United States Bioengineering Research Programs: A Critical Analysis

Josh Leonard
Washington Internships for Students of Engineering
August 1999

Table of Contents

About the Author

Josh Leonard is in his fourth year of undergraduate studies in Chemical Engineering at Stanford University. This study is the product of research conducted through his participation in the Washington Internships for Students of Engineering (WISE) program of 1999. The American Institute of Chemical Engineers (AIChE) sponsored his participation in this program.

The WISE Program

The WISE program is a 10-week public policy internship for highly qualified engineering students entering their fourth year at universities across the United States. Applicants are selected based upon proven leadership and an interest in public policy. Over the summer, students learn how government officials make decisions on complex technological issues and get a feeling for how engineers can contribute to legislative and regulatory public policy decisions. Visits at various engineering-related public policy organizations in the Washington D.C. area are supplemented with lectures on public policy from the WISE faculty-in-residence. The program culminates in each student's production of a public policy research paper that is of interest to his or her sponsoring society.

Acknowledgements

The author would like to express his copious thanks to the American Institute of Chemical Engineers and the WISE program for providing the opportunity to participate in this unique experience and for supporting the development of his research.

Special thanks go to Darlene Schuster and Bill Doumas, who succeeded in making this experience both fruitful and rewarding. Also, thanks to Dr. Juan Lucena - the 1999 WISE faculty-in-residence, and Sean Bersell for their countless hours invested in the WISE program and its students.

Issue Definition

In May 1999, Rep. Burr (R-NC) and Senate Majority Leader Trent Lott (R-MS) introduced H.R. 1795[1] and S. 1110[2] – two identical bills calling for the establishment of a National Institute of Biomedical Imaging and Engineering (NIBIE) at the National Institutes of Health (NIH). With a general consensus in Congress that NIH's budget (which was $15.6 billion in FY99) should be significantly increased, perhaps doubled, over the next few years, it is crucial that NIH be modernized to best manage such an enormous taxpayer investment.[3] This study analyzes these measures to centralize the NIH's bioengineering[*] programs, examines the consequences involved with this significant reorganization, and suggests feasible policy alternatives. It focuses on the following issues:

1) How should federal bioengineering programs be organized to **ensure efficient government spending on diverse, high quality bioengineering research?**
2) How would the establishment of the NIBIE affect the **budget making process,** in relation to federal spending on bioengineering research?
3) How, other than at the NIBIE, might federal bioengineering programs be structured to best **further the nation's bioengineering enterprise**[4]?

Who would be affected by this legislation?

Federal bioengineering programs affect many individuals across both academia and private industry. Scientists and engineers from backgrounds including chemical engineers, mechanical engineers, biomedical engineers, biologists, and chemists currently conduct bioengineering research and development, which is often divided into two categories:

- *Basic research* concentrates on the acquisition of fundamental scientific knowledge without focusing on a particular application.
- *Applied research* to utilizes this basic knowledge to develop technology for a specific function or gain new knowledge for a predetermined application.[5]

In fiscal year 1993 (FY93), the federal government contributed $484 million to bioengineering research funding. The majority of such funding, $300 million, was appropriated by the NIH, with the remainder disbursed by a "diffuse" network of other federal agencies and departments including: the National Science Foundation (NSF), the Department of Energy (DOE), the Department of Defense (DOD), the Centers for Disease Control and Prevention, the Department of Education (ED), the Department of Transportation(DOT), the Food and Drug Administration (FDA), the National

[*] The NIH defines bioengineering in such a manner that limits the usage of this term to applications involving the human body. Thus NIH's definition of *bioengineering* includes applications in human medicine and health, but it *does not* include other fields, such as biotechnology and bioremediation, which sometimes fall under the rubric of *bioengineering* in common speech. The NIH is unclear on its usage of *biomedical engineering*, but it often uses this term interchangeably with *bioengineering*. (See page 4 of this study, under "Definition of 'Bioengineering' " for more detail). In order to be consistent with the legislation being analyzed, this study uses *bioengineering* as per the NIH definition unless otherwise specified.

Aeronautics and Space Administration (NASA), the National Institute of Standards and Technology (NIST), and the Department of Veterans Affairs.[6]

Private industry spends at least 6-10 times more money on bioengineering R&D than does the federal government. Virtually all commercial research is focused on application, rather than on fundamental research (which is conducted mainly at academic institutions).[7] Private industry depends upon the basic research conducted by government sponsored programs to provide the scientific knowledge with which industry can develop new commercial products. Since this fundamental research is general in nature, it is applicable to many diverse fields including biotechnology, pharmaceuticals, and bioremediation. ***Thus, academic institutions, the commercial sector, and the general public have vested interests in promoting the efficacy of federal bioengineering programs.***

How does this concern AIChE?

AIChE's membership spans academia and various areas of the private sector. A restructuring of the federal government's bioengineering programs could affect those members who currently conduct bioengineering research, at universities or elsewhere, with federal support. A more efficient and streamlined federal program would presumably lead to increased funding for existing research and/or a greater number of federal grants available to qualified research ventures. With improved basic research and mechanisms to assist technology transfer, AIChE members in the commercial sector would receive a richer influx of scientific findings to boost industrial R&D.

The definition of *bioengineering* used in legislation determines which types of research are eligible for funding from a federal bioengineering organization. The trend among researchers is to consider *bioengineering* a broad category of which *biomedical engineering* and other fields involving *any* living system(s) are subsets.[8] The NIH definition of *bioengineering*, in contrast, limits usage of this term to applications for the human system. Thus chemical engineers and companies in fields such as biotechnology, which commonly are classified as a subset of *bioengineering*, would <u>*not*</u> be eligible to receive funding from a federal bioengineering organization using the NIH's current definition of *bioengineering*. Therefore, for many chemical engineers the wording and definitions of the legislation being considered determine the availability of NIH's vast funding resources.

Over the past 30 years, advances in bioengineering have drastically improved the quality of life for millions of people through developments such as the pacemaker and a process for manufacturing human insulin through recombinant DNA technology.[9] As a society dedicated in part to public service, it is clearly in AIChE's interest to help promote the optimization of federal bioengineering programs.

Background

Definition of "Bioengineering"

The definition of *bioengineering* established by the NIH is:

> Bioengineering integrates physical, chemical, or mathematical sciences and engineering principles for the study of biology, medicine, behavior, or health. It advances fundamental concepts, creates knowledge from the molecular to the organ systems level, and develops innovative biologics, materials, processes, implants, devices, and informatics[10] approaches for the prevention, diagnosis, and treatment of disease, for patient rehabilitation, and for improving health.[11]

This definition was created as a criterion for determining which NIH programs classify as "bioengineering", such that figures for federal and private spending on bioengineering could be calculated. Other uses of the term *bioengineering* might include such fields as biotechnology[12] and bioremediation[13], which may lead to confusion regarding the scope of activities encompassed by this word.[14] The NIH sometimes uses the term *biomedical engineering* and treats it as a synonym for *bioengineering*. The legislation to establish the NIBIE also uses the terms *biomedical engineering* (which is the wording in the title of the proposed institute) and *bioengineering* interchangeably. Though the NIBIE legislation seems to use *bioengineering* in a manner compatible with the NIH definition, it *does not* state an exact definition of the term. This contrasts with earlier legislation (H.R. 4170 – which is described below)[15], in which an exact definition for *bioengineering* was given.[16]

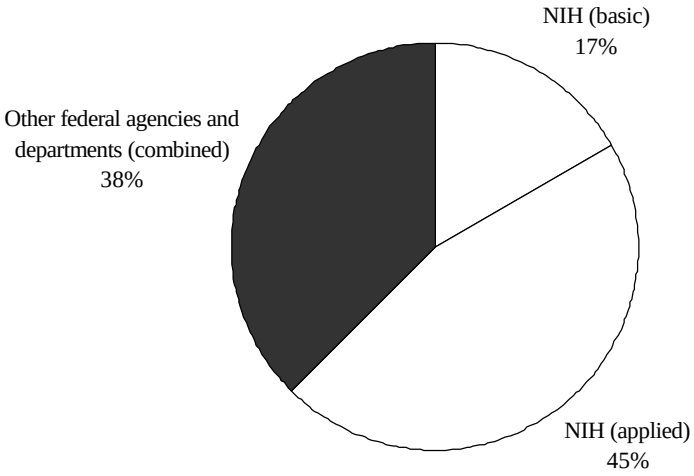
Support for Bioengineering Research

Bioengineering research has recently made great strides and experienced tremendous growth due to advancements in scientific knowledge, much of which was funded by the federal government. Recognizing the need to assess the status and requirements of the bioengineering field, the Senate Labor and Human Resources Committee passed Public Law 103-43 in 1993, which obligated the Secretary of Health and Human Services to conduct a study on support for bioengineering research. That study found that the NIH was the largest federal financial supporter of bioengineering research (approximately $300 million), with ten other Federal agencies and departments also contributing (approximately $180 million in total).[17] Within the NIH, an agency under the Department of Health and Human Services (HHS), every Institute and Center supports some bioengineering research.[18]

Other sources also contribute significantly to bioengineering research. Private organizations such as the nonprofit Whitaker Foundation ($23 million in FY93) provide funding for bioengineering research.[19] Private industry is by far the largest financial supporter of bioengineering research. Though corporate funding for R&D outweighs federal funding more than six-fold, this research is geared towards *product development* and *application* of basic scientific findings. The majority of funding for *basic*

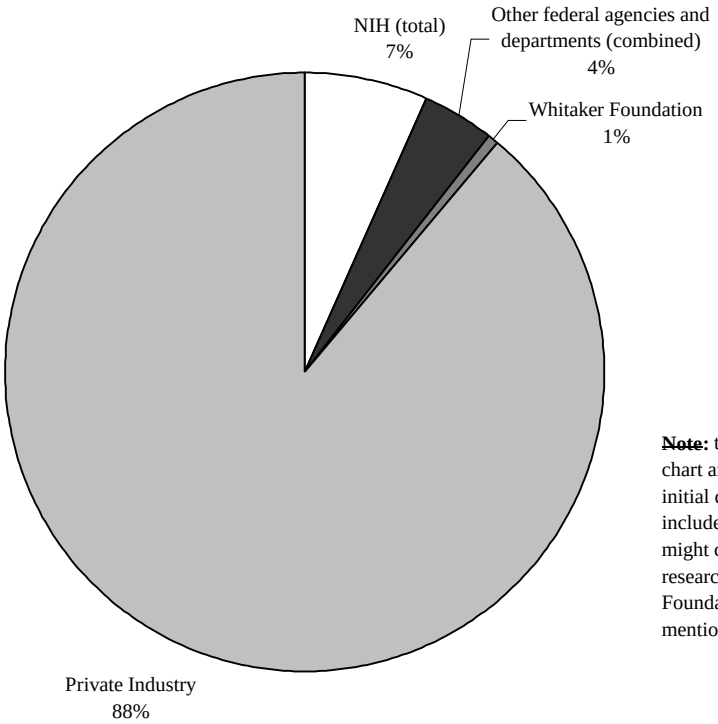
bioengineering research (upon which private industry's R&D are based) comes from the National Institutes of Health ($80 million in FY93).[20]

Federal Funding for Bioengineering Research (FY93)



Data courtesy of the 1994 External Consultants Committee report, "Support for Bioengineering Research", prepared for the NIH.

Total Funding for Bioengineerng Reserach - Basic & Applied (FY93)



~~**Note:**~~ the values used to create this chart are approximate, as was the initial data. This chart does not include other private sources which might contribute to bioengineering research because the Whitaker Foundation is the only one mentioned in most references.

Data courtesy of the 1994 External Consultants Committee report, "Support for Bioengineering Research", prepared for the NIH.

Reports on the State of Bioengineering

In 1993, Congress requested that the HHS prepare a study on support for bioengineering. For this task, NIH convened an External Consultants Committee (ECC) including individuals from academia, industry, the Whitaker Foundation, research centers, and the NSF. [21] The resulting **1994 ECC Report** to the NIH recommended that:

1) NIH should establish a central focus for basic bioengineering research. This central focus should be at the highest level and should include resources for the collaborative support of extramural research.
2) The NIH should significantly expand representation of the medical and biological engineering community on advisory groups and in the peer review process (i.e. for awarding grants).
3) NIH should establish an intramural bioengineering research program. This program would focus on cutting-edge research of national significance that complements ongoing intramural (research conducted by government-run NIH laboratories) and extramural (research supported by NIH through a grant, contract, or cooperative agreement) programs.[22]
4) Communication and cooperation should be enhanced among governmental agencies with significant research needs and in facilitating technology transfer.
5) The public sector should increase efforts to foster greater private sector participation in determining basic research needs and in facilitating technology transfer.[23]

In August 1995, Dr. Harold Varmus, Director of the NIH, submitted a report to Congress on behalf of the HHS entitled Support for Bioengineering Research.[24]. This report also recommended that NIH conduct basic bioengineering research through intramural programs. Unlike the ECC report, however, the HHS report called for the NIH to create an Interagency Bioengineering Coordinating Committee (which would not be involved in extramural research).

Creation of the NIH Bioengineering Consortium (BECON)

In February 1997, Director Varmus attempted to follow the HHS report's recommendations by creating the NIH Bioengineering Consortium, (BECON)– a council of extramural and intramural senior level representatives of all NIH Centers, Divisions, and Institutes. Though BECON does serve as a facilitator between NIH, the other federal agencies, and external organizations, it carries neither the responsibility nor the authority of providing or allocating funding.[25] Yet to be proven is BECON's ability to *influence* bioengineering policy and funding decisions through interaction with the leaders of each Institute or Center and through a recently "improved" NIH bioengineering program announcement. This new program announcement aims to attract and award grants to bioengineering research ventures which would otherwise (if not for the new program announcement) have their funding requests denied. [26]

Response to BECON

The American Institute for Medical and Biological Engineering (AIMBE) is a consortium representing a significant sector of the medical and biological engineering community, including 15 scientific societies, 32,000 scientists and engineers, and 53 university institutions. [27] On July 24,1997 Dr. Winfred Phillips (former president and representative of AIMBE) testified before the Subcommittee on Public Health and Safety, (Senate Labor and Human Resources Committee). He stated that although AIMBE supported the establishment of BECON as a transitional organization, it urged for the establishment of a stronger agency with the funding authority recommended by the 1994 ECC report.

On this same date Dr. Wendy Baldwin, Director of the Office of Extramural Research at the NIH, testified before the same subcommittee to describe the measures already taken by the NIH, including the actions of BECON, to address the issues raised in the aforementioned reports and Dr. Phillips' testimony.

Legislative Action to Create a Bioengineering Focus

On July 17,1997, Senator Bill Frist (R-TN) introduced a bill (S. 1030)[28] in the Senate of the 105th Congress to establish the "National Center for Bioengineering Research". This bill implied that the creation of BECON would not be sufficient to satisfy the needs of bioengineering research, and legislation would be required to further the NIH's efforts. The bill was referred to the Senate Committee on Labor and Human Resources, and no further action was taken. On June 25,1998, Rep. Gil Gutknecht (R-MN) and Rep. Anna Eshoo (D-CA) introduced a corresponding bill (H.R. 4170)[29]into the House of the 105th Congress. This bill was referred to the House Committee on Commerce, Subcommittee on Health and the Environment, on July 9th, 1998, and no further action was taken.

Legislative Action to Create a Biomedical Imaging Focus

Over the last 30 years, there have been varying amounts of congressional interest in creating a center for imaging at the NIH.[30] On May 22, 1997, Rep. Richard Burr (R-NC) introduced a bill (H.R. 1715)[31] into the House of the 105th Congress to create a National Institute of Biomedical Imaging. Though H.R. 1715 received the support of 79 cosponsors, no further action was taken after the bill was referred to the House Committee on Commerce, Subcommittee on Health and the Environment on June 18, 1997. On July 7, 1997 Sen. Faircloth introduced a corresponding bill (S. 990)[32] in the 105th Congress. On the same day, this bill was referred to the Committee on Labor and Human Resources, and no further action was taken.

The National Institute of Biomedical Imaging and Engineering (NIBIE)

On May 13th,1999, Rep. Burr (on behalf of himself and Rep. Eshoo) combined these two movements and introduced, (in the House of the 106th Congress), H.R. 1795[33] - a bill to establish the National Institute of Biomedical Imaging and Engineering (NIBIE) at the

NIH. On May 24th , Senate Majority Leader Trent Lott (R-MS) introduced a companion bill (S. 1110)[34] in the Senate. Collectively, these two bills are referred to as the **NIBIE Establishment Act**.[35]

The proposed NIBIE would allocate and provide funding and conduct research in biomedical imaging, physics, engineering, mathematics, computer science, biomaterials, informatics, technology for disease screening, and other unnamed related disciplines. The NIBIE Establishment Act calls for "consolidation of programs of the [NIH]" and "the coordination of the activities of the [NIBIE] with related activities of the other agencies of the National Institutes of Health and with related activities of other Federal agencies." The details and extent of this coordination are not specified, this job being left to the NIH Director. The proposed legislation also makes note that the act *does not* authorize "the construction of facilities, or the acquisition of land, for purposes of the establishment or operation of the [NIBIE]". Also, this legislation specifies that the overall level of federal funding allocated for biomedical engineering and imaging is to remain constant. Currently, H.R. 1795 has been referred to the House Commerce Committee, and S. 1110 has been referred to the Senate Health, Education, Labor, and Pensions Committee.

Many of the responsibilities of the proposed NIBIE are currently assigned to the National Science and Technology Council (NSTC), located in the Office of Science and Technology Policy (OSTP). The NSTC is charged with coordinating science, space, technology, and the many federal research and development programs in accordance with the President's science and technology agenda.[36] The Committee on Science (CS) is the organization which deals most directly with the issues to be addressed by NIBIE.[37]

Engineering Societies Get Involved

The American Association of Engineering Societies (AAES), which represents eighteen engineering societies[38], issued a position statement in April 1998 regarding biomedical engineering (which, in AAES's usage, is synonymous with bioengineering). This statement calls for an organizational focus for biomedical engineering at the NIH including representation of engineers in NIH policy and providing "advice on the solicitation, submission and review of proposals with a primary biomedical engineering research emphasis". This document fails to specify detailed recommendations for the duties of the "focus" and does not endorse any specific legislation.[39] AAES organized a Capitol Hill briefing on bioengineering in late 1998 in coordination with the American Institute of Medical and Biological Engineers (AIMBE), Institute of Electrical and Electronics Engineers Inc.- United States of America (IEEE-USA), Optical Society of America (OSA), American Society for Engineering Education (ASEE), the American Society of Mechanical Engineers (ASME), and the American Institute of Chemical Engineers (AIChE).[40]

ASME, which has a Bioengineering division of about 6,000 members, has been actively involved in the movement to restructure federal bioengineering programs.[41] In February 1998, ASME's bioengineering division issued a position statement supporting the establishment of a "National Center for Bioengineering Research" via S. 1030. One key point of this position statement was that an effective bioengineering center must have the funding and authority to provide extramural grants.

AIMBE has been an active participant in promoting a central focus for bioengineering at the NIH. Dr. Winfred Phillips, the Past-President of AIMBE, expressed AIMBE's views and recommendations for reorganizing the NIH in his testimony before the Senate.[42] In addition, AIMBE issued a letter of consideration to the chairs of the House and Senate committees to which H.R. 1795 and S. 1110 (the NIBIE Establishment Act) were referred.[43] This letter included the ECC and HHS reports, and some background description.

IEEE-USA issued a position statement in 1992 recommending a focus for biomedical engineering at the NIH, and this statement was reissued in February, 1998.[44] This statement doesn't make a detailed recommendation, but suggests the possibility of an "Office of Biomedical Engineering and Instrumentation" with authority for extramural activities.

ASEE issued a policy paper on bioengineering at the NIH, but it did not express any opinions regarding or recommendations for a focus for bioengineering.[45] OSA has not issued a statement on this issue.

Increased Funding for NIH

Some medical research advocates seek to double the NIH's budget over the next five years (beginning in 2000). Such an increase would surely impact bioengineering research funding. This emerging campaign is supported by a number of influential members of congress, including John Edward Porter (R-Ill), Chairman of the House Appropriations Subcommittee on Labor, Health and Human Services, and Education; Sen. Arlen Specter (R-Pa), Porter's Senate counterpart; and Sen. Tom Harkin (D-Iowa), the top Democrat on the Senate Labor-HHS Appropriations Subcommittee. [46] Many groups also support this movement, including such prominent organizations as Research!America, The National Health Council, the American Heart Association, the American Medical Association, the Federation of American Societies for Experimental Biology[47], and the Ad Hoc Group for Medical Research Funding. Though Congressional spending caps pose a potential obstacle, many supporters are confident that this can be overcome.[48]

The Congressional Biomedical Research Caucus

The Congressional Biomedical Research Caucus is "an informal bipartisan group of House Members formed to provide an educational forum for discussion and exchange of ideas on issues involving biomedical research".[49] Topics of discussion before this group tend to be controversial, and the NIBIE Establishment Act has not yet been scheduled as an issue to be discussed.[50] Topics can be suggested by submitting a recommendation to the office of Rep. George Gekas (R-PA).[51]

Key Conflicts and Concerns

Concerns about the present condition of bioengineering at the NIH

The following four main concerns about the NIH's bioengineering programs are based upon problems first identified in the 1994 External Consultants Committee (ECC) report. Since that time, the continued testimony, publications, and actions of individuals and organizations in the bioengineering research and industrial sector reveal that the NIH has not yet compensated for these deficiencies.

1. **Basic bioengineering research is insufficiently funded.**

   Of the $300 million that NIH spent on bioengineering research in FY93, less than $80 million (25%) was spent on *basic* research. In contrast, NIH directed an overall average of 60% towards basic research.[52] In 1997, AIMBE asserted that funding for *basic* bioengineering research is still lacking, and levels need to be increased so that bioengineering can keep pace with other biomedical fields.[53] This funding is invaluable because the private sector cannot provide the capital to invest in the fundamental research that enables breakthroughs in bioengineering.[54]

2. **The NIH has no internal coordination between bioengineering programs conducted in its many Institutes and Centers.**

   By the time the ECC report was issued in 1994, a few inter-agency activities in bioengineering had occurred, but the NIH lacked large scale coordination of its bioengineering programs.[55] Since that time, NIH created BECON; this consortium serves as a forum for information exchange, but it lacks the authority to provide and appropriate funding. For this reason, BECON does not have direct control over the scope of bioengineering research ventures. Yet to be proven is BECON's ability to *influence* bioengineering and funding decisions through interaction with the leaders of each Institute or Center and through a recently "improved" NIH bioengineering program announcement.[56]

3. **Bioengineering research funding is not being spent efficiently.**

   When the ECC report was released in 1994, there was no central organization in the federal government to oversee spending on bioengineering research. This created the risk for unintentional duplication of research. Often, *intentional* duplication of research is necessary to establish the repeatability and credibility of a scientific discovery. In contrast, *unintentional* duplication of simple but tedious research, for example, is an inefficient use of research money. Without coordination of bioengineering research, it is difficult for individual Institutes and Centers to encourage research in areas which complement and support other research directions. This delays the progress and increases the cost of these research ventures. BECON now aids in information exchange, but as mentioned above, it does not have direct control over funding for either extramural (research

supported by NIH through a grant, contract, or cooperative agreement) or intramural (research conducted by government-run NIH laboratories) bioengineering research.[57] This limits BECON's ability to coordinate related research and execute an overall strategy for promoting U.S. bioengineering. Some organizations (like AIMBE) assert that BECON will be unable to guide NIH bioengineering research so as to most efficiently use federal monies.[58]

4. <u>There is insufficient coordination between federal agencies.</u>

In 1994, there existed no mechanism for inter-agency coordination of bioengineering programs. The NSTC-CS, which is supposed to coordinate federal science policy issues, has not taken a strong role in bioengineering matters. BECON has taken steps to increase coordination among federal agencies, including the creation of a six-member BECON Agency Liaison Committee.[59] In the last two years, this committee has worked extensively with the NSF and has met formally with the Department of Education (ED), the DOD, and the DOE but *not* the FDA, DOT, NASA, or NIST (all of which were listed in the ECC report as conducting bioengineering activities). But, committee members have met individually with representatives from most of these agencies.[60]

The lack of coordination between federal agencies still poses a barrier to bioengineering researchers, especially those who attempt to obtain partial funding from several agencies. Dr. Joanna Fowler, who researches PET imaging at Brookhaven National Laboratory under the joint funding of NIH and DOE, recalls the numerous obstacles that the Brookhaven program has had to overcome. Though DOE, NIH and Office of National Drug Control Policy were all very interested in establishing a jointly funded imaging center for abuse research at Brookhaven, she attributed eventual success in 1997 to the good fortune that "creative and committed people in each agency wanted this to happen and knew how to make it happen in spite of an enormous amount of bureaucratic red tape." She expressed concern that other valuable research is unable to secure joint funding because the concomitant obstacles are often too great.[61]

Supporters of the NIBIE Establishment Act contend that a central bioengineering focus stronger than BECON is necessary to adequately coordinate the thousands of bioengineering research programs carried out each year by the United States government (in FY93 the NIH ran 1,781 bioengineering research programs while other federal agencies conducted a total of 592 bioengineering programs).[62] In fact, the NIBIE Establishment Act calls for the new NIBIE Director to submit a plan to the Secretary and Director of NIH, which includes recommendations for coordinating NIBIE biomedical imaging and engineering activities with related activities conducted by other institutes and agencies.

How might the NIBIE Establishment Act *decrease* the efficiency of federal spending on bioengineering?

Creation of the NIBIE would increase the federal bureaucracy. The NIBIE Establishment Act does not authorize funding for the purchase of land or the construction of facilities for the NIBIE. Therefore, the NIH would need to use existing facilities to house the NIBIE. However, the NIH would still incur the costs of hiring operation staff. BECON and the NSTC-CS already play roles in coordinating bioengineering and activities of federal agencies, respectively. Since the NIBIE Establishment Act does not specify how these overlaps are to be resolved, it has the potential to create redundancy in the federal government.

NIBIE's effects on congressional oversight

The current "diffuse" state of federal bioengineering programs makes it difficult for Congress to identify every branch of federal bioengineering research, and therefore it is difficult to see the "big picture". This was demonstrated in 1994 when Congress announced that it was unable to verify the bioengineering spending figures cited in the ECC report. However, if all federal bioengineering programs and funding were to be coordinated through the NIBIE, Congress could more easily oversee the entire range of federal bioengineering funds. Oversight of the DOE's science programs has created the need to devote significant manpower and resources to proving to Congress that any given program is worthy of federal spending. This process was described by Jim Decker, the Deputy Director of the Office of Science, DOE, as an ongoing burden for DOE researchers.[63] NASA must also devote significant resources to appeasing Congressional oversight at the expense of research and other programs.[64] The centralization brought about by the NIBIE Establishment Act might lead to augmented Congressional oversight.

NIBIE's effects on the budget making process and scope of research ventures which receive funding.

Like Congress, the Office of Management and Budget (OMB)'s view of bioengineering is obscured by the field's current diffuse state. Centralization of federal bioengineering programs at the NIBIE would make it much simpler for Congress and OMB to influence, through budget actions, the direction of the nation's bioengineering programs. In the past, Congress has forced the NIH to focus on certain issues, such as alternative medicine and women's health, at the expense of neglecting diseases like colon, bladder, brain, and kidney cancer.[65] This kind of intervention is especially threatening to smaller esoteric research ventures. These small projects are usually not highly visible to the public, and therefore they are in greater danger of being axed by constituency-driven politicians. However, these non-mainstream ventures are essential for maintaining a healthy breadth of research.

Impacts of the definition of *Bioengineering*

The definition of *bioengineering* used by the NIH limits its application to the human system. However, other uses of *bioengineering* are broader, including applications in agriculture, industrial biotechnology (such as the microbial production of polymers or pharmaceuticals), and bioremediation. Basic scientific knowledge gained from research in bioengineering, as defined by the NIH, can often be applied to other fields. For example, genetic enhancement of agricultural crops to produce so-called "medicinal foods" would not fall under the NIH's definition of bioengineering because it does not deal directly with the human system. However, such an enterprise may employ the same fundamental technology as biomedical engineering applications. Thus, the NIH's definition of *bioengineering* creates an artificial boundary between human medical applications and related fields. This boundary might hinder information and technology transfer between fields which could benefit from shared basic scientific knowledge, thus creating the potential for redundancy and duplicated research.

In general, the terms *bioengineering* and *biomedical engineering* are often poorly defined or not defined at all. Sometimes, they are used synonymously. This lack of uniformity across the NIH, the federal government, and general discussion leads to confusion and may cause conflict.

NIH's opposition to NIBIE

Under the leadership of Dr. Harold Varmus, the NIH has actively sought to deal with critiques of its bioengineering programs (such as those problems voiced in the ECC and HHS reports and position statements of the engineering societies[66]) and has enacted corrective measures from within its organization. This strategy is exemplified by the creation of BECON in response to the 1994 ECC report and the 1995 HHS report. Like most federal bureaucracies, the NIH and its leadership are opposed to having a massive restructuring imposed by Congress. Dr. Wendy Baldwin, chair of BECON, made clear in her testimony before the Senate that the NIH believes it is capable of addressing bioengineering issues through its internally imposed changes.[67]

Policy Alternatives

The several policy alternatives listed below all pursue the final goal of benefiting the nation's bioengineering enterprise. Options I and II are evaluated based upon effectiveness, efficiency, equity, flexibility, and implementablity. Options III through V were considered as viable alternatives, but each addresses only a subset of the problems discussed in the previous section. Therefore, options III through V are briefly analyzed mainly to present the interesting points that they raise. The alternatives should be viewed as a list of policy *outcomes*. In the *Recommendations* section, this study delineates a course of action which AIChE and its members might pursue to achieve the best policy outcome.

I. Support the NIBIE Establishment Act

One option is to support the NIBIE Establishment Act, exactly as specified in HR1795 & S1110.

- **Effectiveness**

  The NIBIE would provide a strong central focus for bioengineering at the NIH, in accordance with the 1994 ECC Report. Bioengineering and imaging were paired in this bill primarily as a means of garnering political support; this was not a response to any study or recommendation. Still, a close relationship between bioengineering and imaging may be beneficial because of shared technology. However, the NIBIE Establishment Act disregards the relationships between bioengineering, industrial biotechnology, and pharmaceuticals. These relationships could be used to achieve two goals set out by the ECC Report: a) an improved technology transfer program and b) an increase in private industry's role in determining basic research needs. The NIBIE would have only limited effectiveness in influencing the bioengineering programs conducted in governmental agencies outside the NIH. For example, the DOE and the NSF would work in conjunction with the NIBIE, but NIBIE could not *mandate* the bioengineering activities of other federal bureaucracies.

- **Efficiency**

  The NIBIE would increase the federal bureaucracy. The NIBIE Establishment Act does not authorize funding for the purchase of land or the construction of facilities for the NIBIE. Therefore the NIH would need to use existing facilities to house the NIBIE. However, the NIH would still incur the costs of hiring operations staff. BECON and the NSTC-CS already play roles in coordinating bioengineering and activities of federal agencies, respectively. Since the NIBIE Establishment Act does not specify how these overlaps are to be resolved, it has the potential to create redundancy in the federal government. Also, since a central focus for bioengineering would be more susceptible to congressional oversight, the NIBIE might create a burden on researchers and NIH employees to devote more time and resources to appeasing oversight committees. This would, of course, detract from the time and resources available for conducting and promoting research.

According to the ECC Report, an institute such as the NIBIE is needed to increase the efficiency of federal spending on bioengineering research. Like BECON, the NIBIE would be a vehicle for information exchange to ensure that research is not unknowingly duplicated at different federal branches. Unlike BECON, NIBIE would have the authority to award extramural research grants, and therefore, NIBIE could better control the direction of bioengineering research. As the NIH's budget continues to increase (particularly if the movement to double NIH's budget in the next several years is successful), it will be increasingly difficult for BECON to track and influence a growing field of bioengineering research. In this respect, the costs of implementing and maintaining the NIBIE would be insignificant compared with the savings returned through the orderly coordination and distribution of millions of dollars in new NIH research investments.

- **Equity**

  By centralizing bioengineering research, the NIBIE might put smaller, more obscure research ventures in jeopardy of being axed by congressional oversight in favor of research ventures which are more visible to the public.

  Creating a central focus for bioengineering would provide a forum for peer review in which bioengineering research applications could be more fairly reviewed by scientists and engineers who recognize the differences between bioengineering and most other research conducted at the NIH. Traditional NIH research invokes the hypothesis-test method, which requires a large amount of initial data. In contrast, engineering research is often more exploratory, and it begins with much less initial data.[68] This recognition would resolve some major problems with the current system. For example, quality bioengineering research applications are presently turned down in favor of other less qualified applications merely because the engineering research process doesn't conform to NIH convention.

- **Flexibility**

  The NIBIE Establishment Act calls for the Director of the NIBIE to produce a plan detailing how NIBIE will coordinate and intensify research, consolidate related NIH bioengineering programs, and cooperate in conjunction with other federal agencies. Thus, the specifics of the NIBIE strategy are still up for debate and may be molded as the Institute gains experience.

  Once established, the NIBIE will probably develop a resistance to drastic change which is characteristic of large bureaucracies.

- **Implementability**

  The sponsors of the NIBIE Establishment Act hope that it will enjoy the combined support of those Members of Congress who supported previous legislative attempts to create [separate] bioengineering and imaging centers at the NIH. The NIBIE has already received the support of several prominent consortiums, including the AIMBE, the National Electrical Manufacturers Association, and many radiology and imaging

societies. The backing of AIChE or possibly a coalition with biotechnology groups would broaden the act's support base.

The creation of a new Institute at the NIH is a well documented process, and precedence has been established to make this process quite feasible. Also, the expected increase of funding for the NIH would assist in any such reorganization. However, Director Varmus and much of NIH are opposed to being forced to reorganize, and it is possible that he might follow a policy, similar to the creation of BECON, in which NIH attempts to internally address problems with its bioengineering programs.

II. Oppose NIBIE – Maintain the Status Quo

The most simple option is to oppose the NIBIE Establishment Act and continue with the current structure unchanged. BECON would continue to serve as the sole central bioengineering focus in the federal government, and funding for bioengineering would continue to be controlled by the individual institute or center which currently sponsors it. NIH asserts that BECON meets the recommendations outlined in the ECC and HHS reports, including the needs for an improved peer review process for bioengineering and representation of engineers in the determination of program directions. Therefore, in the absence of congressional action, it is likely that NIH would not make any changes in the way these issues are managed.

- **Effectiveness**

BECON provides a focus for bioengineering at the NIH and facilitates cooperation between NIH and other federal agencies conducting bioengineering research, thus partially fulfilling two of the ECC Report's recommendations. However, BECON does not possess the funding authority prescribed in that report.

BECON is composed of representatives from each of the NIH Institutes, Centers, and Divisions (ICDs) which conduct bioengineering activities. However, since these individuals do not directly control budgeting and research grant awards, BECON does not have direct control over funding for the activities it attempts to administrate.

BECON's ability to *influence* bioengineering and funding decisions through interaction with the leaders of each Institute or Center and through a recently "improved" NIH bioengineering program announcement remains to be proven. This new program announcement aims to attract and award grants to bioengineering research ventures which would otherwise (if not for the new program announcement) fail to apply or would have their funding requests denied. [69]. Thus, this announcement will serve as a test of BECON's authority to affect the direction of NIH's bioengineering programs. Over the next few months, the changes brought about by this report, or the lack thereof, will determine whether or not BECON is an effective leader for federal bioengineering policy.

- **Efficiency**
  BECON brings together the experience and information of all NIH bioengineering programs, which reduces the risk of unknowingly duplicating research. However, if several ICDs are currently working on similar research, it is not certain that BECON has the authority or the ability to determine which ICD should proceed.

  Since BECON consists of current federal employees who retain their full time positions, the government incurs no additional salary costs. However, since the members of BECON retain their full time positions as well as serving on this consortium, the amount of time and attention that they can devote to the consortium is limited.

- **Equity**
  Since the NIH conducts the vast majority of bioengineering research, it is fitting that BECON is located at the NIH even though it coordinates the bioengineering activities of several federal departments.

  The engineering problem solving method employs a different strategy than the hypothesis-test method favored by medical scientists. Therefore, bioengineering research is hindered by the under-representation of bioengineers in the study sections of the peer review process. Though BECON might appeal to the Institutes to increase the representation of bioengineers, it does not have the authority to direct the composition of study sections. Moreover, it may not be in the best interests of the Institutes to drastically increase the representation of bioengineers in peer review since bioengineering is only a portion of each ICD program.

- **Flexibility**
  Since BECON membership can be expanded or modified at the discretion of its chair, Dr. Wendy Baldwin, BECON can grow to include representation from any emerging federal bioengineering related projects. However, since BECON is so limited in its authority, it is unlikely that such a consortium could simply be restructured if Congress decides that a stronger bioengineering focus is needed.

- **Implementability**
  Historically, the biggest obstacle to legislation for an institute for bioengineering has been lack of support rather than outright opposition.[70] Therefore, without adequate support, the NIBIE Establishment Act may also be left in committee indefinitely. Therefore this option might be very simple to implement.

III. Establish a National Institute of Bioengineering at the NIH

This option would have all the characteristics of the NIBIE (see the evaluation of Option I) with the exception of the following significant distinctions:

1. Separation from Biomedical Engineering: Though this separation may ensure that the proposed institute delegates adequate time and resources to bioengineering, it may also create a barrier that hinders technology transfer and project coordination between bioengineering research and related biomedical imaging research. Also, this option would lack the support of those who advocate the creation of an imaging focus. This would drastically decrease the implementability of this alternative.
2. Using *Bioengineering* in place of *Biomedical Engineering*: Replacing the term *biomedical engineering* with *bioengineering* in the title of the institute *could* add the flexibility of allowing the proposed institute to fund research which is *related* to biomedical engineering (and wouldn't normally be included under the term *biomedical engineering*) but might fall under a broader definition of *bioengineering*. For example, pharmaceutical production and some types of biotechnology might use the same technology as some biomedical engineering, but they would not be classified as *biomedical engineering* in their own right. Of course, this flexibility is dependent upon the definition of *bioengineering* used in the legislation, and it may vary with time as *bioengineering* is redefined (i.e. through amending the relevant legislation). This issue is discussed further in the **Recommendations** section of this study.

IV. Establish a bioengineering focus under the Executive Branch – National Science and Technology Council

The NSTC, CS currently has sub-committees on "Biotechnology" and "Radiation (Biology) Research". One option is to establish a subcommittee on "Bioengineering" to assist in "interagency policy development, coordination, and information exchange", as per the CS Charter. Such an organizational structure would have the advantage of locating a bioengineering focus *outside* of all federal agencies conducting bioengineering activities. However, the effectiveness (i.e. authority) of such a subcommittee to actually affect policy is questionable- particularly, because the funding for bioengineering research and programs would still be allocated by the existing players (i.e. OMB and Congress) and would be awarded by the same federal agencies that currently award grants.

A variation on this plan would be to expand the role of the "Biotechnology" subcommittee to form a single subcommittee for both biotechnology and bioengineering. This alliance would recognize the close ties between bioengineering and biotechnology and aid in the coordination and technology transfer between these fields.

V. Establish an Office for Bioengineering Research under the Office of the Director, NIH

The Office for AIDS Research (OAR), which is located in the Office of the Director of NIH, would serve as a model for this policy alternative. Congress granted the OAR the responsibilities of planning, coordinating, evaluating, and funding all NIH intramural AIDS research. This alternative would provide the intramural bioengineering focus recommended by the ECC Report, but such an Office for Bioengineering Research would still lack the authority to coordinate and fund *extramural* research, which makes up the bulk of NIH funded research.

Recommendations

Though each alternative has its advantages, it is the conclusion of this study that AIChE should support the NIBIE Establishment Act. However, AIChE should also play an active role, by means suggested below, in amending the NIBIE Establishment Act in order to address the shortcomings described in the previous section.

Amendments to the NIBIE Establishment Act

AIChE and its members should support the following changes in H.R. 1795 and S. 1110 of the 106th Congress – the National Institute of Biomedical Imaging and Engineering (NIBIE) Establishment Act:

1) **The NIBIE should be renamed the National Institute of Bioengineering and Biomedical Imaging (NIBBI).**
   This replacement of *biomedical engineering* by *bioengineering* in the title of the proposed institute would add all the flexibility for funding a broader scope of research that is discussed in the evaluation of policy alternative III (see the previous section of this study). This would also solve the problems of "artificial barriers" between related fields (this is discussed in the **Key Conflicts and Concerns** section of this study - see "Impacts of the definition of *Bioengineering,*" page 12). *Bioengineering* is placed before *Biomedical Imaging* in the title to avoid confusion over the application of the modifier, *Biomedical*. The effectiveness of this recommendation is contingent upon the successful inclusion of the next recommendation (Recommendation 2 in this section).

2) **The NIBBI legislation should include a provision requiring the NIBBI to immediately conduct a study on the relationships between *biomedical engineering, bioengineering, biotechnology, biomedical imaging,* and other "biological" fields. This study is to produce definitions for these terms which highlight their distinctions and commonalties.**
   Though the NIBIE Establishment Act seems to use *bioengineering* in a manner compatible with the NIH definition, the current legislation *does not* state an exact definition of the term. This is contrary to earlier legislation (H.R. 4170), in which an exact definition for *bioengineering* was stated.[71]

   Since multiple interpretations of terms like *bioengineering, biomedical engineering, biotechnology, etc.* are possible, the NIBBI legislation should include precise definitions for these terms. These definitions are critical in determing the scope of activities within which the NIBBI can operate. The study should include input from academia; industry, such as BIO; AIMBE, AAES, FASEB and other societies; the NSF – especially the Biology Program and the Bioengineering and the Environmental Systems Division; and of course, NIH – especially members of BECON.

3) **BECON should be incorporated into the NIBBI.**
Initially, the NIBBI could benefit from the experience of the individuals serving on BECON. Perhaps BECON could convene at monthly intervals as a special-advisory panel to the NIBBI staff. Eventually, perhaps after several such advisory sections, BECON should be dissolved in order to prevent overlaps in authority and inefficient use of resources.

4) **The topics to be included in the NIBBI Director's plan should include**
   a) **recommendations for reforming the review of bioengineering grant applications,**
   b) **increased intramural research in bioengineering, and**
   c) **increased funding for *basic* rather than applied bioengineering research.**

   The NIBIE Establishment Act calls for the new NIBIE Director to submit a plan to the Secretary and Director of NIH which includes recommendations for (a)consolidation of NIH bioengineering and imaging programs and (b)coordination of NIBIE activities with related activities conducted by other institutes and agencies. H.R. 4170 and S. 1030 of the 105th Congress, the National Center for Bioengineering Research Establishment Act, included specific provisions for improving bioengineering research at the NIH. The NIBIE Establishment makes no such provisions, but NIBIE (or NIBBI) would still face the same problems which motivated the authors of H.R. 4170 and S. 1030 to include such directives in these earlier bills. Thus, these specifications should be included among the NIBBI Director's recommendations.

5) **The NIBBI legislation should include a provision for creating an organization within the NIBBI which is responsible for coordinating inter-agency and inter-institute bioengineering and imaging activities.**
Though the current version of the NIBIE Establishment Act calls for the NIBIE Director to include a recommendation for the coordination of NIBIE activities with related activities conducted by other institutes and agencies, this requirement should be strengthened in the NIBBI legislation. The improvement of coordination among agencies and institutes is one of the main driving forces behind this legislation. Thus, the wording of the act on this topic should be *strengthened* to require that a specific organization within the NIBBI be created for the express purpose of managing such coordination.

Plan of Action for AIChE and its Members

AIChE should support the NIBIE and the above amendments through the following actions:

1) **Produce a position statement based on (but not limited to) the above conclusions, and distribute it to Members of Congress.**
   AIChE Position statements are approved by the AIChE Government Relations Committee and are produced in coordination with the Government Relations Office.[72]

2) **Play an active role in forming a coalition of engineering societies. This coalition should then produce a position statement and distribute it to Members of Congress.**
   AAES, AIMBE, ASME, and IEEE-USA have demonstrated interest in federal bioengineering research reform; each has issued a position statement expressing the need for a central bioengineering focus at the NIH. AIChE should contact these societies and set up a conference to determine whether a coalition is viable. It is likely that the position statement issued by such a coalition would broader than the statement of any one society, but it would still send a strong message to Congress. Again, the largest obstacle to this reform is a lack of congressional action, not necessarily a tangible opponent.

3) **Inform membership about this issue through publications and local section meetings, and encourage members to become involved directly in a grass roots campaign.**
   AIChE should supplement its position statements with a grass roots campaign to educate and directly involve members on this issue. Members should then contact their Members of Congress directly to strengthen AIChE's position.[73]

4) **Increase congressional awareness of the importance of bioengineering and of the need to enact legislation on this issue.**
   The biggest obstacle to past legislation on creating a bioengineering focus has been a lack of congressional action, rather than open opposition. One possibility for increasing the visibility of this issue is for AIChE to submit a recommendation to the Congressional Biomedical Research Caucus that the NIBIE Establishment Act be included among the scheduled topics of discussion. Debate over the NIBIE could motivate congressional interest and action. AIChE should include its concerns and suggestions (perhaps based upon this study) in the recommendation. Such proposals are handled through the office of George Gekas (R-PA).[74]

Appendix A: Abreviations and Acronyms

Acronym/Abbreviation	Meaning
AIChE	American Institute of Chemical Engineers
AIMBE	American Institute for Medical and Biological Engineering
ASME	American Society of Mechanical Engineers
BECON	Bioengineering Council (NIH)
CS (NSTC-CS)	Committee on Science (NSTC)
DOD	Department of Defense
DOE	Department of Energy
DOT	Department of Transportation
ECC	External Consultants Committee
ED	Department of Education
FDA	Food and Drug Administration
FY**	Fiscal Year 19**
HHS	Department of Health and Human Services
ICD	Institutes, Centers, or Divisions (NIH)
NASA	National Aeronautics and Space Administration
NIBBI	National Institute of Bioengineering and Biomedical Imaging
NIBIE	National Insitute of Biomedical Imaging and Engineering
NIH	National Insitutes of Health
NIST	National Institute of Standards and Technology
NSF	National Science Foundation
NSTC	National Science and Technology Council
OMB	Office of Management and Budget
OSTP	Office of Science and Technology Policy
R&D	Research and Development

Appendix B: Legislation Quick Reference

H.R. 1715 "A Bill to amend the Public Health Service Act to Establish the National Institute of Biomedical Imaging". Introduced May 22,1997 in the 105th Congress.

S. 990 "A Bill to amend the Public Health Service Act to establish the National Institute of Biomedical Imaging". Introduced July 7,1997 in the 105th Congress.

S. 1030 "A Bill to amend the Public Health Service Act to establish a National Center for Bioengineering Research". Introduced July 17,1997 in the 105th Congress.

H.R. 4170 "A Bill to amend the Public Health Service Act to establish a National Center for Bioengineering Research'. Introduced June 25,1998 in the 105th Congress.

H.R. 1795 "A Bill to amend the Public Health Service Act to establish the National Institute of Biomedical Imaging and Engineering". Introduced May 13,1999 in the 106th Congress.

S. 1110 "A Bill to amend the Public Health Service Act to establish the National Institute of Biomedical Imaging and Engineering". Introduced May 24, 1999 in the 106th Congress.

[1] H.R. 1795. "A Bill to amend the Public Health Service Act to establish the National Institute of Biomedical Imaging and Engineering". Introduced May 13,1999 in the 106th Congress. Hereafter, this source is referred to as "H.R. 1795".

[2] S. 1110. "A Bill to amend the Public Health Service Act to establish the National Institute of Biomedical Imaging and Engineering". Introduced May 24, 1999 in the 106th Congress. Hereafter, this source is referred to as "S. 1110".

[3] Kirchhoff, Sue. "Progress or Bust: The Push to Double NIH's Budget". CQ Weekly. May 8, 1999. Hereafter, this source is referred to as "Kirchhoff".

[4] For the purposes of this study, "the nation's bioengineering enterprise" refers to the segments of academia, research institutions, and private industry which conduct activities involving bioengineering. This term also alludes to the fact that individual members of society eventually benefit from bioengineering progress through improved medical technology.

[5] The HHS's 1995 Report, Support for Bioengineering Research, divides bioengineering research into three categories: Basic, Applied, and Developmental Research. This study combines the NIH definitions for Applied and Developmental research into one category: Applied research. This approach is compatible with the most common usage of these terms.

[6] Support for Bioengineering Research. Report prepared for the NIH by the External Consultants Committee convened for this purpose. 1994. Hereafter, this source is referred to as the "1994 ECC report on Support for Bioengineering Research".

[7] Phillips, Winfred M. Past-President of the American institute for Medical and Biological Engineering (AIMBE). Testimony before the Senate Labor and Human Resources Committee, Subcommittee on public Health and Safety. July 24, 1997. Hereafter, this source is referred to as "Phillips".

[8] Guilbeau, Eric PhD. Chair, Department of Chemical, Bio, & Materials Engineering, Arizona State University. Email correspondence on July 29, 1999.

[9] Phillips.

[10] The Biotechnology Industry Organization (BIO) defines **informatics** as " the management and analysis of data using advanced computing techniques." A related term is bioinformatics- informatics applied to biological research. "Bioformatics is particularly important as an adjunct to genomics research, because of the large amount of complex data this research generates." ("Glossary" : http://www.bio.org/whatis/guide5.html)

[11] "NIH Working Definition of Bioengineering". Published by BECON. July 24,1997. Posted on the internet at http://www.nih.gov/grants/becon/becondefinition.htm

[12] The Biotechnology Industry Organization (BIO) states that **biotechnology** is often defined as "a combination of advances in our understanding of molecular and cellular biology, plant, animal and human genetics and how the human immune system fights disease". (Matthews, Megan. Ed. The 1998-99 BIO Citizens' Guide to Biotechnology. June 1998. http://www.bio.org/whatis/guidecit.html)

[13] According to BIO, "**bioremediation** is a term for a number of biologically-based processes that degrade waste materials into harmless by-products such as water, carbon dioxide and various forms of salt. It is, in effect, using the same processes that take place when lawn or garden waste is composted to be later used as a soil nutrient for future planting." (BIOREMEDIATION:A Natural Answer to Environmental Reclamation. The Biotechnology Industry Organization (BIO). http://www.bio.org/library/5biorem.html

[14] Leon, Pete. Director of Public Policy, AAES. Email correspondence on July 29,1999. Hereafter, this source is referred to as "Leon".

[15] H.R. 4170. "A Bill to amend the Public Health Service Act to establish a National Center for Bioengineering Research'. Introduced June 25,1998. Hereafter, this source is referred to as "H.R. 4170"

[16] The definition for **bioengineering** given in H.R. 4170 is very similar to that established by the NIH. The H.R. 4170 definition reads as follows:
Bioengineering is an interdisciplinary field that applies physical, chemical, and mathematical sciences and engineering principles to the study of biology, medicine, behavior, and health. It advances knowledge from the molecular to the organ systems level, and develops new and novel biologics, materials, processes, implants, devices, and informatics approaches for the prevention, diagnosis, and treatment of disease, for patient rehabilitation, and for improving health.

[17] 1994 ECC report on Support for Bioengineering Research

[18] Baldwin, Wendy. Director, Office of Extramural Research, National Institutes of Health and Human Services. Testimony before the Senate Labor and Human Resources Committee, Subcommittee on Public Health and Safety. Federal News Service. July 24, 1997. Hereafter, this source is referred to as "Baldwin".

[19] 1994 ECC report on Support for Bioengineering Research

[20] Support for Bioengineering Research. Report prepared by the HHS, Public Health Service, NIH at the direction of Congress. 1995. Hereafter, this document is to be cited as the "1995 HHS report on Support for Bioengineering Research"

[21] The External Consultants Committee consisted of the following individuals:

Robert M. Nerem Ph.D. (Chair). Parker H. Petit Chair for Engineering Medicine G.W. Woodruff School of Mechanical Engineering, Georgia Institute of Technology

Frances Arnold, Ph.D. Associate Professor Chemical Engineering, California Institute of Technology

Peter Katona, Sc.D. Vice President Biomedical Engineering Programs, The Whitaker Foundation.

William D. Young. Senior Vice President Manufacturing and Process Sciences, Genentech Inc.

Kenneth D. Taylor, Ph.D. (Vice-Chair). Vice President Research and Development Valleylab, Inc.

Shu Chien. M.D., Ph.D. Director Institute for Biomedical Engineering, University of San Diego.

Candace Littell. Executive Director Health Care Technology Institute.

Fred G. Heineken, Ph.D. (Liaison Member). Program Director Biotechnology, Bioengineering, and Environmental Systems, National Science Foundation.

[22] "Glossary of Confusing NIH Terms". Definitions established by the National Institute of Allergy and Infectious Diseases, NIH. http://www.niaid.nih.gov/ncn/gloss.htm

[23] 1994 ECC report on Support for Bioengineering Research

[24] 1995 HHS report on Support for Bioengineering Research

[25] Baldwin.

[26] Fouke, Janie. Division Director, Bioengineering and Environmental Systems, NSF. Email correspondence on July 27, 1999. Hereafter, this source is referred to as "Fouke. July 27, 1999".

[27] Phillips.

[28] S. 1030. "A Bill to amend the Public Health Service Act to establish a National Center for Bioengineering Research". Introduced July 17,1997. Hereafter, this source is referred to as "S. 1030".

[29] H.R. 4170

[30] Fouke, Janie. Division Director, Bioengineering and Environmental Systems, NSF. Meeting on June 16, 1999.

[31] H.R. 1715. "A Bill to amend the Public Health Service Act to Establish the National Institute of Biomedical Imaging". Introduced May 22,1997. Hereafter, this source is referred to by "H.R. 1715".

[32] S. 990. "A bill to amend the Public Health Service Act to establish the National Institute of Biomedical Imaging". Introduced July 7,1997 by Sen. Faircloth. Hereafter, this source is referred to as "S. 990".

[33] H.R. 1795

[34] S. 1110

[35] Burr,Richard; Eshoo, Anna. "The National Institute of Biomedical Imaging and Engineering Establishment Act of 1999"; Dear Colleague Letter. May 13,1999.

[36] Executive Order 12881 of November 23, 1993: Establishment of the National Science and Technology Council. By President William Jefferson Clinton.

[37] The NSTC was created in 1993 by an executive order from President Bill Clinton. One of five committees at the NSTC, the Committee on Science (CS) has the following charter:

> The purpose of the CS is to advise and assist the NSTC, with emphasis on those federally supported efforts that develop new knowledge in the sciences, mathematics, and engineering, whatever its application. The CS will address significant national policy matters that cut across agency boundaries and shall provide a formal mechanism for interagency science policy development, coordination, and information exchange.[37]

The CS is lead by Dr. Neal Lane, Director the National Science Foundation; Dr. Harold Varmus, Director of the National Institute of Health; and Dr. Arthur Bienenstock, Associate Director for Science, Office of Science and Technology Policy.

[38] The AAES member societies are:
American Indian Science & Engineering Society
American Institute for Medical & Biological Engineering
American Institute of Chemical Engineers
American Institute of Mining, Metallurgical & Petroleum Engineers
American Nuclear Society
American Society for Engineering Education
American Society of Agricultural Engineers
American Society of Civil Engineers
ASME International
Association for Facilities Engineering
Human Factors and Ergonomics Society
Institute of Electrical & Electronics Engineers - USA
National Institute of Ceramic Engineers (part of NACE)
Optical Society of America
Society of Fire Protection Engineers
Society of Hispanic Professional Engineers
Society of Women Engineers
SPIE - The International Society for Optical Engineering

[39] Biomedical Engineering. AAES position statement adopted April 17, 1998.

[40] Leon.

[41] Dietz, Francis. "Bio what? Medical Applications of and Legislative Proposals Affecting Bioengineering". Mechanical Engineering-CIME, No. 1, Vol. 121, Pg. 36. Jan 1, 1999. Hereafter, this source is referred to as "Dietz".

[42] Phillips.

[43] This letter is published on the internet at http://www.bmenet.org/BMEnet/societies/AIMBE/amsuprt1.html

[44] A Focus for Biomedical Engineering At the National Institutes of Health. Position statement issued by IEEE-USA. February 12, 1998.

[45] National Institutes of Health a Key to Bioengineering Advances. A policy paper produced by ASEE. http://www.asee.org/policy/html/nih.htm

[46] Kirchhoff.

[47] Yount, Ralph, President, Federation of American Societies for Experimental Biology. Testimony before the House Appropriations Labor, Health and Human Services, and Education FY99 Labor-HHS Appropriations Committees.

[48] Kirchhoff.

[49] "Congressional Biomedical Research Caucus". The Congressional Yellow Book; Spring 1999. Pg. 838.

[50] Zonarich, Matt. Email correspondence on July 29,1999.

[51] To submit a recommendation, contact Matt Zonarich – Office Manager/Scheduler to Rep. Gekas (R-PA). Tel: (202)225-4315 ; email: matt.zonarich@mail.house.gov

[52] 1994 ECC report on Support for Bioengineering Research

[53] Phillips.

[54] Dietz. Reference is to the words of Robert Nerem, a professor and director of the Petit Institute for Bioengineering and Bioscience at Georgia Institute of Technology.

[55] Baldwin.

[56] Fouke. July 27, 1999.

[57] "Glossary of Confusing NIH Terms". Definitions established by the National Institute of Allergy and Infectious Diseases, NIH. http://www.niaid.nih.gov/ncn/gloss.htm

[58] Phillips.

[59] BECON Agency Liaison Committee members:
Jeffery A. Schloss (co-chair)
Tom Aigner (co-chair)

William Heetderks
Dov Jaron
Gregory Milman
Nada Vydelingum

[60] Schloss, Jeff. Co-chair BECON Agency Liaison Committee. Email correspondence on July 27,1999.

[61] Fowler, Joanna. Researcher at Brookhaven National Laboratories. Interview on July 28, 1999.

[62] 1995 HHS report on Support for Bioengineering Research

[63] Decker, Jim. Deputy Director, Office of Science, Department of Energy. Discussion on June 8,1999.

[64] Anonymous. NASA. Discussion on June 10,1999.

[65] Kirchhoff.

[66] AAES, AIMBE, IEEE-USA, ASEE, and ASME issued position statements including critiques of the present organization of the NIH.

[67] Baldwin.

[68] Fowler.

[69] Fouke. July 27, 1999.

[70] Rampy, Stacey. Staff for Rep. Anna Eshoo (D-CA). Email correspondence on June 28, 1999.

[71] The definition for *bioengineering* given in H.R. 4170 is very similar to that established by the NIH. The H.R. 4170 definition reads as follows:
Bioengineering is an interdisciplinary field that applies physical, chemical, and mathematical sciences and engineering principles to the study of biology, medicine, behavior, and health. It advances knowledge from the molecular to the organ systems level, and develops new and novel biologics, materials, processes, implants, devices, and informatics approaches for the prevention, diagnosis, and treatment of disease, for patient rehabilitation, and for improving health.

[72] AIChE
1300 I Street N.W., Suite 1090 East Tower
Washington, DC 20005-3314
Phone: 202-962-8690
Fax: 202-962-8699
E-mail: dc@aiche.org.
http://www.aiche.org/government/index.htm

[73] The following internet site can help members contact their Members of Congress:
http://congress.nw.dc.us/aiche/

[74] To submit a recommendation, contact Matt Zonarich – Office Manager/Scheduler to Rep. Gekas (R-PA).
Tel: (202)225-4315 ; email: matt.zonarich@mail.house.gov