Medical and Biological Engineering in the Next 20 Years: The Promise and the Challenges

College of Fellows, American Institute for Medical and Biological Engineering

(Invited Paper)

***Abstract*—In 2011, the American Institute for Medical and Biological Engineering (AIMBE) (www.aimbe.org) celebrated its 20th anniversary by undertaking to identify major societal challenges to which medical and biological engineers can contribute solutions in the next 20 years. This report is a summary of the six major challenges that were identified. The report also discusses some specific areas within these high-level challenges that can form the basis for policy action, provides a brief rationale for pursuing those areas, and discusses roadblocks to progress. The six overarching challenges are: 1) engineering safe and sustainable water and food supply, 2) engineering personalized health care, 3) engineering solutions to injury and chronic diseases, 4) engineering global health through infectious disease prevention and therapy, 5) engineering sustainable bioenergy production, and 6) engineering the 21st century US economy. While arrived at independently by AIMBE, many of the elements overlap with similar challenges identified by other bodies. The similarities highlight the central mission of medical and biological engineers, working with other experts, which is to solve important problems central to human health and welfare.**

***Index Terms*—Biological engineering, biomedical engineering, engineering, medical engineering, public policy.**

I. Introduction

SINCE 1991, the American Institute for Medical and Biological Engineering (AIMBE) (www.aimbe.org) has been working to increase public understanding of the value of medical and biological engineering innovation to human health. The 20th Anniversary Annual Event in February, 2011, celebrated the accomplishments of the field and focused on societal grand challenges that could benefit greatly from research, discovery, and developments in medical and biological engineering over the next 20 years.

AIMBE Fellows consist of those who have made important contributions to the field of medical and biological engineering as well as other professionals whose work has impacted advancements in innovation, discovery, and research. Fellows are peer elected from the top two percent of these individuals in corporations, universities, national laboratories, and other government agencies, and other professional organizations. As its primary mission, the AIMBE acts in the general interest of the public regarding all aspects of medical and biological engineering and is committed to being an objective voice for the field.

This report is the culmination of a multiyear collaborative effort among AIMBE Fellows. Its intention is to highlight societal needs and opportunities for addressing them through medical and biological engineering. This report is a beginning. Many of the topics identified here are worthy of extended analysis. Over the next several years, more detailed papers on selected topics will be prepared, using the expertise of the College of Fellows of the AIMBE, as well as the other divisions of the AIMBE, its Academic Council, Industry Council, and Council of Societies, to recommend policies and actions that will lead to improved societal health and welfare. It should also be noted that other organizations have identified grand challenges for medical and biological engineering and for engineering as a whole, and the relationship of AIMBE's challenges to several others will be reviewed toward the end of this report.

Medical and biological engineering has already provided numerous advances that impact the lives of all Americans and many others around the world. The role of engineering is sometimes overlooked in the advances we have enjoyed over the last century, but improvements in sanitation, water supply, food availability, drugs, and medical devices would not have occurred without the engineering that made them realities. Many previous innovations in medical devices and imaging systems, production of pharmaceuticals, and the assurance of food safety and quality have been identified in the AIMBE Hall of Fame: http://www.aimbe.org/aimbe-programs/aimbe-hall-of-fame/. AIMBE's perspective is that further innovations in both technologies (e.g., regenerative medicine, nanotechnology, imaging, bioenergy production) and policies (e.g., manufacturing standards, regulatory procedures) will be just as important in the future. The purpose of this report is to outline some of those areas where engineering innovations will make major contributions.

AIMBE recognizes that medical and biological engineers generally do not solve societal problems single handedly, but as members of teams that include other engineers, scientists, medical professionals, corporations, trade associations, social scientists, policy makers, and patient advocacy groups. Action on the challenges will take continued and improved cooperation of academia, industry, government, and the public.

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The College of Fellows of the American Institute for Medical and Biological Engineering (AIMBE) is a distinguished body of medical and biological engineers and others who support work in this field. AIMBE is based at 1701 K Street, NW, Suite 510, Washington, D.C. 20006. (Milan Yager, Executive Director, myager@aimbe.org). This report was prepared by Robert A. Linsenmeier in his role as Chair of the College of Fellows of AIMBE during 2010–2011, culminating in the 2011 Annual Event. R.A. Linsenmeier is in the Departments of Biomedical Engineering, Neurobiology, and Ophthalmology at Northwestern University, Evanston and Chicago, IL, 60208 USA (r-linsenmeier@northwestern.edu).

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II. Method of Identifying the AIMBE Challenges

In early 2010, a group of Fellows in diverse areas was organized, and leaders were identified to identify challenges in each of several areas. These leaders, identified at the end of this report, solicited additional input from other Fellows and/or groups and a list was constructed during conference calls. Individual challenges were then grouped into the large challenges described previously with the assistance of the AIMBE Board of Directors, and all AIMBE Fellows were invited to participate in a web survey to rank the overall importance of the larger challenges. Eighty Fellows took the survey. Fellows were then asked to rate the importance of each individual challenge within those major topics on three dimensions: societal importance, economic importance, and feasibility. These were ratings and not rankings, so there was no constraint on the number of challenges that could be rated as having high importance. Here, many of the individual items were rated highly on all three dimensions.

Selected topics formed the basis of the AIMBE Annual Event in February, 2011, with speakers from academia, industry, and government. This report is the culmination of these different processes.

III. Major Challenges for Medical and Biological Engineering

AIMBE grouped the challenges under a few broader headings. The main themes, which are significant in terms of a combination of societal impact, role for medical and biological engineering, and feasibility over the next 20 years, are as follows:

1) engineering a safe and sustainable water and food supply;
2) engineering personalized health care;
3) engineering solutions to injury and chronic diseases;
4) engineering global health through infectious disease prevention and therapy;
5) engineering sustainable bioenergy production;
6) engineering the 21st century US economy.

The challenges that ranked highest were engineering food safety, engineering solutions to chronic disease, and engineering global health, with 45% or more of respondents rating each of these challenges as first or second most important. The fraction rating the others as one of the top two in importance was at most 33%, but this does not mean that they were seen as unimportant, because Fellows were forced to choose rankings and could not identify all as equally important.

The challenges identified previously are benefiting already from tremendous efforts in academia and industry, and they are so important that work is certain to extend beyond a 20-year time frame. The term "challenges" reflects the fact that major technical work lies ahead, and the methods and resources may not be fully available at the present. In addition, there may be challenges in the regulatory and policy environment. While challenging to accomplish, these are also areas of great promise within this time frame for improved health and well-being. The six major challenges are described further below, along with specific issues identified with that theme and brief explanations of their importance. Many of the individual challenges are cross cutting and could be placed under several of the larger themes, so that the major challenges are linked together with different amounts of overlap, as schematically depicted in a rough way in Fig. 1. For instance, the food and water supply are critical to global health, and personalized health can be broadly defined to go beyond use of specific drugs to touch on many aspects of wellness and disease prevention and management.

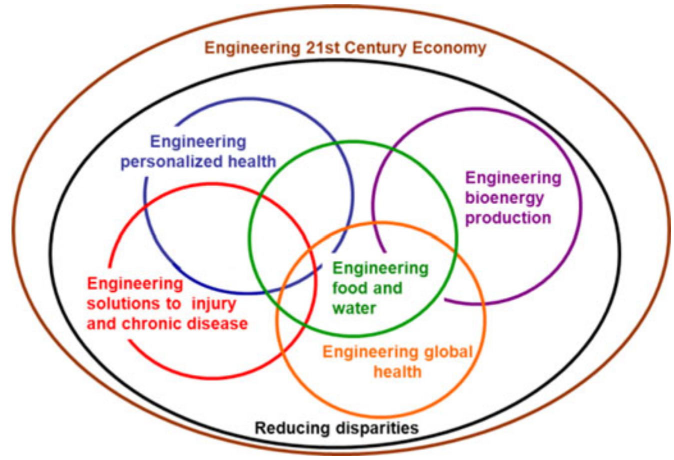

Fig. 1. Major challenges, and one view of relationships among them.

As shown in this representation, an important goal that applies across the major challenges is to reduce disparities in access to health resources for prevention, diagnosis, and treatment of injuries and diseases, and in access to food, water, and energy. Major disparities now exist across many dimensions: gender, race, ethnicity, age, and socioeconomic status, e.g., [1]–[6]. Appropriate solutions may vary for different individuals and communities. One size, both literally and figuratively, does not fit all. In addition to disparities across the demographic groups already mentioned, there are significant differences in the availability of devices and other treatments for individuals of different size and weight. Furthermore, treatments are generally not tested on all demographic groups, which lead to complications, or to the inability to use certain treatments if they have not been tested. Engineering has a role to play by ensuring that a range of solutions can be produced efficiently at moderate cost, and that these are tested on appropriate groups of individuals. Disparities should be addressed at the front end of new technologies rather than after successful implementation in certain populations.

The goal of reducing disparities in health care will also be furthered by reducing disparities in the availability of education and access to careers in medical and biological engineering. A more diverse workforce will improve decisions about design and implementation of new technologies [1], [7]. In addition, full inclusion of the talents and perspectives of different segments of our population in the workforce will ensure that we remain maximally innovative and competitive.

A. *Engineering a Safe and Sustainable Water and Food Supply*

By 2050, the United Nations estimates that there will be 9.3 billion people on an already resource-limited planet that had a population of 6.9 billion in 2010 [8]. The expanding global demand for food, feed, fuel, and fiber will threaten already stressed habitats and further accelerate biodiversity loss. Biological engineers play a critical role in sustainable agriculture production and the minimization of environmental impact. Effective use of shared resources, such as water, may lessen supply and demand issues and lead to reduced conflict. Biological engineering can play a significant role in sustaining and improving resources related to food and water. Some of the specific elements of this follow.

1) Improve Food Safety Through Engineering Innovations: Biological Engineering-driven solutions have already had significant impact on food safety and security of the food supply [9], [10]. There is, however, considerable work yet to be completed with the goal of fast, reliable, inexpensive, and accurate detection of bacteria causing illnesses in fresh as well as prepared foods. The transport of food around the world adds great complexity to achieving food safety. Biologically based and engineered sensors and anticontamination processes will reduce the loss of lives and wastage of food in both developed and developing countries.

2) Implement Improved Policies for the Management of Water, Soil, and Air, Recognizing Their Importance for Human Health: High quality water and soil, in particular, are becoming more scarce as the global population grows. Air and water pollution have both acute and chronic effects on health, and the quality of soil affects the quality of food. Over the next 20 years, ecological and natural resource engineers need to develop methods and metrics that enable these constructs to be factored into setting regulatory limits and management objectives for the physical environment of air quality, water quality, and soil quality.

3) Engineer Sustainable Food Production Systems for the Growing World Population: Currently, 845 million people in predominantly subtropical countries are chronically malnourished, and world population is increasing. Short-term yields can be increased by use of man-made fertilizers, herbicides, and pesticides, and large inputs of energy and water. However, inattention to the overall health of the soil can lead to depletion of micronutrients, with consequent loss of plant vigor and the nutritional value of food. Herbicides and pesticides can cause resistance to develop in organisms, requiring ever-larger doses with health risks to farmers, consumers, and wildlife. Energy and water both are limited resources across the globe. Biological engineers will play a critically important role in achieving large-scale sustainable agriculture production to double current yields without further taxing water, land, or energy resources.

4) Improve the Engineering of Measurement and Control Systems for Plant, Animal, and Human Quality of Life: Engineering advances in sensors, instrumentation, computing power, and fuzzy/soft system analytic tools can be brought to bear on the problem of quantifying concepts of wellness, well-being, and quality of life in ways that enable reporting, management, and control. Such concepts as wellness represent complex physical, attitudinal, and context-sensitive integration of multiple factors that are beyond our capability to measure or accurately integrate today. However, advancements in the medical, psychological, and social sciences can be combined with engineering to develop working sensor and decision support systems for the human condition. The existing state of the art in animal welfare assessment, objective setting, and measurement may enable early deployment for mammalian systems. Plant wellness measurement in controlled environments and open systems may enable much more comprehensive control strategies that incorporate climate, environment, nutrition, moisture, and other factors into integrated optimizations.

5) Implement Policies That Improve the Ability to Understand, Regulate, and Minimize Consequences of Human Impacts on Ecological Systems: Species are becoming extinct at an alarming rate [11], [12]. In many cases, it is unknown whether these species have direct importance to human activities, but once gone, the genetic resources that they represent will never be recovered. There are also unintended consequences to human ecological manipulations. For example, when Zebra mussels were inadvertently introduced to Lake Erie, they filtered the water to a clarity not seen in many years. This clarity allows blooms of algae that deplete lake oxygen and kills many fish. It is important for engineers and biologists to have the resources to study the whole ecological system to understand likely events, and then use global models to guide future public policies. Partial approaches may cause more problems than they solve.

6) Discover Concepts, Based on Analogies Among Different Levels of Biological Systems, to Guide Applications of Biology: One feature of biological engineering is the ability to consider the entire system of internal and external influences on the actions of living things. To avoid having to determine specific responses of each living thing to environmental influences, it is important for biological engineers to understand the connections (syllogism, similitude, fractal natures, or other descriptors) among various levels of living things. Information about one level should, in many cases, be generalizable to other levels as well. Making use of the similarities and connections from microbial to ecological levels will allow biological engineers to discover basic principles that can guide an engineering approach to the utilization of biology for useful purposes.

7) Improve the Framework for Research, Monitoring, and Regulation of Genetically Modified Organisms (GMOs): Genetically modified organisms (GMOs) can make agricultural products more resistant to drought, disease, and pests and can increase yields [10], [13]. The release of GMOs into the environment comes with some protections against the ability of recombinant genetic material to alter other plants, animals, and microbes. However, dispersion of the genetic material has biological, legal, and ethical consequences. Further monitoring and analysis are necessary to know whether the present safeguards are adequate to protect against possible biological disasters. There may be unintended effects of huge tracts of Roundup-Ready corn, genetically modified salmon raised in ocean facilities, or synthetic biology microbes that produce biofuels.

B. Engineering Personalized Health Care

Personalized medicine is often conceived of as matching treatments to an individual's genetic profile in order to provide better efficacy and fewer side effects. The concept of personalized health includes this important topic, but goes beyond it in many ways, for example: to provide prevention and treatment strategies relevant to specific populations, remote monitoring of individual's compliance with treatment regimens, understanding relationships between an individual's environment and his or her health, and identifying risk factors, diagnostic features, and therapies based on large databases of health records.

1) Create New Medical Diagnosis Capabilities by Utilizing a Universal Medical Image Database: A universal image database would allow all medical images worldwide to be collected and sorted by a disease state and/or pathology. A database of image data from around the world would allow for novel development of automated machine-vision-based diagnosis algorithms that would otherwise be limited to smaller samples, and allow improved detection of disease.

2) Improve Health Care by Developing and Implementing an Electronic Health Records System that Insures Privacy and Security: A standardized electronic health records system would allow better transfer of records among medical providers, fewer errors caused by inadequate information, and better monitoring of individual health. It would make the practice of evidence-based medicine more feasible by tracking the efficacy of particular treatments in individuals and particular subgroups, with consequent reductions in cost. It would also allow understanding of health trends and disease patterns. Privacy and security are critical to insure that this information is not misused.

3) Improve Medical Care by Developing Expanded Capabilities in Telemedicine: Telemedicine has enormous potential benefits. It can be used for patient monitoring and diagnosis, health care consultation, patient education, and health care professional continuing education. This will not only increase access to health care for patients in remote or underserved areas, but will also facilitate electronic consultations and help to contain the cost of health care delivery.

4) Utilize Genomic Discoveries for Disease Prevention and Treatment: High throughput technologies were (and are) essential in analyzing the genome. Now the challenge is to process large amounts of data efficiently so as to characterize and make use of genetic differences among individuals. This will allow targeting of specific genetic pathways to provide appropriate medications with improved efficacy and fewer adverse reactions. More data and better analyses will also allow characterization of subtypes of diseases that have similar symptoms but different underlying molecular bases. It may also be possible to develop therapeutics for the treatment of rare or currently untreatable diseases.

5) Improve Early Diagnosis and Treatment of Disease Through Improved Methods for Noninvasive Medical Imaging: Imaging has allowed physicians to both diagnose and treat diseases more rapidly and less invasively. In the next 20 years, the focus will be on earlier detection, improved diagnostic precision, and reduced cost in cancer and cardiovascular, neural, and gastrointestinal disease, ultimately saving lives as well as cost.

6) Develop Technology for Diagnosing and Assessing Mental Disorders: Serious mental illnesses, those impairing or limiting one or more life activities, affect approximately 5% of the population in the US, with women and individuals from 18 to 25 being disproportionately affected. The National Institute of Mental Health estimated in 2002 that the total direct and indirect costs were over $300 billion per year [14]. Diagnostic technology that is more sensitive and better able to discriminate among mental disorders such as schizophrenia, depression, and other affective disorders will lead to earlier and more informative screening of affected children and adults, more effective treatments, and more appropriate societal responses to those with mental disorders.

7) Develop Technologies to Restore Motor Function to Individuals With Spinal Cord Injury: A second set of challenges at the interface between neuroscience and medical and biological engineering is spinal cord injury. Such injuries often impair bladder and bowel control as well as control of limbs. The goal is to allow individuals with spinal cord injury to live independent, productive lives by restoring critical functions. This can significantly reduce the lifetime costs of caring for those injured in accidents and veterans of military service, who are often young when the injuries occur. The approaches will include a combination of neural engineering, regenerative medicine, and new biomaterials.

8) Prevent Traumatic Brain Injury (TBI) in at Risk Populations and Reduce the Development of Secondary Conditions and Other Adverse Outcomes: A third set of challenges at the interface between neuroscience and engineering involves TBI. TBI occurs in about 1.5 million Americans every year from a variety of causes, with car accidents leading the list, followed by falls and violence. It can lead to sudden and often irreversible changes in personality and/or functionality of any body system [15]. Military cases are often difficult to diagnose, but have been leading causes of morbidity and mortality in the US forces in Iraq and Afghanistan. Prevention, diagnosis, and treatment of the TBI require further translation of science into practice.

9) Develop New Therapies for the Growing Number of Diabetics, Including Improved Delivery of Insulin: Personalized solutions could be discussed for many different diseases. Diabetes is one that is extremely important because the American Diabetes Association estimates that more than 8% of Americans (26 million) now have diabetes [16]. Many diabetics require multiple insulin injections every day. Insulin pumps currently exist and can be used by a fraction of diabetics. The challenge is to develop and implement a permanently implantable pancreas (insulin pump and glucose sensor) featuring ten-year sensor life, a wearable pump requiring not more than a monthly insulin refill, and control strategies to prevent low blood glucose, tuned to the needs of individual patients. Improved glucose control will reduce the demands for renal dialysis and the other enormous costs of diabetic complications. Other strategies on the horizon for the treatment of diabetes are the development of tissue engineering and/or gene transfer approaches to restore pancreatic function.

10) Bridge the Domains of Public Health Informatics and Personal Health Records: Combining individual health data with public health information will allow short- and long-term correlation of health with environmental factors (air, water, and food quality) and toxins, prevention and prediction of diseases based on genetic composition, and tracking, understanding, and improved treatment of epidemics and food and water-borne illnesses.

C. Engineering Solutions to Injury and Chronic Diseases

Injuries, chronic illnesses, and degeneration during aging all reduce the quality of life for millions of people. Biomedical engineers play an important role, along with others in the medical community, in creating restorative and rehabilitation technologies to assist these people in allowing them to return to their full potential. In the short term, medical and biological engineers will continue to create medical products that are less invasive and/or integrate better with the body. Engineers are also central to the transition from "replacement medicine" to "regenerative medicine," stimulating human cells in various ways so that they can perform their own division, repair, and reprogramming. Discovering and quantifying how cells work, and using that knowledge to assist the body in repair will impact patients with cardiovascular disease and cancer, the two major causes of death in the United States [17], as well as diabetes, spinal cord injury, and neurodegenerative disease. Only a few diseases are specifically mentioned below, but the principles described in these sections, as well as those in Section III-B, will apply broadly.

1) Transition From "Replacement Medicine" to "Regenerative Medicine" by Solving Technological, Social, Regulatory, and Economic Issues: Regenerative medicine has the ability to cure rather than treat disease. It will require developments in regulatory science to aid in the creation of tools, standards, approaches and policies for the assessment of safety, efficacy, and quality of novel therapies and medical products (e.g., cell-based therapies, regenerative medicine). It will also require solving technical challenges, such as managing differentiation of cells, and solving economic and logistical challenges, such as methods to deliver these therapies [18].

2) Establish Testing Protocols that Accurately Predict Human Tissue and Blood Responses to Materials and Drugs: The time required for the transition from discovery to clinical practice for any treatment that has a materials or chemical aspect could be significantly shortened if it were possible to accurately predict interactions rather than testing them experimentally. Experimental systems simpler than the whole body are also important. For instance, creation of *in vitro* systems that employ appropriate spatial relationships among different types of cells and realistic mechanical forces can enhance testing in ways not possible with standard cell culture [19].

3) Develop Standardized Experimental Procedures in Tissue Engineering to Accelerate Technology Development: Global progress in the field of tissue engineering will be significantly accelerated if a coordinated strategy is developed and utilized to compare data and enhance methods of data sharing. This will make it easier to validate proof of principle, accelerate the capacity to fully characterize a product or material, and ultimately speed up technology development. The benefits of standardization have been recognized by virtually every industry sector, from the production of automobiles and airplanes to the fabrication of textiles. For tissue engineering, which involves scientists from a myriad of disciplines from developmental biology to bioengineering, such a need is even more pronounced. The multidisciplinary nature of the field has led to a shocking degree of fragmentation and lack of standardization in the research methodology and reporting of results in peer-reviewed journals. The adoption of early researched-focused standards in tissue engineering will enhance our understanding of the processes involved, reduce the variability of research results, and accelerate translation of research to the clinic.

4) Create Robust Stimuli-Responsive "Smart Biomaterials" and Smart Devices for In Vitro and In Vivo Applications: Materials whose properties change depending on the local environment will facilitate placement of the materials in the body, for instance by being pliant, but then expanding or stiffening once they encounter a particular pH or temperature or other stimulus [18]. With embedded sensors and microelectronics, electromechanical biomedical devices can also be responsive to their environment.

5) Shift the Concept of Biomaterials Biocompatibility From Those That Produce a Scar to Those That Contribute to Regeneration: Currently, many of the standard biomaterials are relatively inert so that they can be implanted with minimal possibility of rejection, but they are "walled off" by the body, producing scar tissue. Advanced biomaterials could promote healing and integration with the body [18].

6) Harness the Principles of Developmental Biology to Control Collective Cell Movement and Differentiation: Both adult and embryonic stem cells are promising sources for creating or repairing tissues and organs, but the ability to specifically direct their properties is not yet under control. Another promising approach is transforming adult, mature cells from one type to another, which could allow individuals to serve as their own donors, but the molecular programs needed to do this are not yet quantifiable [18].

7) Improve the Treatment of Neurodegenerative Disorders in the Aging Population: Alzheimer's disease, Parkinson's disease, and other degenerative conditions are increasing as the population ages. Twenty percent of the US population will be over 65 in 2050, and the percentage over 85 is expected to double [20]. Progress in understanding and treating these diseases can improve the quality of life for a large number of people. Management of Parkinson's and epilepsy with neurostimulation has proven to be remarkably effective in some cases, but current techniques are not suitable for everyone, and other diseases, notably Alzheimer's, remains essentially untreatable. Further neural engineering and targeted gene delivery approaches hold promise in curing these disorders.

8) Develop the Ability to Regenerate a Human Limb: Certain animals have the capability to grow a completely new limb after one is severed. Being able to understand and direct this process would not only assist those with missing limbs, but would provide a wealth of knowledge that could be used to regenerate other complex organs, such as the kidney or heart [18].

9) Improve the Treatment of Cardiac Rhythm Disorders by Creating Noninvasive Pacemakers: Cardiovascular disease continues to be the major cause of death of Americans, and an important challenge is to devise treatments for the failing heart or damaged blood vessels. One solution that would not replace current therapies, but could expand the number of individuals with cardiac rhythm disorders who could be successfully treated, is to develop and produce an external, wearable, noninvasive pacemaker that offers all current capabilities of implantable systems today (sensing and pacing). The solution would be the size of a small cell phone wearable on the belt.

D. Engineering Global Health by Preventing and Treating Infectious Diseases

There are many challenges in global health, and engineering approaches will be important in solving them. In particular, infectious diseases that are prevalent in resource poor countries require approaches different from those in the US. They must be low cost, low energy, and stable under a wide range of environmental conditions. Improved access to clean water, better food storage, and sanitation are also critical. Thus, some of the specific ideas covered earlier are critical to this challenge, but there are others not yet mentioned.

1) Improve Diagnostics and Therapeutics for Infectious Diseases in Resource-Poor Environments: Diseases such as malaria, tuberculosis, AIDS, and diarrheal diseases are still prevalent in resource-poor countries and take an enormous human toll. They require diagnostic and treatment approaches that can be delivered in areas with minimal power, refrigeration, or laboratory facilities by health care workers with modest levels of training. Development and deployment of vaccines that do not require refrigeration are a promising approach.

2) Develop and Implement Low-Cost Desalinization and Water Purification Methods: Water is a scarce resource in many parts of the world, and even where it is plentiful, human activities have often rendered it unsuitable for consumption. Increasing pressures on water resources require more utilization of seawater, development of low-cost, low-impact technologies, and better recycling of used water.

E. Engineering Sustainable Bioenergy Production

Biological organisms can capture and convert solar energy and be a component of reducing dependence on fossil fuels. Over the next 20 years, engineers competent in biology, ecology, and related fields will be sought to advance production, processing, and yields of energy from aquatic, terrestrial, and artificial environments toward theoretical limits. The challenge will be to do this sustainably and without compromising food production. Today, the solar energy conversion efficiency of photosynthesis is less than 20%, water use is excessive, and nutrient mass balance is low. As theoretical limits are defined in the near term, engineering objectives must be to discover, invent, or identify breakthroughs that lead to quantum increases in yield and efficiency. The disciplines of bioenergy and biofuels engineering today are defined by traditional engineering fields. In the future, the education and practice of engineering for the production of bioenergy feedstocks will be defined by the working environment for the plant and/or animal subjects. Thus, the specialties will revolve around soil/terrestrial substrates for crops and forestry materials, aquatic systems encompassing fresh and saline water-based production of algae, shrimp, and microbial biomass, and around controlled environments for artificial substrate-based production. Genetic, biomolecular, and systems engineering all come into play in addressing these challenges. Bioenergy on a much smaller scale may also be used in a biomedical context. For some applications, it appears to be possible to scavenge energy from sources in the body or environment in order to power medical sensors and other devices, reducing the need for traditional sources of power [21].

F. Engineering the 21st Century US Economy

Medical and biologically based industries will continue to be one of the strongest pillars of the US economy and can serve as a model for other sectors in terms of job growth. A report prepared for The Advanced Medical Technology Association (AdvaMed) showed that in 2008 the medical technology industry employed nearly 423000 workers in the U.S., and shipped \$136 billion worth of products [22]. These represented increases of 12.5 and 11.6% over just three years. These were direct financial benefits, supplemented by multipliers of 1.5 additional jobs and 90 cents per dollar of additional sales. Every state benefited from these industries. The Bureau of Labor Statistics projects 62% growth in the employment of biomedical engineers between 2010 and 2020, much above the average for engineering fields [23]. As one example, in 2008, the Seattle Post Intelligencer reported that in a six-year period, the biomedical device industry in the Puget Sound area had added 2500 high-paying jobs, an increase of more than 100%, with an estimate of 10% continued growth per year [24].

Huge biology based industries produce pharmaceuticals, food, or fuel. According to the Biotechnology Industry Organization: "Currently, there are more than 250 biotechnology health care products and vaccines available to patients, many for previously untreatable diseases. More than 13.3 million farmers around the world use agricultural biotechnology to increase yields, prevent damage from insects and pests and reduce farming's impact on the environment. And more than 50 biorefineries are being built across North America to test and refine technologies to produce biofuels and chemicals from renewable biomass, which can help reduce greenhouse gas emissions [25]." In 2006, more than 1.3 million people were employed by the biotech industry, and, as with medical devices, there was a very strong multiplier effect of these jobs through other sectors [26].

Several elements are critical to the continued success of these industries in providing jobs. Educational institutions need to continue to improve the innovative and entrepreneurial skills of the engineering workforce, government needs to sustain high levels of funding for the basic and translational research that feeds economic growth, and innovation needs to be rewarded with tax incentives.

A critical additional factor is that the regulatory environment, particularly at the Food and Drug Administration (FDA), needs to be streamlined and have the resources to adapt to new technologies and systems. The United States is often slow to adopt medical technologies even if they have been extensively validated elsewhere, and this makes innovation risky and expensive. There are many actions that could be taken. A recent article by A. v. Eschenbach, former commissioner of the FDA, and D. Hall,

NAE Grand Challenges / AIMBE Challenges	Manage the nitrogen cycle	Provide access to clean water	Advance health informatics	Engineer better medicines	Reverse-engineer the brain	Engineer the tools of scientific discovery
1) Engineering a safe and sustainable food and water supply	✓	✓				✓
2) Engineering personalized health			✓	✓	✓	✓
3) Engineering solutions to injury and chronic diseases			✓	✓	✓	✓
4) Engineering global health by preventing and treating infectious diseases		✓		✓		✓
5) Engineering sustainable bioenergy production						✓
6) Engineering the 21st century US economy	✓		✓	✓		✓

Fig. 2. Mapping of AIMBE challenges to the NAE grand challenges.

a law professor, suggested three: 1) development of alternatives to clinical trials in some cases, 2) more and better postmarket surveillance, and 3) better and earlier collaboration between industry, the FDA, and other parties [27]. Medical and biological engineering research can contribute to the first of these (see Sections III-C1–C3), and engineers are important partners for the others.

IV. Other Perspectives on Challenges for Medical and Biological Engineering

AIMBE's committee attempted to be comprehensive in identifying the challenges, but other groups of experts have also considered the problems we face in human health and welfare. There is a great deal of agreement about the important challenges, suggesting that these are areas where resources and effort should be directed. In this section, we map AIMBE's challenges to those identified by other experts.

A. Grand Challenges for Engineering—National Academy of Engineering

The National Academy of Engineering (NAE) convened a panel of experts to propose grand challenges that would occupy engineers during the 21st Century [28]. Of the 14 that were identified and reported in 2008, six are clearly related to medical and biological engineering. They are framed somewhat differently, but map well to the top-level AIMBE Challenges, as shown in Fig. 2.

B. National Institutes of Health (NIH) National Institute of Biomedical Imaging and Bioengineering (NIBIB) Vision Statement

The strategic plan of the NIBIB has identified several major goals [29].

1) Develop innovative biomedical technologies that integrate engineering with the physical and life sciences to solve complex problems and improve health.
2) Enable patient-centered health care through development of point-of-care, wireless, and personal health informatics technologies.
3) Transform advances in knowledge of cell and molecular disease mechanisms into precise medical diagnostics and therapeutics.
4) Develop medical technologies that are low cost, effective, and accessible to everyone.
5) Train the next generation of diverse and interdisciplinary scientists, bioengineers, and health care providers and promote the value of research that synergizes these disciplines.

These correspond strongly to challenges in AIMBE's categories of Engineering Solutions to Chronic Disease and Engineering Personalized Health, with the last goal reflecting one component of AIMBE's overarching challenge of promoting diversity in the workforce. The NIBIB plan also identifies strategies for accomplishing each goal, which are also closely aligned with AIMBE's specific challenges. For example, the strategies to accomplish the second goal are to

1) develop improved sensor and related information technologies for home and mobile use that will sustain wellness and facilitate coordinated management of chronic diseases;
2) advance wireless and mobile health technologies and integrate point-of-care technologies with medical information systems;
3) gather evidence-based information to inform individualized, clinical decision-making.

C. Society for Biomaterials

The Society for Biomaterials convened a panel in 2010 on challenges specific to biomaterials. The members of that panel were also Fellows of the AIMBE, but acting in a more restricted context. Several of the challenges in list presented previously arose partly from that list. Further information on those challenges can be found in [18].

D. International Federation for Medical and Biological Engineering

H. Voigt, a past President of the International Federation for Medical and Biological Engineering (IFMBE) and of AIMBE, surveyed the members of the Administrative Council of the IFMBE, a diverse group representing several countries, about what they felt were the major challenges for the field [30]. Briefly, these challenges were:

1) *Branding the Profession*: Clarifying the training of biomedical engineers and their value to industry.
2) *The Hospital of the Future:* Taking advantage of robotics and smart technologies in all aspects of medical care.
3) *The Valley of Death:* Finding mechanisms to bridge the gap between discovery and the availability of technologies to

the medical community during preclinical development and the long regulatory process.

4) *Mind/Machine Interface:* Interfacing the nervous system to prosthetics to achieve improved functionality
5) *Telepresence:* Ability to transmit personal medical information with computer technology.
6) *GMOs; Synthetic Biology; Nanotechnology:* Specific technologies that will make improved nutrition and personalized health possible.

Several of these, especially the last three, echo aspects of the AIMBE Challenges.

E. Institute of Electrical and Electronics Engineers

The most recent effort to define challenges for engineering was undertaken by the Institute of Electrical and Electronics Engineers (IEEE) at a conference in October of 2012. It defined the following five *Grand Challenges in Engineering Life Sciences and Medicine*: 1) engineering the brain and nervous system; 2) engineering the cardiovascular system; 3) engineering the diagnostics, therapeutics, and preventions of cancer; 4) translation from bench to bedside; and 5) education and training in biomedical engineering. Again the similarity of these themes to the AIMBE challenges should be noted. Like the AIMBE Challenges and others already discussed, the IEEE Challenges identified both technical and regulatory challenges that need to be overcome. A report summarizing the IEEE conference has been published in [31], and other papers in the same issue expand on some of the five challenges as well as reporting on several emerging technologies.

V. AIMBE Committee on Challenges

Chair (Chair, College of Fellows)	Robert Linsenmeier, PhD Northwestern University
Issue Team Leaders	
Medical Device Engineering	George Pantalos, PhD University of Louisville
	Walter Baxter, PhD Medtronic, Inc.
Pharmaceutical Engineering	Arthur Tipton, PhD SurModics, Inc.
Biotechnology / Genetic Engineering	Arthur Coury, PhD Genzyme Corporation (retired)
Workforce / Education Issues	Warren Grundfest, MD University of California, Los Angeles
Health Information Technology	Luis Kun, PhD National Defense University
Biological / Agricultural Engineering	Ronald E. Yoder, PhD University of Nebraska
	William Bentley, PhD University of Maryland
Business / Tech Transfer	John Watson, PhD University of California, San Diego
Regulatory Agency Policy	David Jones Philips Home Healthcare Solutions
Injury Prevention And Control	Martha Bidez, PhD BioEchoes, Inc.
Regenerative Engineering	Alan Russell, PhD Carnegie Mellon University
AIMBE Leadership	
President (2010)	Thomas Skalak, PhD University of Virginia
President (2011)	Kenneth Lutchen, PhD Boston University
President (2012)	Raphael Lee, MD, ScD University of Chicago
Executive Director (to 2012)	Jennifer Ayers

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