entire state. The study committee agreed with both of these changes.

The study committee next heard a report from its counsel describing the present status of the federal government's efforts to implement a regulatory structure for biotechnology research and development. There is in existence a committee known as the Cabinet Council Working Group on Biotechnology, chaired by Dr. George Keyworth, President Reagan's Science Advisor, which includes representatives from the National Institutes of Health, the Federal Drug

Administration, the Environmental Protection Agency, the Department of Agriculture, and the Department of Commerce. It is the present feeling of the working group that the full spectrum of biotechnology-related research and development can be regulated within the confines of the existing regulatory agencies. At this time, there is discussion by the working group concerning the creation of two new committees. One would be an interagency committee which would deal with jurisdictional and administrative issues. The second committee would be an advisory committee made up of outside consultants who would advise the agencies on science related issues. The working group expects to publish its findings, which will include guidelines for the various agencies involved, around January 1, 1985. This will also include an analysis of the existing laws and the existing regulatory procedures of the various agencies, as they relate to biotechnology.

Meanwhile the Environmental Protection Agency has already published interim guidelines for field testing of microbial pesticides, because there were some commercial entities ready to do such testing who had asked that guidelines first be established. Federal Register, Volume 49, Number 202, October 17, 1984, pages 40659-40661. Of course, as was pointed out to the committee in its meeting of December of 14-15, 1983, there already exists a regulatory structure for experiments carried out with federal funds. This is administered by the National Institutes of Health's

Recombinant Advisory Committee (RAC). See the study committee's Report to the 1983 General Assembly, 1984 Session, page 18.

The study committee then directed its counsel to draft a final report embodying the proposal from the October 15 meeting, taking into account the changes suggested at this meeting, as well as the current information on regulation and control discussed above, and adjourned with the intention of meeting on December 4, 1984, to review the draft and adopt a final report.

The draft of the report was prepared and mailed to the committee members in advance of the December 4 meeting in accordance with the rules of the Legislative Research Commission. The committee held its last meeting on December 4, 1984, and adopted this report.

APPENDICES

MEMBERS
LEGISLATIVE RESEARCH COMMISSION 1983-84

House Speaker Liston B. Ramsey
Chairman

Representative Chris S. Barker, Jr.

Representative John T. Church

Representative Bruce Ethridge

Representative John J. Hunt

Representative Margaret Tennille

Senate President Pro Tempore
W. Craig Lawing, Chairman

Senator William N. Martin

Senator Helen R. Marvin

Senator William W. Staton

Senator Joseph E. Thomas

Senator Russell Walker

MEMBERS
BIOTECHNOLOGY STUDY COMMITTEE

Senator William G. Hancock, Jr.
Cochairman

Senator Robert M. Davis, Sr.

Senator Charles W. Hipps

Senator Robert B. Jordan, III

Senator Kenneth C. Royall, Jr.

Senator William Staton

Dr. Wendell Allen

Dr. Roy E. Morse, Sr.

Mr. William Veeder

Representative Bobby R. Etheridge
Cochairman

Representative Sam Beam

Representative Marie Colton

Representative John J. Hunt

Representative J. P. Huskins

Mr. Charlie Carpenter

Dr. Frank Hart

Mr. James E. Gapinski

Steven Rose, Committee Counsel

Jerry Batchelor, Committee Clerk

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 1983

S

I

SENATE JOINT RESOLUTION 620*

Sponsors: Senators Hancock, Jordan.

Referred to: Rules and Operation of the Senate.

June 15, 1983

A JOINT RESOLUTION AUTHORIZING THE LEGISLATIVE RESEARCH COMMISSION TO STUDY THE NEEDS FOR THE DEVELOPMENT OF BIOTECHNOLOGY IN NORTH CAROLINA.

Whereas, biotechnology is a new frontier of science that will lead to new products and processes worth 40 billion dollars in the year 2000 and that will affect 70 percent of the GNP in 30 years; and

Whereas, biotechnology is already the basis for new products in the human and animal health field and has even greater potential to lead to new, valuable agriculture and forestry products; and

Whereas, advances in biotechnology will be critical to maintaining the health and vitality of the State's traditional industries - agriculture and forestry - and of many of its developing industries - pharmaceuticals and health care - and biotechnology also will be the basis for the development of new small businesses; and

Whereas, a strong educational, research, financial, and institutional base is necessary to attract the substantial funds

now being invested in biotechnology and to nurture the development of existing industry and new small businesses; and

Whereas, North Carolina has the potential to realize economic benefits from advances in biotechnology, but the competition is severe among the states to attract the investments and to nurture the growth in biotechnology; and

Whereas, earlier concerns with the safety of biotechnology research and development have decreased substantially;

Now, therefore, be it resolved by the Senate, the House of Representatives concurring:

Section 1. The Legislative Research Commission shall review the basis of the projections that biotechnology will have a pervasive impact on industries such as pharmaceuticals, agriculture, forestry, chemicals, pollution control, and other areas that the Commission might identify.

Sec. 2. The Commission shall review the devlopment of the federal guidelines for the safe conduct of biotechnology research and development and the experiences of other states that have addressed this issue.

Sec. 3. The Commission shall review the steps being taken by other states to strengthen their education, research, financial, and institutional resources in biotechnology.

Sec. 4. The Commission shall review the current status and future plans of the biotechnology programs in North Carolina's universities, the North Carolina Biotechnology Center, North Carolina companies, the Department of Commerce, and any

other organizations concerned with nurturing the development of biotechnology in the State.

Sec. 5. The Commission shall determine the short-term and long-term needs for North Carolina to be at the forefront of the technological and economic developments in the rapidly advancing field of biotechnology.

Sec. 6. The Commission may call upon any State department or agency to provide it with information pertinent to its inquiry. In addition, the Commission may invite representatives of private industry and universities as well as experts from other states and the federal government to offer pertinent testimony.

Sec. 7. The Commission shall appoint a Committee to conduct the study outlined above. The membership of the Committee shall consist of five members of the House and five members of the Senate, two representatives of North Carolina universities with programs in biotechnology, two officials from North Carolina companies engaged in research, development, and production in biotechnology, and two representatives from the financial community knowledgeable concerning the investment climate in biotechnology.

Sec. 8. The Commission shall file a report with the Governor and the General Assembly no later than May 1, 1984. The report shall set forth the Study Commission's findings, conclusions, recommendations, and proposed legislation, if any. At this time, the Commission also may request that the study be continued.

Sec. 9. The Legislative Services Commission shall provide professional and other staff assistance upon the request of the Commission. The Commission may wish to seek additional staff assistance from the North Carolina Biotechnology Center and the universities. In addition, up to twenty-five thousand dollars ($25,000) of the appropriations in 1983-84 and 1984-85 to the Biotechnology Center in "The New Technology Jobs Act" shall be used by the Center to support this study.

Sec. 10. This resolution shall become effective July 1, 1983.

GENERAL ASSEMBLY OF NORTH CAROLINA

SESSION 1983

H

I

HOUSE JOINT RESOLUTION 1282*

Sponsors. Representative Bob Etheridge.

Referred to: Rules and Operation of the House.

June 14, 1983

A JOINT RESOLUTION AUTHORIZING THE LEGISLATIVE RESEARCH COMMISSION TO STUDY THE NEEDS FOR THE DEVELOPMENT OF BIOTECHNOLOGY IN NORTH CAROLINA.

Whereas, biotechnology is a new frontier of science that will lead to new products and processes worth 40 billion dollars in the year 2000 and that will affect 70 percent of the GNP in 30 years; and

Whereas, biotechnology is already the basis for new products in the human and animal health field and has even greater potential to lead to new, valuable agriculture and forestry products; and

Whereas, advances in biotechnology will be critical to maintaining the health and vitality of the State's traditional industries - agriculture and forestry - and of many of its developing industries - pharmaceuticals and health care - and biotechnology also will be the basis for the development of new small businesses; and

Whereas, a strong educational, research, financial, and institutional base is necessary to attract the substantial funds

now being invested in biotechnology and to nurture the development of existing industry and new small businesses; and

Whereas, North Carolina has the potential to realize economic benefits from advances in biotechnology, but the competition is severe among the states to attract the investments and to nurture the growth in biotechnology; and

Whereas, earlier concerns with the safety of biotechnology research and development have decreased substantially;

Now, therefore, be it resolved by the House of Representatives, the Senate concurring:

Section 1. The Legislative Research Commission shall review the basis of the projections that biotechnology will have a pervasive impact on industries such as pharmaceuticals, agriculture, forestry, chemicals, pollution control, and other areas that the Commission might identify.

Sec. 2. The Commission shall review the devlopment of the federal guidelines for the safe conduct of biotechnology research and development and the experiences of other states that have addressed this issue.

Sec. 3. The Commission shall review the steps being taken by other states to strengthen their education, research, financial, and institutional resources in biotechnology.

Sec. 4. The Commission shall review the current status and future plans of the biotechnology programs in North Carolina's universities, the North Carolina Biotechnology Center, North Carolina companies, the Department of Commerce, and any

other organizations concerned with nurturing the development of biotechnology in the State.

Sec. 5. The Commission shall determine the short-term and long-term needs for North Carolina to be at the forefront of the technological and economic developments in the rapidly advancing field of biotechnology.

Sec. 6. The Commission may call upon any State department or agency to provide it with information pertinent to its inquiry. In addition, the Commission may invite representatives of private industry and universities as well as experts from other states and the federal government to offer pertinent testimony.

Sec. 7. The Commission shall appoint a Committee to conduct the study outlined above. The membership of the Committee shall consist of five members of the House and five members of the Senate, two representatives of North Carolina universities with programs in biotechnology, two officials from North Carolina companies engaged in research, development, and production in biotechnology, and two representatives from the financial community knowledgeable concerning the investment climate in biotechnology.

Sec. 8. The Commission shall file a report with the Governor and the General Assembly no later than May 1, 1984. The report shall set forth the Study Commission's findings, conclusions, recommendations, and proposed legislation, if any. At this time, the Commission also may request that the study be continued.

Sec. 9. The Legislative Services Commission shall provide professional and other staff assistance upon the request of the Commission. The Commission may wish to seek additional staff assistance from the North Carolina Biotechnology Center and the universities. In addition, up to twenty-five thousand dollars ($25,000) of the appropriations in 1983-84 and 1984-85 to the Biotechnology Center in "The New Technology Jobs Act" shall be used by the Center to support this study.

Sec. 10. This resolution shall become effective July 1, 1983.

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 1983
RATIFIED BILL

CHAPTER 899
HOUSE BILL 1122

AN ACT TO CREATE THE NEW TECHNOLOGY JOBS ACT.

Whereas, unemployment rates vary considerably from one region of the State to the next; and

Whereas, the creation of more and better job opportunities for North Carolinians at all age and skill levels in all regions of the State are a top priority in relation to balanced growth considerations; and

Whereas, small businesses of all kinds, including but not limited to agriculture, aquaculture and forestry enterprises, are the primary sources of employment throughout the State and they are likely to remain the primary sources of employment in the future; and

Whereas, biotechnology is a new frontier of science that is already the basis for new products and businesses in the human and animal health field and has even greater potential to lead to new, valuable agriculture and forestry products; and

Whereas, in recognition of the importance of biotechnology to the industrial base of the State, the North Carolina Board of Science and Technology established the North Carolina Biotechnology Center to pursue opportunities in biotechnology research, education, and business development special benefit to the State; and

Whereas, the Biotechnology Center has documented that it can leverage its State funds with at least an equal additional amount from non-State sources and that it can contribute to the development of new and existing businesses and research opportunities; and

Whereas, scientific and technical advances in general flowing from research and academic institutions can be applied to the development of existing and new small businesses throughout the State; and

Whereas, principal growth in employment has come from the introduction of new technology; and

Whereas, adequate capital and affordable space for the research activities of existing and new small businesses are key ingredients to the development of new and existing small businesses; and

Whereas, partnerships between State and local government, financial institutions, business, labor, and research and academic institutions provide the most effective means for utilizing technological resources to create new jobs throughout the State; Now, therefore,

The General Assembly of North Carolina enacts:

Section 1. G.S. 143B-433 is amended by inserting a new subsection to read:

"(22) The North Carolina Technological Development Authority,".

Sec. 2. Article 10 of Chapter 143B of the General Statutes is amended by adding a new Part to read:

"Part 12. North Carolina Technological Development Authority.

"§ 143B-471. Creation of Authority.--There is hereby created the North Carolina Technological Development Authority, to increase the rate at which new jobs are created in all regions of the State, by stimulating the development of existing and new small businesses. The Authority shall be administratively located within the Department of Commerce, but shall exercise its powers independently of the head of that department, as if it had been transferred to the Department of Commerce by a Type II transfer as defined in G.S. 143A-6(b).

"§ 143B-471.1. Composition of Authority.--(a) The Authority shall be governed by a board composed of 12 members, eight of whom shall be appointed by the Governor, two of whom shall be appointed by the General Assembly upon the recommendation of the President of the Senate under G.S. 120-121, and two of whom shall be appointed by the General Assembly upon the recommendation of the Speaker of the House of Representatives in accordance with G.S. 120-121. Consideration should be given to the appointment of persons, including minorities and females, with technical expertise as well as experience in entrepreneurial business development and capital formation.

(b) Members shall serve four-year terms effective July 1, 1983, and quadrennially thereafter, except that the two members appointed by the General Assembly upon the recommendation of the Speaker of the House of Representatives shall serve for two-year terms effective July 1, 1983, and biennially thereafter. No person appointed to a four-year term shall serve more than two consecutive terms.

(c) Vacancies shall be filled by the Governor to serve the remainder of the unexpired term, except that vacancies in appointments made by the General Assembly shall be filled in accordance with G.S. 120-122.

"§ 143B-471.2. Officers; meetings.--(a) The Governor shall appoint from the members of the Authority a chairman. The Authority shall elect from among its members a Vice-Chairman and shall elect a secretary.

(b) The Authority shall meet at the call of the Chairman, upon the written call of the majority of its members or upon resolution of the Authority.

(c) A quorum shall consist of seven members of the Authority.

"§ 143B-471.3. Compensation.--Members of the Authority shall receive per diem and necessary travel and subsistence expense in accordance with G.S. 138-5.

"§ 143B-471.3A. Powers.--In order to enable it to carry out the purposes of this Part, the Authority may:

(1) Exercise the powers granted corporations under G.S. 55-17;

(2) Employ an Executive Director, whose salary shall be set by the Governor and the Authority, after consultation with the Advisory Budget Commission. The Authority may employ such other professional staff and clerical and secretarial staff as it deems necessary within the funds available to it. The salaries of such other personnel shall be set under the State Personnel Act;

(3) Establish an office for the transaction of its business at Raleigh;

(4) Apply for and accept grants of money from the State of North Carolina, or any political subdivision thereof, from the United States, or from any person, corporation, foundation, trust, or business or from any foreign government for any of the purposes authorized by this Part;

(5) Establish and administer the incubator facilities program;

(6) Administer the North Carolina Innovation Research Fund; and

(7) Adopt reasonable rules to effectuate the purposes of this Part.

"§ 143B-471.4. Incubator facilities program.--(a) The Authority shall establish one or more incubator facilities within the State. An incubator facility is a building or buildings that provides space and support services for small businesses concerns which are beginning. 'Small business concern' has the same meaning as that contained in Chapter 14A of Title 15, United States Code, and regulations promulgated under it.

(b) The Authority shall select sites for incubator facilities. The Authority in selecting sites shall evaluate areas for potential sites using the following criteria but is not limited to them:

(1) the unemployment rate,

(2) the need for industrial and economic diversification and development,

(3) the interest by the locality in the establishment of an incubator facility in the area as manifested by grants from public and private sources and cooperation agreements between local government, business, labor and educational institutions demonstrating the probability of the success of the incubator facility.

(c) The Authority may make one-time grants to establish incubator facilities. A grant may not exceed two hundred thousand dollars ($200,000). Local government and interests must at least equal in cash or real estate value any grant made by the Authority; provided, however, that contributions by State agencies may not be included in the matching grant.

(d) Only nonprofit corporations which are affiliated with local universities, colleges, community colleges or technical institutes or combinations thereof to advance the educational and research programs of these institutions shall be eligible to receive a grant from the Authority. Pursuant to rules adopted by the Authority, the corporation shall:

(1) manage and maintain the incubator facility,

(2) develop a mechanism to provide technical, management and entrepreneurial expertise to resident small business concerns and to small business concerns throughout the area, and

(3) abide by rules adopted by the Authority.

(e) The incubator facility and any improvements shall be owned by the State but may be leased to the corporation. Small business concern residents of the facility may be provided secretarial and other support facilities and utilities for which

the corporation may charge them a part or all of the cost. No small business concern may remain in the facility for more than two years. Notwithstanding any other provision of law, the State shall not be liable for any act or failure to act of any organization granted funds under this Part, or any small business concern benefiting from the incubator facilities program.

"§ 143B-471.5. North Carolina Innovation Research Fund.--(a) The North Carolina Innovation Research Fund is hereby created to provide equity financing for the research activities of new and existing small business concerns in various regions of the State, including agriculture, aquaculture and forestry enterprises. This financing is designed to enable small business concerns to acquire technical and management assistance and otherwise to conduct research leading to new or improved product or service development.

(b) The Fund will take an equity position in contracting concerns through the purchase of stock, the receipt of royalties, or other equity instruments.

(c) The Fund will consist of appropriations from the State; monies derived from federal, local governments and private grants; receipt of royalties and sale of equities.

(d) Awards per research project shall not exceed fifty thousand dollars ($50,000) per fiscal year. Awards will be limited to concerns physically located in North Carolina, but the awards shall not be limited to incubator-affiliated projects.

(e) To protect its investments, the Authority shall make development agreements with contracting concerns, to ensure proper use of Fund awards and the receipt of royalties, where appropriate. Development agreements shall assign all rights to abandoned projects to the Authority.

(f) Any funds received through the receipt of royalties, dividends, or the sale of equity instruments shall be deposited in the Fund and are available to the Authority for use under this Part."

Sec. 3. G.S. 120-123 is amended by adding a new subdivision to read:

"(6a) The North Carolina Technological Development Authority as created by G.S. 143B-471."

Sec. 4. Of the funds appropriated from the General Fund to the Department of Commerce in Section 2 of Chapter 761 of the 1983 Session Laws, for fiscal year 1983-84 the sum of five hundred thousand dollars ($500,000) and for fiscal year 1984-85 the sum of five hundred fifty thousand dollars ($550,000) is designated for the purposes of the North Carolina Technological Development Authority. Of the funds so appropriated for fiscal year 1983-84, the sum of two hundred twenty-five thousand dollars ($225,000) is available only for the North Carolina Innovation Research Fund, the sum of two hundred thousand dollars ($200,000) is available only for grants to incubator facilities, and the sum of seventy-five thousand dollars ($75,000) is available only for the operation of the Technological Development Authority. Of the funds appropriated for fiscal year 1984-85, the sum of two hundred fifty thousand dollars ($250,000) is available only for the North Carolina Innovation Research Fund, the sum of two hundred thousand dollars ($200,000) is available only for grants

to incubator facilities, and the sum of one hundred thousand dollars ($100,000) is available for the operation of the Technological Development Authority.

Sec. 5. Of the funds appropriated from the General Fund to the Department of Commerce in Section 2 of Chapter 761 of the 1983 Session Laws, for fiscal year 1983-84 the sum of four hundred eighty-five thousand dollars ($485,000) and for fiscal year 1984-85 the sum of four hundred ninety thousand dollars ($490,000) is designated for the purposes of the Biotechnology Center, provided that funds for fiscal year 1984-85 shall not be released unless the Biotechnology Center has raised at least five hundred thousand dollars ($500,000) in non-State funds during the period beginning with the date of ratification of this act and ending on June 30, 1984; provided further that these appropriations shall not become part of the continuation budget for 1985-87 unless the Biotechnology Center has raised a total of one million dollars ($1,000,000) in non-State funds by December 31, 1984.

Sec. 6. Of the funds appropriated from the General Fund to the Department of Commerce in Section 2 of Chapter 761 of the 1983 Session Laws, the sum of fifteen thousand dollars ($15,000) in fiscal year 1983-84 and the sum of ten thousand dollars ($10,000) in fiscal year 1984-85 is transferred to the Legislative Research Commission to conduct a study of the field of biotechnology.

Sec. 7. This act is effective upon ratification.

In the General Assembly read three times and ratified, this the 21st day of July, 1983.

JAMES C. GREEN

James C. Green
President of the Senate

LISTON B. RAMSEY

Liston B. Ramsey
Speaker of the House of Representatives

APPENDIX E

(Reprinted From the Biotechnology Study Committee's Report to the 1984 Session of the 1983 General Assembly.)

BIOTECHNOLOGY: WHAT IS IT AND WHY IS IT SO IMPORTANT?

The development of biotechnology, the ability to manipulate components of a cell and reproduce the results, is a revolution in scientific, agricultural, biomedical, and manufacturing processes and techniques. It is not a new or separate scientific discipline. One way of looking at biotechnology is that it is a collection of new techniques, centering on biology, which make possible novel extensions and combinations of existing scientific disciplines and new industrial applications. These new techniques came about with the understanding of the structure of deoxyribonucleic acid (DNA), composing the genes of all organisms, combined with the ability to manipulate genes and reproduce the results of that manipulation.

These new techniques are revolutionizing many sciences and manufacturing processes and will have a pervasive effect on everyone's life in the very near future. It is important to understand that these techniques are already in use today. For example, on April 26, 1984, the New York Times Service newswire reported that a major biotechnology company, Genentech, Inc., announced that it had created in the laboratory a complex protein vital to the normal clotting of blood. It is the protein that is missing or deficient in hemophiliacs. Previously, the substance had to be extracted from donated blood. By using gene splicing and cloning techniques, that substance can now be produced artificially

and, as a by product of that research, scientists will be better able to study the molecular basis of hemophilia and possibly develop techniques for prenatal diagnosis of this hereditary disease. Insulin is another pharmaceutical product that can already be produced using biotechnology techniques. Such a product is presently undergoing clinical trials. Interferon, which is important to the body's immune functions and is thought to inhibit viral infections, can also already be produced using biotechnology techniques and is thought to hold great promise for such diverse results as a cure for the common cold and for certain kinds of cancer.

The importance of biotechnology in the areas of agriculture and forestry is enormous. Hybridization has always been at the forefront of progress in these areas, with scientists developing various strains of plants and trees having desirable characteristics for particular applications. These include faster growing varieties, disease, pest and drought resistance, and characteristics desirable for the ultimate use of the product, such as straight-growing knot-free trees. The problem has always been that the creation of these plants and trees through selective breeding has taken many, many years because of the need to go through the entire growing cycle for a number of plants (in trees this can be 20 years or more) and then attempting to select out the ones with the desirable traits and reproduce them again, refining the end product each time. Using

cloning techniques, this whole process can be shortened dramatically.

In the area of pharmaceuticals and medicine, the most intriguing idea which the committee heard is the so called "magic bullet" technique of disease treatment. This involves the possibility of producing drugs which will seek out only those cells within the body responsible for an illness and deliver medication to those cells without affecting the rest of the body. For example, in the treatment of cancer using chemotherapy, the present techniques involve the administration of drugs which are poisonous to the cancer cells. The problem is that once placed in the body the drugs also affect the other, noncancerous cells in the body. Hence, chemotherapy becomes a balancing act of administering enough of the treatment to kill the cancer causing cells without producing so much other damage in the patient's body that the patient is killed by the treatment. This is why success rates in chemotherapy treatment are erratic and why people experience such harsh side effects while undergoing treatment. Using biotechnology innovations, the desired treating agent could be attached to cells which would seek out only those cells in the body affected by the cancer, killing those cells but not the other healthy ones around them. This same technique would also lend itself to the production of all types of vaccines, some already produced by other means, others still in research stages.

In the areas of pollution control and waste management, biotechnology should lead to creation of substances which can break down pollutants or waste products into harmless products more easily disposed of. A so-called oil eating bacteria which can be used to clean up oil spills has already been produced and patented .

The production of chemicals will probably undergo one of the most important changes, although this is probably one of the longer range results from biotechnology research. At the present time, virtually all chemicals are petroleum based. In the future, however, it seems very likely that a biological, and therefore renewable, basis for chemical production will be developed, thus vastly reducing this country's, and the world's, dependence on oil.

The committee has heard that even such things as mining may some day be done with biological substances produced by biotechnology research. These would seek out and remove ores from the earth, having been developed to seek out only a particular mineral and separate it from other substances which surround it. This technique will probably never change the way we mine iron ore or coal, but it may very well change the way we seek out rare elements and precious metals useful to industry and science.

Research is presently going on to develop a biological basis of information storage for computers. Thus, the high technology field of computer development is already being viewed as capable of undergoing a further and more

revolutionary change than that which was brought about by the development of microelectronics.

The economic potential of all of this is so enormous as to be incalculable. Estimates of the value of biotechnology produced products by the year 2000 have ranged from 40 billion dollars to 100 billion dollars yearly. The point to be remembered is that not only will we have new products and processes, but that the greatest economic impact will come because of the development of new ways of making and growing existing products and performing existing processes. This means that there will be economic development not only because new businesses will be developed to produce new products, but also because existing businesses will be producing or processing their products by other than their traditional techniques. This will mean that they, too, must invest in new production and processing facilities.

The economic benefits to be realized come in the form of new investments by businesses and the related jobs and economic ripple effect from such investments, and in the form of direct benefits from the creation of products important to the economy of a given state. In the case of North Carolina, these direct benefits would be in the areas of agriculture, forestry, and pharmaceuticals, areas upon which the state is already greatly dependent for its economic well being.

Finally, if academically strong universities, public and private, are important to the well being of the people

of the state, the ability of those universities to participate in the biotechnology revolution is a necessity, because biotechnology related techniques will become part of basic research and teaching in many scientific disciplines. It is a necessity our universities have already recognized and begun to participate in to the extent that their resources allow.

APPENDIX F
(pages 56-90)

(Includes the Summary of Findings and Recommendations, Appendix C and Appendix D from the September, 1984 report of the Biotechnology Study Committee's Economic Advisory Panel, entitled Economic Effects of a North Carolina Biotechnology Initiative: A Preliminary Study. See the preceding text, pages 27-32, in connection with the material which follows.)

Summary of Findings and Recommendations

Finding #1: If a significant portion of the various state biotechnology programs are focused on the application of research to state-specific problems in agriculture and forestry, then significant returns in the form of farming profits are likely in the next 15 years at levels substantially in excess of the state investment. A breakthrough in agricultural biotechnology even in one major category (e.g. corn or hogs) would alone return up to $50 million dollars in incremental farming profits, in discounted 1985 dollars.

Finding #2: With proper targeting, the state should be able to generate new firm growth and attract new plants and research facilities of existing firms to the point of being a major player in the world-wide biotechnology industry. The degree of success in this regard depends critically on creating centers of research (and supporting existing ones) in applied and basic science and engineering which are seen as sources of excellence in the field of biotechnology. In the bioprocess instrumentation sector alone, the state could realize an added payroll of $200 million in 1985 dollars over the next 15 years, provided a focus on this technology arena is adopted by state funded programs.

Finding #3: The effects of biotechnology will be realized in a wide variety of economic sectors in North Carolina. The impact on new and existing jobs will extend to all geographic regions of the state, in part because

key promising segments of the biotechnology industry require the skills already in place in cities and towns across North Carolina. Major basic research facilities of firms will likely be based near the Triangle universities.

******* ********

Recommendation #1: State funds should be used to support basic and applied research in biotechnology. To attract top-quality talent and to help focus the research on problems generic to industry and state-specific agricultural problems, a substantial portion of "people-related" support should be allocated to the North Carolina Biotechnology Center for the following purposes: direct support of interdisciplinary applied research staff; competitive grants to researchers at various institutes and universities; salary supplements for faculty; grants to public and private universities to aid in attracting world-class scientists. Up to 80% of the "people" support should go for these purposes. The other 20% of "people" support should be allocated directly to support faculty positions in the state-university system. Estimated cost: $30 million over 5 years.

Recommmendation #2: The state through the Biotechnology Center should engage appropriate expertise to examine the costs and merits of a partially state-funded biotechnology pilot plant. This effort should be part of specific targeting of bioprocess engineering and separation processes for industrial development in the state. Studies should be undertaken to

assess the types of industry infrastructure required to establish world leadership in this industry segment. No monies should be allocated to a technology- specific pilot plant until the study is completed. Estimated cost: $50,000.

Recommendation #3: Significant investment in plant and equipment by the state in specific biotechnologies should for the most part be made jointly with industry and other non-state funds (e.g. NSF, foundations).

Recommmendation #4: The NC Biotechnology Center should acquire and maintain computer software and databases which can be shared with the university and industry community (primarily in NC, but also worldwide).

Recommendation #5: The NC Biotechnology Center should lead a cooperativeeffort in consultation with appropriate groups to frame a NC biotech industry strategy - with specific industry segments targeted (eg bioprocess engineering, bioprocess waste management, marine biotechnology). Collaboration between NCBC and universities should include a focus on opportunities and problems unique to NC and the southeast region. NCBC should report annually on the degree of effort which has gone toward NC specific problems and opportunities.

Recommendation #6: The Department of Commerce should broaden its programs to include significant attention to industrial applications of biotechnology and on the problems faced by new start-up companies in the state. In

cooperation with the Agricultural Research Service and the Agricultural Extension Service, it should also develop programs for speeding the diffusion of new biotechnology products and services in the state economy. Specific funding for training state agriculture and industrial agents in biotechnology subjects should be allocated.

Recommendation #7: Specific attention should be paid to training production workers and technicians in the state's schools and colleges. Appropriate state agencies should seek the advice of various biotechnology industry representatives about the nature and scope of such training.

AN ECONOMIC MODEL OF BIOTECHNOLOGY EFFECTS ON NORTH CAROLINA AGRICULTURE : THE CORN EXAMPLE

A SUMMARY OF THE PROCESS UNDERTAKEN TO EVALUATE CORN

In developing the corn model we first studied the literature to determine what sort of impact biotechnology would have on corn yields. We found that a growth regulator would be available to farmers within the next five years which, it is expected, will enable farmers to increase their yields by 10%. Using this as a base, we compiled revenue data for each North Carolina county for 1981 (which we believe to be a representative year).

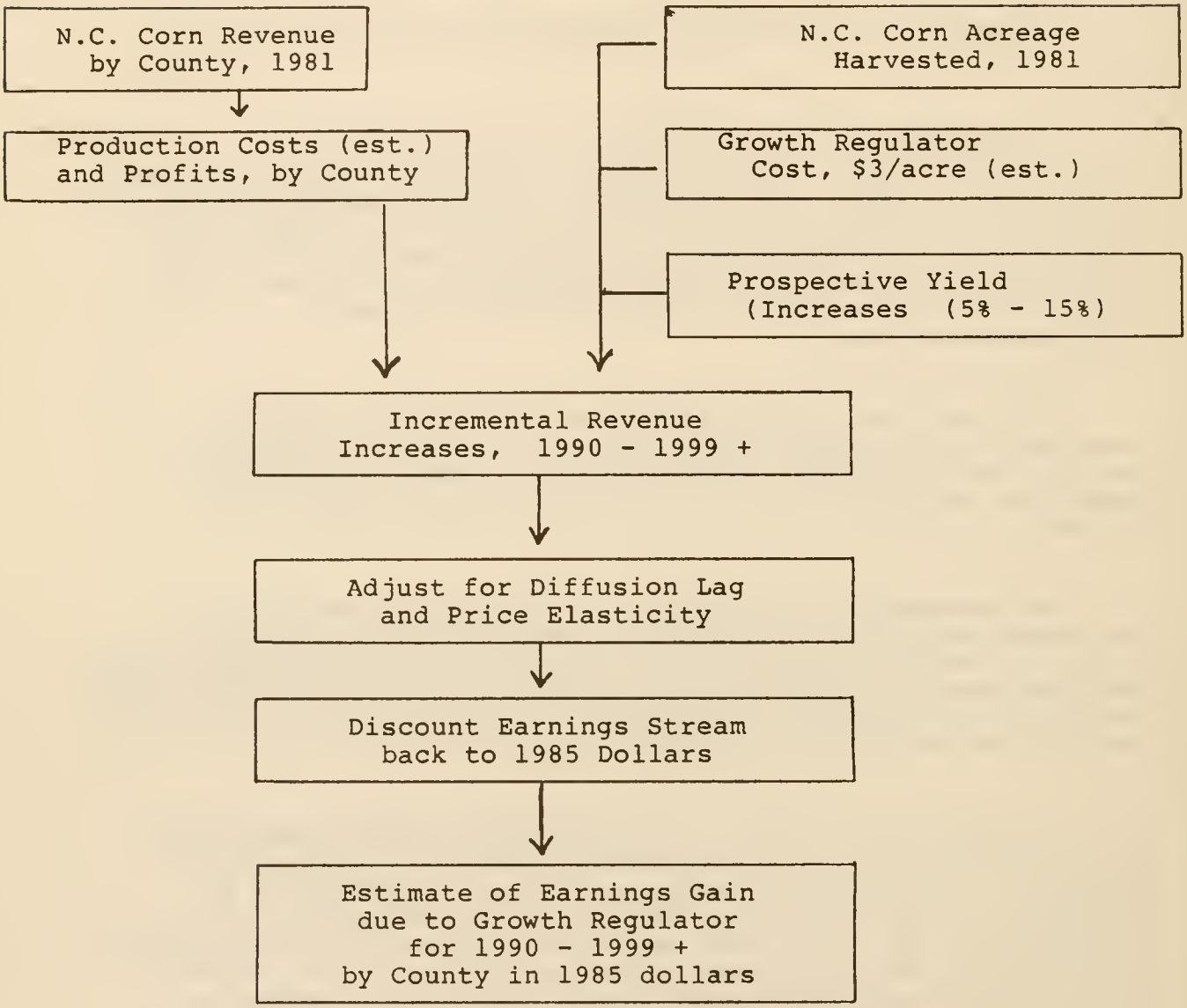
This data was adjusted upwards beginning in 1990 (a reasonable time frame based on the literature) to reflect anticipated incremental revenue gains. Costs for the growth regulator (estimated at $3 an acre) were also taken into account.

The assumption was made in the model that the yield increases were specific to the the North Carolina region (and climate), and the elasticity of demand for corn was incorporated into the model in such a way as to take this into account. If a yield gain is achieved nationwide, then all farmers will suffer because the demand for corn is inelastic.

As adoption of the new (biotechnology) hybrid would be gradual and likely follow a pattern similar to that of other successful agricultural introductions, we incorporated a diffusion curve to simulate this real life phenomena. The incremental cash flows less costs were discounted back to 1985 to determine the net present value of such a gain to farmers. We have also computed the net present value on a county by county basis. For ease of evaluation, the net present value figures were separated into two parts - those that accrue before the year 2000, and those that accrue during that year and after.

To provide some sensitivity analysis, we have used three different discount rates (6%, 10%, and 14%), three different levels of yield increase, and two different rates of diffusion. The model is set up so that further adjustments of the parameters may be made if so desired.

MODEL OF BIOTECHNOLOGY IMPACT ON NORTH CAROLINA CORN EARNINGS, 1990 - 1999



CORN MODEL BASED ON REGULATOR

METHODOLOGY:

- Revenue (production value) data for corn (for grain) was entered
- The percentage of production figures were then determined for each county based on the percentage of aggregate N. C. revenue received
- N. C. corn production costs were then determined by county based on a U. S. cost per bushel figure and the percentage of production figures for each county
- Next profits (revenue - costs) were estimated for each county
- Total revenues for several different increased yield scenarios were then computed -- these yield scenarios were based on literature that discussed prospective yield gaina
- As increased costs are expected to accompany the prospective yield gains, these costs were incorporated at a rate of $3.00 per acre of 1981 acreage harvested (our best estimate)
- Incremental revenue gains were then computed for the prospective yield increases -- first without accounting for elasticities of demand, and then applying them
- An expected time frame over which the biotechnology advancement could be brought to fruition was arrived at (based on the literature) and incorporated into the model
- Based on this time frame, a diffusion curve was applied to provide us with expected revenue gains for each N. C. county over the first ten years following introduction
- The figures arrived at were totalled for each year and discounted back to 1985 (the year the project would be initiated) at three different discount rates (6%, 10%, and 14%) to provide an expected range of net present values for the project

NOTE: We use the term "revenue(s)" to mean value of production

CORN
(FOR GRAIN)
ELASTICITY OF DEMAND EQUALS -0.63

	1979	1980	1981	1982	1983
ACRES HARVESTED (IN THOUSANDS)	1690	1730	1830	1570	1280
BUSHELS HARVESTED (IN THOUSANDS)	128440	103800	140910	158570	76800
YIELD PER ACRE (IN THOUSANDS)	76	60	77	101	60
COST PER ACRE (EXCLUDING LAND)	178.62	212.01	245.24	269.76 *	296.74 *
COST PER BUSHEL (EXCLUDING LAND)	1.63	2.35	2.24	2.37	2.52
TOTAL COST N. C. PRODUCTION (EXCL. LAND, IN THOUS.)	209357	243930	315638	375811	193536
TOTAL VALUE N. C. PRODUCTION (IN THOUSANDS)			377639	403344	
TOTAL PROFIT (EXCL. LAND, IN THOUS.)			62001	27533	

NOTE: COSTS WERE BASED ON A PER BUSHEL BASIS RATHER THAN ON A PER ACRE BASIS, WHICH PROVIDES LOWER COST ESTIMATES FOR N. C. COST ESTIMATES ARE LOWER UNDER THIS APPROACH BECAUSE N. C. GETS LESS YIELD PER ACRE THAN THE NATIONAL AVERAGE, AS CLIMATE AND SOIL CONDITIONS ARE LESS THAN IDEAL FOR GROWING CORN.

NOTE: THERE IS CONSIDERABLE VARIATION IN THE YIELD PER ACRE FROM ONE REGION TO ANOTHER ACROSS THE STATE. WE MAY WANT TO TAKE THIS INTO ACCOUNT AT A LATER DATE.

* ASSUMES 6% INCREASE IN COST PER BUSHEL ANNUALLY -- THIS WAS THE APPROXIMATE AVERAGE INCREASE IN COST BETWEEN 1975 AND 1981 BASED ON THE USDA's "ECONOMIC INDICATORS OF THE FARM SECTOR: FARM SECTOR REVIEW, 1982" p.37

ELASTICITY OF DEMAND TAKEN FROM:
THE STRUCTURE OF INDUSTRY (1977), EDITED BY WALTER ADAMS, p.6

ACRES HARVESTED AND BUSHELS HARVESTED WERE TAKEN FROM:
USDA's AGRICULTURAL STATISTICS, 1982 p.32
USDA's CROP PRODUCTION, 1983 SUMMARY p. B-16

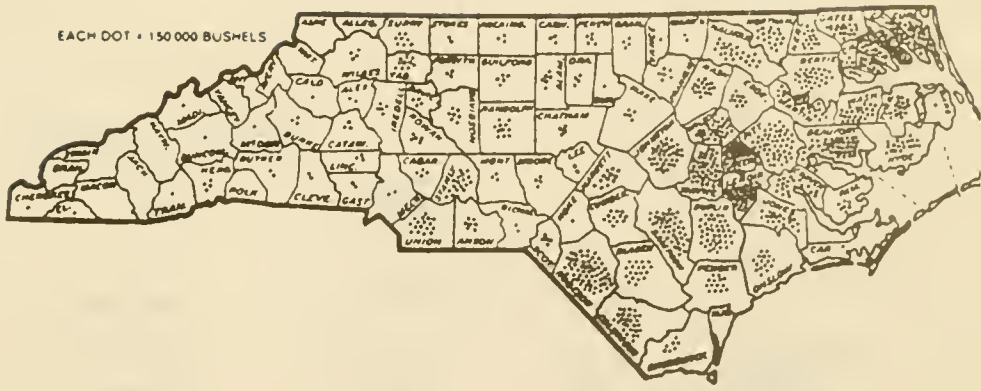
COST PER ACRE AND COST PER BUSHEL DATA WERE TAKEN FROM:
ECONOMIC INDICATORS OF THE FARM SECTOR: FARM SECTOR REVIEW, 1982 p. 37

TOTAL VALUE OF N. C. PRODUCTION TAKEN FROM:
NORTH CAROLINA AGRICULTURAL STATISTICS, 1983 p.15

CORN FOR GRAIN

LEADING COUNTIES	BUSHELS
Robeson	8,544,000
Pitt	7,623,000
Beaufort	6,787,000
Wayne	6,262,000
Duplin	6,237,000
Sampson	6,100,000
Johnston	5,562,000
Lenoir	5,319,000
Greene	4,762,000
Wilson	4,494,000

CORN: Production, 1982



CORN YIELD INCREASE

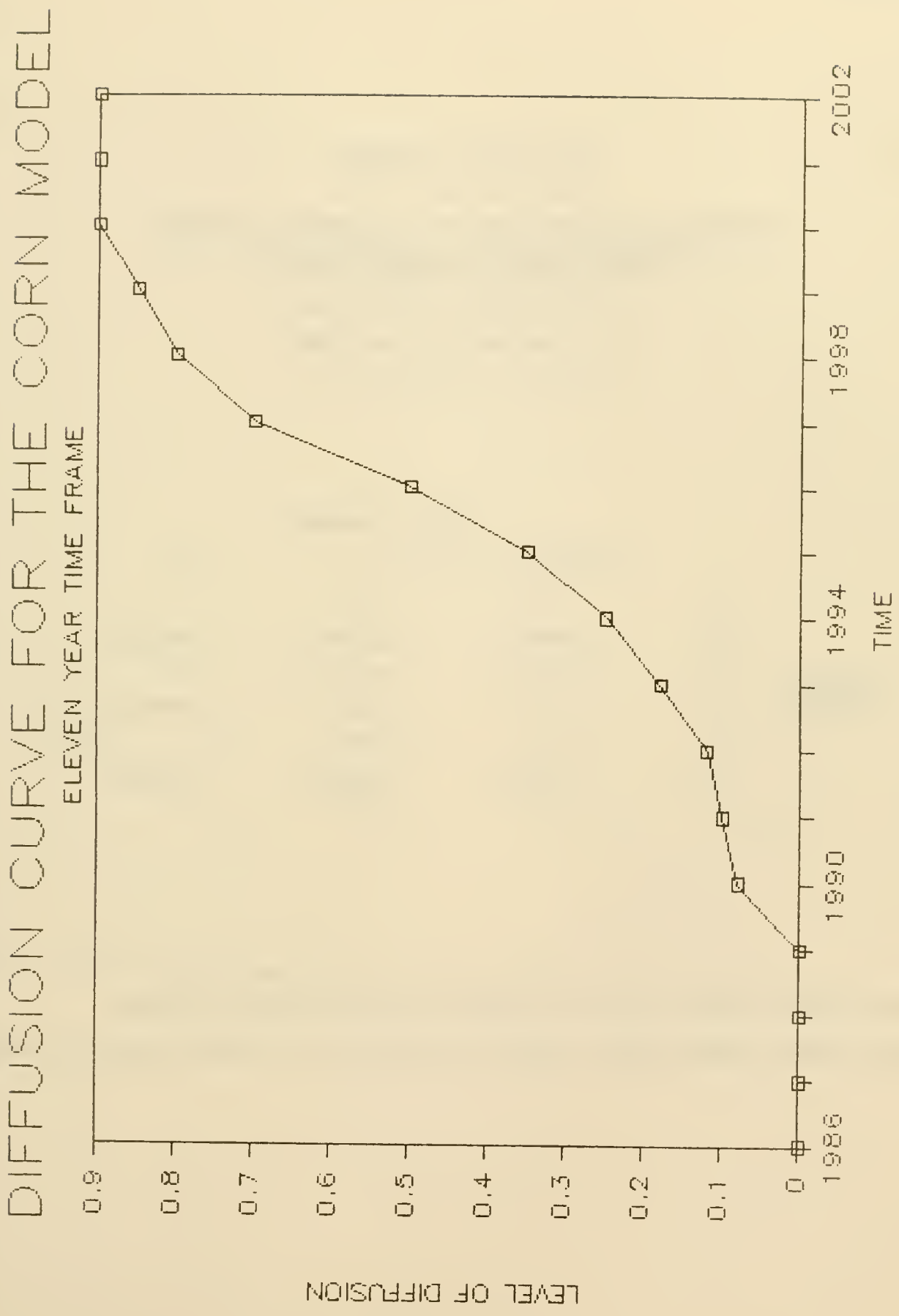
PRESENT VALUE IN 1985 OF INCREMENTAL REVENUES
RECEIVED USING VARIOUS
DISCOUNT RATES

(IN THOUSANDS OF DOLLARS)

		YIELD INCREASE		
		5%	10%	15%
DISCOUNT RATES	6%	105772.3	256528.7	406825.5
	10%	44681.9	108366.7	171857.3
	14%	23165.1	56182.1	89098.4

NOTE: THESE FIGURES TAKE INTO ACCOUNT ELASTICITIES OF DEMAND

NOTE: THESE FIGURES RESULT FROM THE USE OF AN 11 YEAR DIFFUSION CURVE


DIFFUSION CURVE FOR THE CORN MODEL
ELEVEN YEAR TIME FRAME
LEVEL OF DIFFUSION
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1986
1990
1994
1998
2002
TIME

CORN YIELD INCREASE

PRESENT VALUE IN 1985 OF INCREMENTAL REVENUES RECEIVED PRIOR TO THE YEAR 2000 USING VARIOUS DISCOUNT RATES

(IN THOUSANDS OF DOLLARS)

		YIELD INCREASE		
		5%	10%	15%
DISCOUNT RATES	6%	25873.7	62795.2 /	99586.0
	10%	17178.4	41677.7	66096.2
	14%	11668.3	28305.3	44888.9

NOTE: THESE FIGURES TAKE INTO ACCOUNT ELASTICITIES OF DEMAND

NOTE: THESE FIGURES RESULT FROM THE USE OF AN 11 YEAR DIFFUSION CURVE

CORN YIELD INCREASE

PRESENT VALUE IN 1985 OF INCREMENTAL REVENUES RECEIVED AFTER 1999 USING VARIOUS DISCOUNT RATES

(IN THOUSANDS OF DOLLARS)

		YIELD INCREASE		
		5%	10%	15%
DISCOUNT RATES	6%	79898.6	193733.5	307239.5
	10%	27503.5	66689.0	105761.1
	14%	11496.8	27876.8	44209.5

NOTE: THESE FIGURES TAKE INTO ACCOUNT ELASTICITIES OF DEMAND

CORN YIELD INCREASE

PRESENT VALUE IN 1985 OF INCREMENTAL REVENUES
RECEIVED USING VARIOUS
DISCOUNT RATES

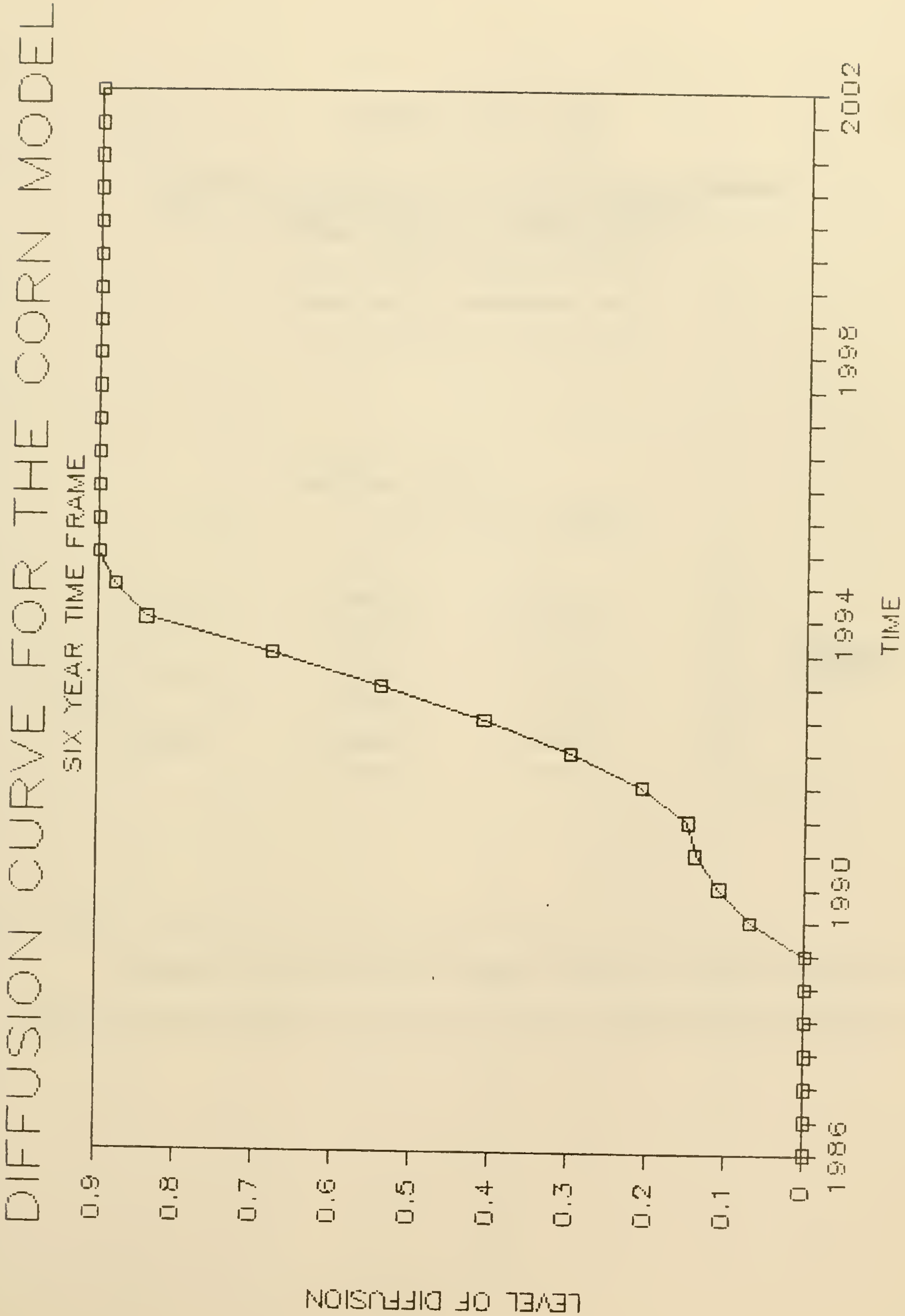
(IN THOUSANDS OF DOLLARS)

		YIELD INCREASE		
		5%	10%	15%
DISCOUNT RATES	6%	123982.5	300715.7	476866.5
	10%	57533.8	139546.5	221288.9
	14%	32385.8	78550.8	124563.7

NOTE: THESE FIGURES TAKE INTO ACCOUNT ELASTICITIES OF DEMAND

NOTE: THESE FIGURES RESULT FROM THE USE OF A 6 YEAR DIFFUSION CURVE

EXHIBIT C-11


DIFFUSION CURVE FOR THE CORN MODEL
SIX YEAR TIME FRAME
LEVEL OF DIFFUSION
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
TIME
1986
1990
1994
1998
2002

CORN YIELD INCREASE

PRESENT VALUE IN 1985 OF INCREMENTAL REVENUES
RECEIVED PRIOR TO THE YEAR 2000
USING VARIOUS DISCOUNT RATES

(IN THOUSANDS OF DOLLARS)

		YIELD INCREASE		
		5%	10%	15%
DISCOUNT RATES	6%	44083.9	106982.2	169627.0
	10%	30030.3	72857.5	115527.8
	14%	20889.0	50674.0	80354.2

NOTE: THESE FIGURES TAKE INTO ACCOUNT ELASTICITIES OF DEMAND

NOTE: THESE FIGURES RESULT FROM THE USE OF A 6 YEAR DIFFUSION CURVE

CORN YIELD INCREASE

PRESENT VALUE IN 1985 OF INCREMENTAL REVENUES RECEIVED AFTER 1999 USING VARIOUS DISCOUNT RATES

(IN THOUSANDS OF DOLLARS)

		YIELD INCREASE		
		5%	10%	15%
DISCOUNT RATES	6%	79898.6	193733.5	307239.5
	10%	27503.5	66689.0	105761.1
	14%	11496.8	27876.8	44209.5

NOTE: THESE FIGURES TAKE INTO ACCOUNT ELASTICITIES OF DEMAND

INCREASE IN REVENUES DUE TO YIELD INCREASE OF 10%
(IN THOUSANDS OF DOLLARS) ****

COUNTY	1990 % DIFF. 8%	1991 % DIFF. 10%	1992 % DIFF. 12%	1993 % DIFF. 18%	1994 % DIFF. 25%	1995 % DIFF. 35%	1996 % DIFF. 50%	1997 % DIFF. 70%	1998 % DIFF. 80%	1999 % DIFF. 85%	DISCOUNTED INCREMENTAL REVENUES RECEIVED AFTER 1999	1985 NPV BY COUNTY (DISCOUNTED AT 10%)
Alamance	19.0	23.8	28.5	42.8	59.4	83.2	118.8	166.4	190.1	202.0	2139.1	813.8
Alexander	4.2	5.3	6.4	9.6	13.3	18.6	26.5	37.2	42.5	45.1	477.7	186.4
Alleghany	0.2	0.2	0.3	0.4	0.6	0.8	1.2	1.7	1.9	2.1	21.7	8.5
Anson	15.3	19.1	22.9	34.4	47.8	66.9	95.6	133.8	153.0	162.5	1720.7	681.8
Ashe	0.4	0.5	0.6	0.9	1.2	1.7	2.5	3.5	4.0	4.2	45.0	17.5
Avery	0.2	0.2	0.2	0.4	0.5	0.7	1.0	1.4	1.6	1.7	17.8	7.2
Beaufort	97.7	122.1	146.5	219.7	305.2	427.3	610.4	854.6	976.6	1037.7	10987.1	4135.1
Bertie	65.1	81.4	97.7	146.5	203.5	284.9	406.9	569.7	651.1	691.8	7325.1	2846.6
Bladen	55.3	69.1	82.9	124.3	172.7	241.8	345.4	483.5	552.6	587.1	6216.9	2390.4
Brunswick	14.4	18.0	21.6	32.5	45.1	63.1	90.1	126.2	144.2	153.2	1622.5	641.4
Buncombe	1.2	1.5	1.8	2.7	3.7	5.2	7.4	10.4	11.8	12.6	133.1	51.6
Burke	5.9	7.4	8.9	13.3	18.5	25.9	37.1	51.9	59.3	63.0	666.9	262.3
Cabarrus	15.9	19.9	23.9	35.9	49.8	69.8	99.6	139.5	159.4	169.4	1793.7	672.9
Caldwell	3.0	3.8	4.5	6.8	9.4	13.2	18.8	26.3	30.1	32.0	338.5	138.6
Camden	48.8	61.0	73.2	109.8	152.5	213.4	304.9	426.9	487.9	518.4	5488.6	2023.1
Carteret	14.3	17.9	21.4	32.2	44.7	62.5	89.3	125.1	142.9	151.9	1607.9	635.6
Caswell	5.8	7.2	8.7	13.0	18.1	25.3	36.1	50.5	57.8	61.4	649.9	265.6
Catawba	9.1	11.3	13.6	20.4	28.3	39.7	56.7	79.3	90.6	96.3	1019.8	385.1
Chatham	13.2	16.5	19.8	29.7	41.2	57.7	82.5	115.5	132.0	140.2	1484.6	561.9
Cherokee	2.6	3.2	3.9	5.8	8.1	11.3	16.2	22.7	25.9	27.6	291.7	112.9
Chowan	22.0	27.5	33.0	49.4	68.7	96.1	137.3	192.3	219.8	233.5	2472.2	948.4
Clay	1.6	2.0	2.4	3.6	5.0	7.0	10.0	14.0	15.9	16.9	179.4	71.3
Cleveland	4.5	5.7	6.8	10.2	14.2	19.9	28.4	39.7	45.4	48.2	510.8	212.9
Columbus	69.3	86.6	103.9	155.9	216.5	303.1	432.9	606.1	692.7	736.0	7792.8	2988.7
Craven	36.7	45.8	55.0	82.5	114.6	160.4	229.2	320.9	366.7	389.6	4125.4	1601.2
Cumberland	28.2	35.3	42.3	63.5	88.2	123.5	176.4	246.9	282.2	299.8	3174.6	1268.4
Currituck	45.9	57.4	68.9	103.3	143.5	200.8	286.9	401.7	459.1	487.8	5164.6	1916.0
Dare	1.4	1.8	2.1	3.2	4.4	6.2	8.8	12.4	14.1	15.0	158.9	61.4
Davidson	18.6	23.3	27.9	41.9	58.1	81.4	116.3	162.8	186.1	197.7	2093.2	789.7
Davie	10.6	13.2	15.9	23.8	33.0	46.3	66.1	92.5	105.7	112.3	1189.4	446.5
Duplin	99.6	124.4	149.3	224.0	311.1	435.6	622.2	871.1	995.6	1057.8	11200.3	4432.1
Durham	2.2	2.8	3.3	5.0	6.9	9.7	13.8	19.4	22.1	23.5	249.0	98.3
Edgecombe	61.2	76.5	91.8	137.7	191.3	267.8	382.6	535.7	612.2	650.5	6887.1	2810.8
Forsyth	7.9	9.9	11.9	17.9	24.8	34.7	49.6	69.5	79.4	84.3	893.0	342.3
Franklin	11.1	13.8	16.6	24.9	34.5	48.3	69.1	96.7	110.5	117.4	1243.3	513.4
Gaston	3.3	4.1	4.9	7.3	10.2	14.3	20.4	28.6	32.6	34.7	367.1	145.8
Gates	34.1	42.6	51.1	76.6	106.4	149.0	212.9	298.0	340.6	361.9	3831.8	1505.1
Graham	0.2	0.2	0.3	0.4	0.5	0.8	1.1	1.5	1.7	1.8	19.3	7.8
Granville	9.1	11.3	13.6	20.4	28.3	39.6	56.6	79.3	90.6	96.3	1019.5	403.8
Greene	68.0	85.0	102.0	153.0	212.6	297.6	425.1	595.2	680.2	722.7	7652.4	2955.7
Guilford	18.3	22.8	27.4	41.1	57.1	79.9	114.1	159.8	182.6	194.0	2054.1	776.8
Halifax	45.9	57.4	68.8	103.2	143.4	200.7	286.8	401.5	458.8	487.5	5161.8	2089.1
Harnett	11.8	14.7	17.7	26.5	36.8	51.6	73.7	103.2	117.9	125.3	1326.4	625.6
Haywood	1.1	1.4	1.7	2.5	3.5	5.0	7.1	9.9	11.3	12.0	127.4	48.3
Henderson	8.6	10.7	12.9	19.3	26.8	37.6	53.7	75.1	85.9	91.3	966.2	364.7
Hertford	30.4	38.0	45.6	68.4	95.1	133.1	190.1	266.2	304.2	323.2	3422.1	1343.0

Hoke	5.4	6.7	8.0	12.1	16.7	23.4	33.5	46.9	53.6	56.9	602.6	274.0
Hyde	46.2	57.8	69.4	104.0	144.5	202.3	289.0	404.6	462.4	491.3	5201.6	1972.8
Iredell	14.5	18.1	21.7	32.6	45.3	63.4	90.5	126.7	144.8	153.9	1629.1	623.0
Jackson	0.6	0.8	1.0	1.5	2.0	2.8	4.0	5.6	6.5	6.9	72.6	28.4
Johnston	72.5	90.6	108.7	163.0	226.4	317.0	452.8	633.9	724.5	769.8	8150.7	3188.1
Jones	42.1	52.7	63.2	94.8	131.7	184.4	263.4	368.8	421.4	447.8	4741.2	1820.8
Lee	3.3	4.1	4.9	7.4	10.3	14.4	20.5	28.7	32.8	34.9	369.3	148.8
Lenoir	79.2	99.0	118.8	178.2	247.6	346.6	495.1	693.2	792.2	841.7	8912.3	3440.6
Lincoln	6.3	7.9	9.5	14.3	19.8	27.7	39.6	55.4	63.4	67.3	712.9	271.2
Macon	1.0	1.3	1.5	2.3	3.2	4.5	6.4	8.9	10.2	10.9	115.0	44.2
Madison	1.4	1.7	2.0	3.1	4.2	5.9	8.5	11.9	13.6	14.4	153.0	59.9
Martin	62.1	77.7	93.2	139.8	194.2	271.9	388.4	543.7	621.4	660.3	6990.9	2644.3
McDowell	2.1	2.6	3.1	4.6	6.4	9.0	12.9	18.0	20.6	21.9	231.5	91.7
Mecklenburg	3.5	4.4	5.3	7.9	11.0	15.3	21.9	30.7	35.0	37.2	394.3	161.5
Mitchell	0.4	0.4	0.5	0.8	1.1	1.6	2.2	3.1	3.6	3.8	40.0	15.2
Montgomery	6.5	8.1	9.7	14.6	20.3	28.4	40.6	56.8	64.9	69.0	730.3	291.3
Moore	11.0	13.8	16.5	24.8	34.4	48.2	68.9	96.4	110.2	117.1	1239.6	489.8
Nash	28.6	35.7	42.9	64.3	89.3	125.1	178.7	250.2	285.9	303.8	3216.3	1340.1
New Hanover	2.3	2.9	3.5	5.2	7.2	10.1	14.4	20.2	23.1	24.5	259.7	101.9
Northampton	39.0	48.8	58.5	87.8	121.9	170.6	243.8	341.3	390.0	414.4	4387.7	1761.9
Onslow	30.9	38.6	46.3	69.4	96.4	135.0	192.8	270.0	308.6	327.8	3471.2	1378.8
Orange	11.6	14.5	17.4	26.1	36.2	50.7	72.5	101.4	115.9	123.2	1304.2	491.6
Pamlico	15.4	19.2	23.1	34.6	48.1	67.4	96.2	134.7	153.9	163.6	1731.9	661.4
Pasquotank	45.2	56.5	67.8	101.7	141.3	197.8	282.5	395.5	452.0	480.3	5085.2	1905.4
Pender	40.1	50.1	60.1	90.1	125.2	175.2	250.3	350.5	400.5	425.5	4505.8	1718.9
Perquimans	44.3	55.4	66.5	99.7	138.5	193.9	277.1	387.9	443.3	471.0	4987.2	1908.3
Person	14.9	18.6	22.3	33.4	46.4	65.0	92.9	130.0	148.6	157.9	1671.6	637.0
Pitt	126.6	158.3	190.0	284.9	395.7	554.0	791.5	1108.1	1266.4	1345.5	14246.8	5416.3
Polk	1.4	1.7	2.1	3.1	4.3	6.0	8.6	12.0	13.7	14.6	154.4	60.4
Randolph	33.5	41.8	50.2	75.3	104.6	146.4	209.2	292.8	334.7	355.6	3765.2	1431.3
Richmond	3.8	4.8	5.8	8.6	12.0	16.8	24.0	33.6	38.4	40.8	431.6	182.7
Robeson	109.3	136.6	163.9	245.9	341.5	478.1	683.0	956.2	1092.8	1161.1	12293.8	4882.6
Rockingham	9.6	12.0	14.4	21.6	30.0	42.0	60.0	84.0	96.0	102.0	1079.7	412.9
Rowan	15.0	18.7	22.5	33.7	46.8	65.6	93.6	131.1	149.8	159.2	1685.6	632.7
Rutherford	4.0	5.0	6.1	9.1	12.6	17.7	25.2	35.3	40.4	42.9	454.2	183.1
Sampson	93.5	116.9	140.3	210.4	292.2	409.1	584.4	818.2	935.1	993.6	10520.0	4234.1
Scotland	8.4	10.5	12.5	18.8	26.1	36.6	52.3	73.2	83.7	88.9	941.1	404.6
Stanly	34.6	43.2	51.9	77.8	108.0	151.2	216.1	302.5	345.7	367.3	3889.1	1508.0
Stokes	6.3	7.9	9.4	14.1	19.6	27.5	39.3	55.0	62.9	66.8	707.1	273.8
Surry	21.1	26.3	31.6	47.4	65.8	92.2	131.7	184.3	210.7	223.8	2369.8	925.7
Swain	0.2	0.3	0.4	0.6	0.8	1.1	1.5	2.2	2.5	2.6	27.7	11.1
Transylvania	3.0	3.8	4.5	6.8	9.4	13.2	18.9	26.4	30.2	32.1	339.8	127.9
Tyrrell	34.2	42.7	51.2	76.8	106.7	149.4	213.5	298.8	341.5	362.9	3842.1	1443.4
Union	24.7	30.9	37.1	55.7	77.3	108.2	154.6	216.5	247.4	262.9	2783.3	1160.5
Vance	1.4	1.7	2.0	3.0	4.2	5.9	8.4	11.8	13.5	14.4	151.9	65.4
Wake	10.6	13.3	15.9	23.9	33.1	46.4	66.3	92.8	106.0	112.6	1192.7	482.4
Warren	4.3	5.4	6.5	9.7	13.5	18.9	27.0	37.8	43.2	46.0	486.6	200.0
Washington	61.9	77.4	92.8	139.2	193.4	270.8	386.8	541.5	618.9	657.6	6962.5	2624.2
Watauga	0.6	0.8	1.0	1.5	2.0	2.8	4.0	5.6	6.5	6.9	72.6	27.5
Wayne	95.8	119.7	143.7	215.5	299.3	419.1	598.7	838.1	957.9	1017.7	10775.9	4231.2
Wilkes	9.6	12.0	14.5	21.7	30.1	42.2	60.2	84.3	96.4	102.4	1084.2	420.7
Wilson	58.2	72.8	87.3	131.0	182.0	254.7	363.9	509.5	582.3	618.7	6550.7	2604.1
Yadkin	30.9	38.6	46.4	69.5	96.6	135.2	193.1	270.4	309.0	328.3	3476.5	1322.6
Yancey	0.5	0.6	0.7	1.1	1.5	2.1	3.0	4.1	4.7	5.0	53.1	21.1
TOTALS	2476.2	3095.3	3714.4	5571.5	7738.2	10833.5	15476.5	21667.0	24762.3	26310.0	278576.3	108366.7

C-14-2

THE NET PRESENT VALUE ARRIVED AT WHEN DISCOUNTING THE PROJECTED INCREMENTAL REVENUE FLOWS IS INDICATED BELOW. IT IS DISCOUNTED BACK TO 1985, THE YEAR WHEN THE PROJECT WOULD MOST LIKELY BEGIN.

	1985	YIELD INCREASE EQUALS	10%
			$$$$
NPV @			
10%	108366.7		

ASSUMPTIONS:

Revenues per bushel are the same for all N. C. counties

Costs are similar to U. S. average corn production costs per bushel excluding land

Costs are allocated across counties in proportion to (as a set % of) the revenues of that county

The cost of the regulator-that allows for increased yields is $3.00 per bushel as expected

The pace of diffusion follows a time frame similar to what we have laid out

There is a reduction in price accompanying the increase in the quantity produced by N. C.

- this is based on available information on the elasticity of demand for corn (we used -0.63 as the elasticity)
- it is also assumed that the increase in yield exclusively takes place in N. C.
- it is also assumed that there is no major change in planting in N. C. or in other states
- finally, this price and quantity relationship is based on the premise that there are no major changes in cross-elasticities of demand

NOTE: The term "revenue(s)" is frequently used in the accompanying charts. In the context of these charts we have used it to refer to the value of production.

C-1

POTENTIAL FOR NORTH CAROLINA INDUSTRY DEVELOPMENT IN BIOPROCESS ENGINEERING

BIOPROCESS ENGINEERING AND BIOLOGICAL SEPARATION TECHNIQUE PRODUCING FIRMS

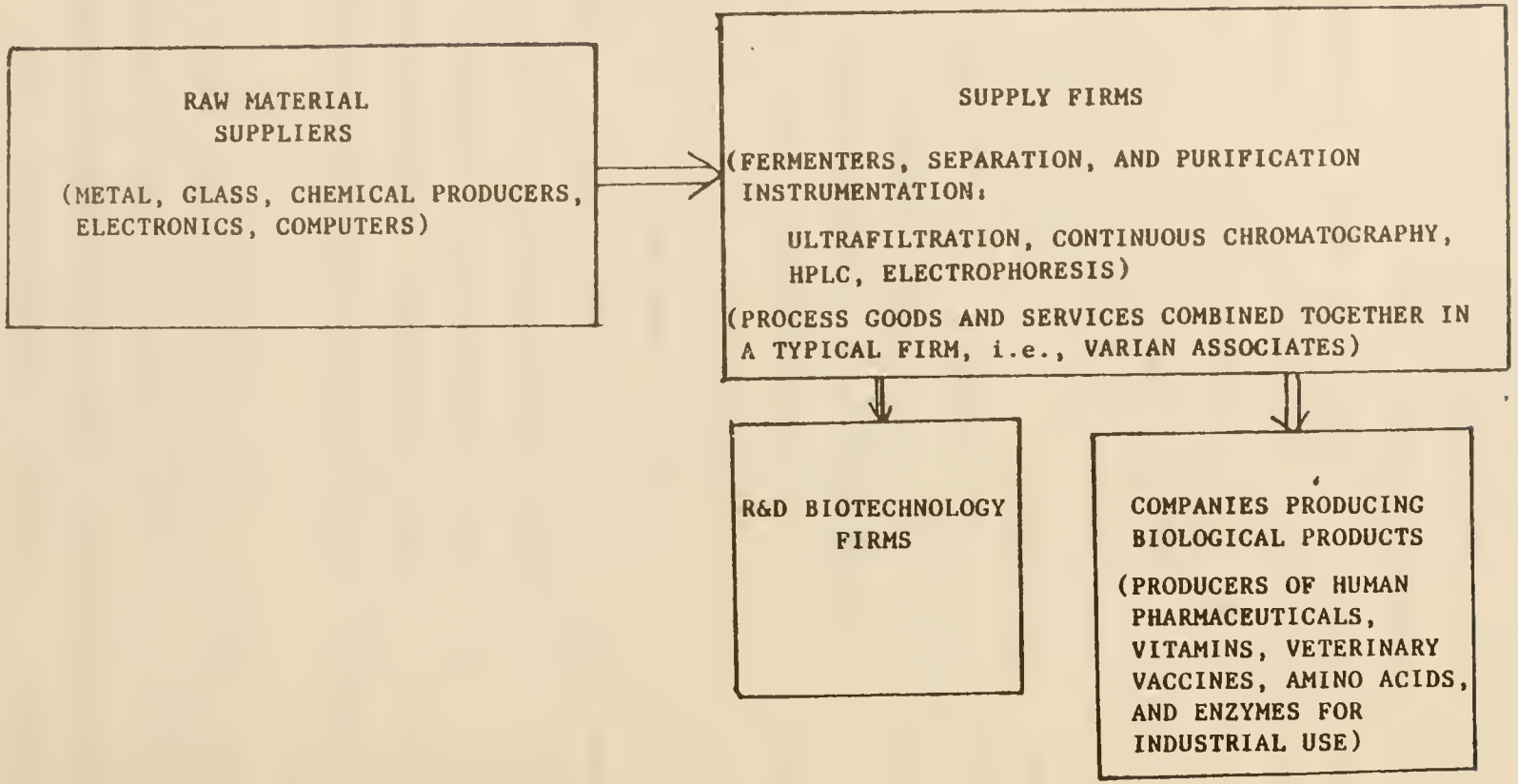
The generalized definition of bioprocessing is the following: The substrates and the nutrients are prepared in a sterile medium and are then put in to a fermenter with some form of a biocatalyst such as enzymes. Under controlled conditions the substrate is converted into the product and, when the desired degree of conversion has been achieved, byproducts such as new proteins, different enzymes and waste products are separated from one another.

The importance of bioprocessing separation instrumentation and techniques is that they are all used presently or will be used in the future in an effort to make the production of biotechnological products cost-effective as well as profitable to the manufacturing companies that are involved with these compounds. Areas of business in which separation and purification instrumentation will be or are presently used are the following: 1) pharmaceutical industry; 2) food processing industry; 3) the specialty and commodity chemical industries; 4) waste management industry and pollution control efforts, and 5) farming (plants and animals). (See TABLE I)

The design and manufacture of separation and purification instrumentation is one very important and very open industrial niche in which small companies have the chance to become leaders in this area of

TABLE I.

SUMMARY OF MAIN SUPPLY FIRMS AND THEIR INTERRELATIONSHIPS WITH R&D BIOTECHNOLOGY FIRMS
(SUPPLIERS OF FERMENTERS, SEPARATION AND PURIFICATION INSTRUMENTATION)



biotechnology. As the principles and applications of biotechnology lead to a more mature industry in the future, this would allow for a major new industry to become well established in North Carolina over the next several years. Also, with more cost effective production processes available for biotechnological products, financial and commercial success for North Carolina companies making final products will be more likely, given a head start through working with area-based bioprocess research groups.

Separation and Purification of Products.

The aspects of bioprocess engineering most in need of development are separation and purification techniques. The need for development is quite apparent when the production of novel products such as proteins is considered. The current possibilities for improving techniques are the following:

(1) Ultra-filtration--membranes and other filtration systems: According to the Congressional Office of Technology Assessment the U.S. companies making advances in this area include Millipore, Amicon and Nucleopore.

(2) Continuous chromatography and high performance liquid chromatography: According to the OTA, if these laboratory-proven techniques could be scaled up to the level required by industry, it would be possible to collect a crude product from the medium and then selectively recover the product, reusable nutrients and

inhibitory substances separately. A Millipore subsidiary, Waters, claims to have developed a pilot scale chromatographic unit of this type.

(3) Electrophoresis: Electrophoretic methods, especially continous flow, can separate proteins, peptides and nucleic acids on the basis of their electrical charge. The major advantage of electrophoresis is that it can run continously and can effectively separate molecules in large sample volumes.

(4) Monoclonal antibody affinity columns: Immobilized MAbs are being used as purification agents for protein products because this technique best suits large molecular weight and high value added products such as proteins.

High performance liquid chromatography (HPLC) is used to identify particular compounds in a mix of compounds and is one of the fastest growing instrumentation fields according to the OTA. Another technique, flow cytometry, has potential use in measuring process variables such as cell size and cell viability. Growing sales of HPLC are due to its expanded use in both analytical and preparative areas. HPLC's are also considered standard analytic tools in the laboratory to accurately isolate an purify organic molecules, drugs and proteins. HPLC's have recently been scaled-up successfully to monitor bioprocesses and purify large quantities of leukocyte interferon (protein entity).

According to the Congressional Office of Technology Assessment, technical advances in separation and purification as well as monitoring will affect both laboratory research and commercial production, and, in the long run, the U.S. competitive position in biotechnology. The production of low-volume, high value-added products and high-volume products through the use of recombinant DNA technology has greatly increased the need to further support research and development programs centering on the development of more economic bioprocesses. One determinant of how quickly companies can reach international product markets is the ability to have large scale production of biotechnology derived products along with the ability to isolate and purify large quantities of desired products. According to the well known report, "Commercial Biotechnology: An International Analysis,OTA," a country that possesses the most advanced separation and purification technology in relation to commercially important compounds might gain some commercial advantages in the early stages of production. success in biotechnology may be difficult to achieve.

In the United States, Europe, and Japan, there is intense competition in research and development to develop improved large-scaled separation and purification techniques for biological compounds as well as techniques for monitoring and controlling bioprocesses. To decrease the manufacturing costs of compounds such as proteins,

there is a concerted effort to apply HPLC, continuous - flow electrophoresis, and flow cytometry to bioprocesses. There is also an increased research and development effort to solve problems involved with the scaling-up of analytical instruments, particularly HPLCs, from the laboratory level to the industrial level for use in larger volume production processes. According to the Office of Technology Assessment, the United States is a recognized leader in analytical instrumentation used in biological research as well as in hollow fiber and membrane technology (hardware support, i.e., advanced solid matrix, membrane, and hollow fiber design). With increasing research and development centering around the automation of bioprocesses and the use of sophisticated instrumentation to monitor and control the production process, there will be a gradual transformation of bioprocessing from an art to a science, thereby making production more economical. Also as this transformation occurs, a few United States companies, such as Varian, Beckman Instruments, Waters, Perkin Elmer, and Hewlett Packard, will be in a strong competitive position to remain leaders in this technically innovating field. However the growth in the market and continuing innovation would seem to leave plenty of room for new start-ups in this industry segment.

Other examples of instrumentation will most likely be developed and used as bioprocess engineering is supported

by research and development funding. An example of this could be computer - coupled bioprocesses. This process can greatly improve the monitoring and controlling of growth conditions during a bioprocess run, since computers can be used to analyze the data from sensors and other monitoring instrumentation and respond to these data by adjusting process variables. According to the OTA, purification and separation protocols have been developed for existing bioprocesses, but new and presently unknown bioprocesses will present new challenges to research and development teams in the future.

According to the Congressional Office of Technology Assessment, the priorities for future research concerning bioprocesses are the following: 1) continued work on the practical use of and design of bioreactors for immobilized cell and enzyme systems; 2) development of a wider range of sterilizable sensors for process monitoring and control; 3) improved product recovery techniques, especially for the proteins; 4) general reactor design and practical approaches to better oxygen transfer; 5) inhibition of intracellular protein degrading enzymes; 6) improving the genetic stability of recombinant DNA organisms; 7) protein secretion mechanisms; 8) improved methods for heat dissipation during bioprocessing; 9) biochemical and physiological mechanisms for temperature and pressure tolerance, and 10) the development of new

bioreactor designs and instrumentation for the control of cell growth.

According to Flannery and Steinschneider, the costs and profitability of an industrial fermentation process will depend upon a large number of variables such as the following: 1) the characteristics of the microorganisms chosen for the fermentation; 2) the cost of the media; 3) the equipment required; 4) the fermentation time, and 5) the cost of operations, together with the cost of isolation and purification. Also, Flannery and Steinschneider said the following about fermentation: "The advantages of fermentation processes and the potential impact of genetic engineering increase with the chemical complexity of the product....Genetic engineering opens the way to the production of polypeptides and other complex molecules on a large scale and at a potentially great cost reduction. For instance, we estimate that interferon may be produced using the Genetech process at one hundred thousandfold lower cost than isolation from natural resources". With the increased potential use of fermentation processes in the future, there is a problem with the management of the scale-up from the laboratory to the industrial setting, according to Flannery and Steinschneider. This scale-up requires high capital investment in mixing, aeration, and refrigeration equipment as well as in monitoring and control devices.

Potential Economic Effect

What follows is an economic analysis of the employment levels and sales volume for the separations processes used with recombinant DNA manufacturing processes through 1999, with an estimate of the potential effect on the state of North Carolina if this segment is targeted for development.

According to Emyanitoff and Weinert, the purification finishing steps for pharmaceutical industry goods must be kept to a maximum of 20 percent of the manufacturing costs of goods sold, which itself is kept at approximately 20 percent of sales volume. Therefore, the separation process costs are constrained by the sales value of the end pharmaceutical or other important end-product produced by conventional manufacturing or recombinant DNA manufacturing.

Emyanitoff and Weinert estimated the total worldwide market potential for separations processes by considering only the finishing steps for the following high value end products which require a high degree of purity and lack of toxicity in their production: 1) human pharmaceuticals, 2) vitamins, 3) veterinary vaccines, 4) amino acids, and 5) enzymes for industrial use. The projected total worldwide market will grow from $48.5 million in 1985 to $148.8 million in 1989. Also, the share for recombinant DNA products will increase from 28% in 1985 to over 70% in

1989. These projected data were derived by estimating the markets for products from both recombinant DNA based manufacturing and conventional manufacturing and then calculating the manufactured cost of goods sold (20 percent of sales: recombinant DNA manufacturing and conventional manufacturing) and then calculating the resulting cost of extraction, isolation, and purification (separation processes) as 20 percent of recombinant DNA manufactured cost of goods sold and 10 percent of conventional manufactured cost of good sold.

The projected sales volume of separation processes, extrapolating from this study, is between $460 million and $1,400 million for the year 1999. The worldwide market potential is broken down into the potential but unavailable market and the potential available market. The projected growth in separations process sales is based on an average annual growth rate of sales of approximately 60 percent, according to Emyanitoff and Weinert. An example of how to calculate the 1989 worldwide market potential in recombinant DNA manufacturing separations goes as follows: 1) Projected total sales of recombinant DNA products in 1989 = $2621 million sales/year. 2) Manufacturing cost of goods sold (20% of sales) = $2621 million x 0.20 = $524.2 million/year. 3) Cost of extraction, isolation, and purification (20% of manufacturing costs): $524.2 million x 0.20 = $104.8 million sales of separations processes/year. The

projected total sales of recombinant DNA products include sales to end-users, the volume of products manufactured during scale-up and pilot studies, and products manufactured for internal use (clinical trials and other tests necessary for obtaining regulatory approval).

The total potential market for separation processes is unlikely to be available to outside vendors, according to Emyanitoff and Weinert. There are many manufacturers of recombinant DNA products that will prefer to design their own separations techniques and systems. These manufacturing companies have an interesting combination of a "do-it-yourself mentality" and an extremely competitive nature in regard to protecting their proprietary process information and technology. Also, the major manufacturers of recombinant DNA pharmaceuticals will be established corporations that have experienced process engineering groups with their own designs and systems for bioprocess separations techniques. According to Emyanitoff and Weinert, as much as 30 percent of the separations processes from recombinant DNA manufacturers will be unavailable to outside vendors by 1985, the percentage used in our estimates beyond 1985. This percentage of firms having self designed separation processes may increase as young firms develop their own process engineering capabilities and attempt to retain proprietary control over designs.

If North Carolina targets this industry segment for development we have assumed that the state could eventually capture ten percent (10%) of the world market for separation and purification instrumentation, perhaps an ambitious but acheivable share. At 1985 wage levels averaging $18,000 per worker, the employment in North Carolina firms in 1999 is projected between 4200 and 13,500, depending on whether one uses the pessimistic or optimistic industry growth rates. This translates into a 1985 present value payroll of $200 million to $400 million for the period including 1986 to 1999.

It should also be noted that the nature of the work in this industry segment is of the kind already done in many towns and cities of the state. Thus the labor force and skill base can be found readily in many locations, making it possible that the firms would locate in disperse localities and regions of the state.

Key References:

Flannery,R. and Steinschneider A.,
"Sensitivity Analysis: Fermentation, Economics In Relation to Genetic Engineering", Biotechnology,,Nov. 1983

Emyanitoff,R. and Weinert, H.,
"Market-based Analysis of the Economics of Process Engineering" Genetic Engineering News,, July/August 1984

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November 19, 1984

Senator William G. Hancock
Representative Bobby R. Etheridge
Biotechnology Study Committee
North Carolina General Assembly
Raleigh, North Carolina 27611

Dear Senator Hancock and Representative Etheridge:

In response to your request, I have completed some additional analyses of potential economic benefits to the State of North Carolina from a significant state biotechnology initiative. The summary results address examples from the biomedical and forestry sectors; I will send you the detailed report under separate cover. The efforts of Dr. Phil Carl and Dr. Howard Reisner, UNC-CH School of Medicine, were most helpful in selecting and preparing the biomedical example.

Biomedical Sector
--Diagnostic Aids for Rocky Mountain Spotted Fever

In the last two decades Rocky Mountain spotted fever (RMSF) has risen in incidence from about 200 cases per year to over 1100, and is now the most frequently reported insect-born disease in the U.S.. North Carolina reports more cases of RMSF than any other state, with over 250 reported cases and 18 deaths in one year. The costs of the disease can be measured in direct costs of hospitalization, the loss of wages while ill and the loss of economic support for families of those who have died

from the illness. In addition, there is a growing fear of contracting the disease from contact with infected ticks, which most certainly has a negative effect on tourism and recreational enjoyment.

Currently there is only one diagnostic test to confirm that a person indeed has RMSF during the acute phase. This test is expensive and not widely available. As a result there is likely to be an under-diagnosis of the disease, leading to higher rates of mortality.

Modern biotechnology has made available the generation of highly specific monoclonal antibodies which can be used to detect traces of infectious organisms. There is good scientific reason to believe that through additional basic and applied research, a reliable, rapid and inexpensive diagnostic kit can be developed which could be easily used in a typical doctor's office. Such a testing device could provide early and accurate diagnosis of RMSF so that appropriate treatment could begin soon after symptoms appear.

Some of the important research related to this problem is already underway in the state. Assuming that the manufacture and distribution of the RMSF diagnostic kits is done by a company in the state beginning in the next five years, the economic benefits from this development through 1999 are estimated as:

Reduced mortality and hospitalization	$32 million
Reduced negative effects on tourism	5 million
Added corporate wages paid	4 million
(in 1985 dollars) Total	$41 million

Forestry Sector

The report of the Economic Advisory Panel, Appendix-E, discusses the several potential effects of biotechnology on North Carolina forestry. The major areas of impact expected in the future are:

-Improved resistance of trees to pollutants and disease
-Improved forest yields through genetic breeding programs
-Improved pest and herbicide resistence
-Selective tree growing for specialty chemical output
-Reduced growing time to maturity
-Availability of more uniform quality in trees

These benefits are expected from basic and applied research in the public and private sectors. In many cases the benefits to a particular forest-growing region are dependent on having a local or regional research effort which is focused on the forestry conditions and problems most prominent in the region.

Assuming that regionally focused research generates a combination of productivity improvements of 5% net of costs, the value to North Carolina producers would be about $70 million in increased profits over the next 15 years (in 1985 dollars).

I hope that this analysis will be useful in the final deliberations of the Biotechnology Study Committee.

Sincerely,

Herbert L. Schuette

Herbert L. Schuette
Professor of Business

SESSION 19 85 ST: Biotechnology Development Program

INTRODUCED BY: *

Referred to:

A BILL TO BE ENTITLED

AN ACT TO PROVIDE FOR BIOTECHNOLOGY DEVELOPMENT IN NORTH CAROLINA.

Whereas, the field of biotechnology will have a strong economic impact on agriculture, forestry, marine biology and aquaculture, pharmaceuticals, medical care, chemicals, pollution control, and many other industrial and commercial areas important to North Carolina; and

Whereas, biotechnology-related developments will also have positive effects on human health and the environment; and

Whereas, research and teaching in biotechnology is necessary for the maintenance of academic excellence in the public and private universities and colleges, and the public schools in North Carolina; and

Whereas, a carefully planned State effort in biotechnology development can bring substantial benefits to every area of the State through industrial expansion, increased employment, increased agricultural productivity, and better health care for the citizens of the State; Now, therefore,

The General Assembly of North Carolina enacts:

Section 1. Board of Governors Appropriation for Programs. - In addition to all other funds appropriated, there is appropriated from the General Fund to the Office of the

Governor, Office of State Budget and Management, the sum of four million eight hundred thousand dollars ($4,800,000) for the fiscal year 1985-86 and the sum of four million eight hundred thousand dollars ($4,800,000) for the fiscal year 1986-87, to be placed in a nonreverting Biotechnology Reserve for use by the Board of Governors of The University of North Carolina to establish new biotechnology research and teaching programs. Upon the application of the Board of Governors, funds in the Reserve shall be disbursed by the Governor as needed, with the advice of the Advisory Budget Commission and after notification to the Joint Legislative Commission on Governmental Operations.

Sec. 2. Board of Governors Appropriation for Construction. - In addition to all other funds appropriated, there is appropriated from the General Fund to the Office of the Governor, Office of State Budget and Management, the sum of eight million five hundred seventy-seven thousand five hundred dollars ($8,577,500) for the fiscal year 1985-86 and the sum of eight million five hundred seventy-seven thousand five hundred dollars ($8,577,500) for the fiscal year 1986-87, to be placed in a nonreverting Biotechnology Reserve for use by the Board of Governors of The University of North Carolina to construct new space or renovate existing space for the purposes stated in Section 1 of this act. Upon the application of the Board of Governors, funds in the Reserve shall be disbursed by the Governor as needed, with the advice of the Advisory Budget Commission and after notification to the Joint Legislative Commission on Governmental Operations.

Sec. 3. Restrictions On Biotechnology Reserve. - No portion of the funds appropriated in Section 1 of this act shall be used for maintenance of efforts or programs funded prior to fiscal year 1985-86. No portion of the funds appropriated in Section 2 of this act shall be used to provide space for efforts or programs funded prior to fiscal year 1985-86 nor shall they be used for any purpose other than providing physical space. Any efforts or programs funded with the appropriation described in Section 1 of this act that are funded during the fiscal year 1985-86 and that are in the nature of continuation items, must be funded in the succeeding fiscal year out of the appropriations described in Section 1 of this act.

Sec. 4. Restrictions on Expending Reserve; Reports. - No funds appropriated in Section 1 or Section 2 of this act shall be released from the Biotechnology Reserve until the Board of Governors of The University of North Carolina submits to the President and President Pro Tempore of the Senate, and the Speaker and Speaker Pro Tempore of the House of Representatives, with copies being sent to the Governor and the North Carolina Biotechnology Center, a report specifically describing the present status of the biotechnology efforts of The University of North Carolina system, and a report describing its biotechnology development program for fiscal years 1985-86 through 1989-90, based upon current perceptions of its needs and expected State and other funding, and provided further that in any event, the Board of Governors shall submit those reports not later than January 1, 1986. Not later than January 1, 1987, the Board of Governors shall submit to the President and

President Pro Tempore of the Senate, and the Speaker and Speaker Pro Tempore of the House of Representatives, with copies being sent to the Governor and the North Carolina Biotechnology Center, an update of the biotechnology development program report to take into account changes in its biotechnology development program for the remaining years covered by that report. In preparing its biotechnology development program report and the update, the Board of Governors shall consult with the North Carolina Biotechnology Center. No further funds may be allocated from the Reserve established in Section 1 and Section 2 of this act unless this update is submitted; however, the update must be submitted by the date specified regardless of whether additional funds are requested from the Reserve.

Sec. 5. Board of Governors; Activity Reports. - By January 1, 1987, the Board of Governors of The University of North Carolina shall submit to the President and President Pro Tempore of the Senate, and the Speaker and Speaker Pro Tempore of the House of Representatives, with copies being sent to the Governor and the North Carolina Biotechnology Center, a report of the specific activities carried out during the fiscal year 1985-86 with the funds provided in Section 1 and Section 2 of this act, as well as the specific activities related to biotechnology carried out with other funds, regardless of the source. This report shall include the economic impact of these activities and a description of the efforts that have been made to disseminate the results of these activities. A similar

report shall be submitted to the same parties by January 1, 1988, covering the activities in fiscal year 1986-87.

Sec. 6. Department of Commerce; Appropriation for Biotechnology Center Programs. - In addition to all other funds appropriated for this purpose, there is appropriated from the General Fund to the Department of Commerce the sum of four million eight hundred thousand dollars ($4,800,000) for the fiscal year 1985-86 and the sum of four million eight hundred thousand dollars ($4,800,000) for the fiscal year 1986-87, said sums to be used for the purpose of entering into an agreement with the North Carolina Biotechnology Center to promote biotechnology research and development in North Carolina. The full amount of each appropriation shall be transferred to the North Carolina Biotechnology Center pursuant to such agreement.

Sec. 7. Department of Commerce; Appropriation for Biotechnology Center Facilities. - There is appropriated from the General Fund to the Department of Commerce the sum of one hundred twelve thousand dollars ($112,000) for the fiscal year 1985-86 for the purpose of planning, site acquisition, and site preparation for facilities for the North Carolina Biotechnology Center, and the sum of one million eight thousand dollars ($1,008,000) for the fiscal year 1986-87 to be used to complete the construction of facilities for the North Carolina Biotechnology Center. No funds appropriated in this section may be expended until the North Carolina Biotechnology Center has obtained commitments from nonState sources for one million one hundred twenty thousand dollars ($1,120,000) in additional funds for the construction of these facilities. The

commitments for nonState funds must be obtained not later than June 30, 1986, in order for these funds to be expended. If the commitments for nonState funds are not obtained by June 30, 1986, the funds appropriated in this section shall revert to the General Fund. The facilities constructed with the funds appropriated in this section shall remain the property of the State.

Sec. 8. Restrictions on Biotechnology Center Appropriations; Report of Proposed Activities. - Prior to receiving the funds appropriated in Section 6 or Section 7 of this act, the North Carolina Biotechnology Center shall produce a report detailing its proposed activities for fiscal years 1985-86 and 1986-87 and submit copies of this report to the President and President Pro Tempore of the Senate, the Speaker and Speaker Pro Tempore of the House of Representatives, the Governor, the Advisory Budget Commission, the Joint Legislative Commission on Governmental Operations, the Department of Commerce, the Commissioner of Agriculture, the Secretary of Natural Resources and Community Development, the Board of Science and Technology, the Board of Governors of the University of North Carolina, the President of the North Carolina State Board of Community Colleges, the Superintendent of Public Instruction, and the administrations of the private universities and colleges in the State. A similar plan, covering the proposed activities for fiscal years 1987-88 and 1988-89, shall be prepared and sent to the same parties not later than January 1, 1987.

Sec. 9. Biotechnology Center; Reports From Funding Grantees. - The North Carolina Biotechnology Center shall

require annual reports of the activities of its funding grantees and the economic impact or potential economic significance of their work. These reports shall include the grantees' efforts at disseminating the results of their work.

Sec. 10. Biotechnology Center; Reports to General Assembly. - By January 1, 1987, the North Carolina Biotechnology Center shall submit to the President and President Pro Tempore of the Senate, and the Speaker and Speaker Pro Tempore of the House of Representatives, with a copy being sent to the Governor, a report that details all of the North Carolina Biotechnology Center's efforts during the fiscal year 1985-86, assesses the overall economic impact of those efforts, and describes the dissemination of developments related to biotechnology. In addition, the report shall include all the information the North Carolina Biotechnology Center was required to receive from its grantees under Section 9 of this act. A similar report shall be submitted to the same parties by January 1, 1988, covering the activities in fiscal year 1986-87.

Sec. 11. Department of Commerce Appropriation for Training and Biotechnology Promotion; Report to General Assembly. - There is appropriated from the General Fund to the Department of Commerce the sum of fifty thousand dollars ($50,000) for the fiscal year 1986-87 to be used to train personnel in biotechnology subjects and for the promotion of biotechnology development and business recruitment in North Carolina. Not later than January 1, 1988, the Department of Commerce shall submit a report to the President and President

Pro Tempore of the Senate, and the Speaker and Speaker Pro Tempore of the House of Representatives, with copies being sent to the Governor and the North Carolina Biotechnology Center, outlining its activities in the field of biotechnology during the fiscal year 1986-87, which shall include the economic impact of its efforts and the efforts it has made at dissemination of biotechnology-related information.

Sec. 12. Agricultural Extension Service Appropriation; Report to General Assembly.- There is appropriated from the General Fund to the Board of Governors of the University of North Carolina, for the Agricultural Extension Service, the sum of fifty thousand dollars ($50,000) for the fiscal year 1986-87, to be used to educate farmers and other agricultural and forestry interests in the state about biotechnology and to speed the dissemination of biotechnology-related agricultural and forestry improvements as they become available. Not later than January 1, 1988, the Agricultural Extension Service shall submit to the President and President Pro Tempore of the Senate, and the Speaker and Speaker Pro Tempore of the House of Representatives, with copies being sent to the Governor and the North Carolina Biotechnology Center, a report outlining its activities related to biotechnology during the fiscal year 1986-87 and the economic impact of its efforts.

Sec. 13. Department of Commerce Appropriation for Bioprocess Engineering Facilities. - There is appropriated from the General Fund to the Department of Commerce, for the purpose of entering into a contract with the North Carolina Biotechnology Center for the construction and operation of

bioprocess engineering facilities in the State, the sum of six hundred sixty thousand dollars ($660,000) for the fiscal year 1985-86 for the purpose of planning, site acquisition, and commencement of construction of the facilities, and the sum of two million dollars ($2,000,000) for the fiscal year 1986-87 to complete the construction of the facilities. No funds appropriated in this section may be expended until the North Carolina Biotechnology Center has obtained commitments from nonState sources for five million three hundred twenty thousand dollars ($5,320,000) in additional funds for the construction of these facilities. The commitments for nonState funds must be obtained not later than June 30, 1986, in order for these funds to be expended. If the commitments for nonState funds are not obtained by June 30, 1986, the funds appropriated in this section shall revert to the General Fund. The facilities constructed with the funds appropriated in this section shall remain the property of the State.

Sec. 14. Effective Date. - This act shall become effective July 1, 1985.

SESSION 19 85 Short Title: Biotechnology Study Continued

INTRODUCED BY: *

Referred to:

A BILL TO BE ENTITLED

AN ACT AUTHORIZING THE LEGISLATIVE RESEARCH COMMISSION TO CONTINUE TO STUDY THE NEEDS FOR THE DEVELOPMENT OF BIOTECHNOLOGY IN NORTH CAROLINA.

The General Assembly of North Carolina enacts:

Section 1. The Legislative Research Commission shall continue its study of the development of biotechnology in North Carolina, with particular attention to the aspects of biotechnology referred to in Senate Joint Resolution 620 and House Joint Resolution 1282, 1983 Session, and the recommendations of the Legislative Research Commission's Biotechnology Study Committee submitted to the 1985 Session of the General Assembly.

Sec. 2. The Commission shall file a report with the Governor and the General Assembly prior to the 1987 Session of the General Assembly and may file an interim report prior to the 1986 Session of the General Assembly, if any.

Sec. 3. The Legislative Services Commission shall provide professional and other staff assistance upon the request of the Commission. The Commission may seek additional staff assistance from the North Carolina Biotechnology Center and the universities.

Sec. 4. There is appropriated from the General Fund to the Legislative Research Commission the sum of fifteen thousand dollars ($15,000) for fiscal year 1985-86 and the sum of ten thousand dollars ($10,000) for fiscal year 1986-87 to be used to support this study.

Sec. 5. This act shall become effective July 1, 1985.