Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System: Interim Report

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Committee on Effectiveness of National Biosurveillance Systems: Biowatch and the Public Health System; Institute of Medicine and National Research Council

Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System

Interim Report

Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System

Board on Health Sciences Policy
Board on Chemical Sciences and Technology
Board on Life Sciences

INSTITUTE OF MEDICINE *AND*
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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

Edward H. Kaplan, Yale School of Management
Frances S. Ligler, Center for Bio/Molecular Science and Engineering, U.S. Naval Research Laboratory

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by **Georges C. Benjamin, American Public Health Association**. Appointed by the Institute of Medicine, he was responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

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INTRODUCTION

In 2001, the United States experienced the effects of bioterrorism when envelopes containing anthrax spores were sent through the postal service to several different recipients, including two U.S. senators. It is likely that several thousand people were exposed to anthrax, with antibiotic prophylaxis widely prescribed for those whose exposure was known or suspected. The consequences of this event included five deaths from inhalational anthrax and another 17 inhalational or cutaneous anthrax infections, as well as substantial economic costs and significant operational challenges in public health and health care from the federal level down to the community level (Gursky et al., 2003).

The experience with the anthrax letters combined with long-standing concerns about the threat of biological warfare to give new urgency to ongoing efforts to strengthen domestic biodefense capabilities. Overlapping the "biodefense" concept are related efforts to ensure the capacity to respond effectively to naturally occurring health threats that may arise, such as pandemic influenza or unfamiliar emerging infectious diseases. A presidential policy statement, *Biodefense for the 21st Century* (The White House, 2004), articulated four "pillars" of a national biodefense program: threat awareness, prevention and protection, surveillance and detection, and response and recovery.

Implementation of a biodefense program depends on federal, state, and local components in collaboration with hospitals and health care providers in the private sector, as well as many others. At the federal level, much of the responsibility for civilian biodefense rests with the Department of Homeland Security (DHS) and with the Department of Health and Human Services (HHS). But formal legal authority for public health actions rests with the individual states, and it is exercised at the local level across nearly 2,900 county and city health departments.

Surveillance for and detection of disease outbreaks is a traditional responsibility of public health authorities, which rely heavily on diagnosis and case reporting by health care providers and laboratories. The threat of bioterrorism has spurred interest in finding ways to detect health threats as quickly as possible so that preventive measures or treatment can be administered in time to reduce illnesses and deaths. One approach to early detection has focused on developing techniques for collecting and analyzing data streams from health care settings and other sources in an attempt to identify anomalies that might signal impending health events sooner than

standard diagnosis and case reporting. Another approach to earlier detection of health threats has been the BioWatch program, under which DHS has deployed air samplers, primarily in outdoor locations, in more than 30 major cities with the aim of early detection and characterization of aerosolized biological threats.

BioWatch air samplers were first deployed in 2003. An available technology package—the Biological Aerosol Sentry and Information System (BASIS)—was adapted to allow for rapid implementation of outdoor air monitoring for six major biological threat agents, including the organisms that cause anthrax (CRS, 2003; DHS, 2008). The current version of this technology, referred to as Generation 2.0, requires daily manual collection and testing of air filters from each monitor. Newer technologies being considered by DHS (Generation 2.5 and Generation 3.0) promise to automate the testing process within the monitoring station, which has the potential to produce results more quickly and at lower cost. The Generation 3.0 devices may also eventually have the capability to test for a greater number of threat agents. DHS plans include deploying the next generation of BioWatch monitors in indoor locations.

Questions have been raised about the BioWatch program, including the technological capabilities of BioWatch monitoring devices, operational aspects of the Generation 2.0 deployment, planning for the introduction of Generation 2.5 and Generation 3.0 (e.g., O'Toole, 2007a,b; Downes, 2008; GAO, 2008). Questions have also been raised about the relationship of BioWatch to other surveillance efforts based in the health care and public health sectors, including its contribution to the effectiveness of surveillance and response by the health sectors (e.g., O'Toole, 2007b; Price, 2008), and about the effectiveness of techniques of epidemiologic surveillance such as syndromic surveillance.

Because of such questions, the Congress, through the Subcommittee on Homeland Security of the House Appropriations Committee, directed the Office of Health Affairs (OHA) in DHS to ask the National Academies to evaluate the effectiveness of the BioWatch program, to compare the costs and benefits of the current and planned versions of BioWatch monitoring systems, to examine the costs and benefits of an enhanced national surveillance system that relies on hospitals and the public health system, and to compare the effectiveness of BioWatch to such an enhanced system.[1]

STUDY COMMITTEE AND STUDY CHARGE

To carry out this congressionally mandated study, the National Academies has convened the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System.

The committee has the following charge:

> The Institute of Medicine (IOM) and National Research Council (NRC) will evaluate the effectiveness of BioWatch, including a comparison of benefits and costs for Generations 2 and 3; the costs and benefits of an enhanced national surveillance system that relies on U.S. hospitals and the U.S. public health system will also be assessed, and its effectiveness compared to that of the current BioWatch approach. The evaluation will include examination of the reliability of BioWatch monitoring data and the ability of hospitals and public health officials

[1]Joint Explanatory Statement to Accompany Consolidated Appropriations Amendment (H.R. 2764—State, Foreign Operations, and Related Programs Appropriations Act, 2008) Division E—Department of Homeland Security, Appropriations Act, 2008 [p. 60] http://www.rules.house.gov/110/text/omni/jes/jesdive.pdf.

to respond based on information received from that system. Services under this contract will encompass the evaluation of the effectiveness of both current and enhanced biosurveillance systems to detect biological terrorism or other biothreats to human health, including (1) differing technological generations of BioWatch, (2) current human health-related surveillance systems, including those for zoonotic disease, and (3) describing necessary enhancements to hospital and public health systems based on measures of effectiveness in detecting attacks of bioterrorism or other biothreats. Measures of effectiveness will include the ability of surveillance systems to warn sufficiently to provide effective post-exposure prophylaxis and effective post-infection treatment to affected populations following a bioterrorist attack or other biothreat event.

The IOM and the NRC shall provide expert advisors that reflect expertise in relevant fields, such as biological threat assessments, biological detection systems evaluation, environmental monitoring technologies, biological assays, microbiology, virology, epidemiology, health information technology, the U.S. public health system, hospital operations, local emergency management, public health response, statistical methods, infectious disease modeling, syndromic surveillance, systems engineering, operations research, complex database management and analysis; and economic analysis. The following are specific requirements under this requirement. The IOM/NRC shall provide sufficient staff support to organize meetings, generate reports and manage the contract. The IOM/NRC will:

1. Evaluate the relative merits, and current and potential capabilities of the BioWatch monitoring system (Generation 2 and Generation 3) to detect bioterrorist attacks and other biothreats via environmental monitoring, with the aim of early warning and pre-infection prophylaxis and expedited response and recovery. The evaluation will consider both BioWatch Generation 2 and Generation 3 equipment, and the relative advantages and disadvantages of each, including their costs and benefits.
2. Describe the characteristics of an “enhanced national surveillance system” that relies on U.S. hospitals and the U.S. public health system.
3. Examine the costs, merits, and capabilities of the current and a potential “enhanced national surveillance system” to provide a basis for a rapid response to bioterrorist attacks or other biothreats, including initiation of pre-infection prophylaxis and expedited response and recovery.
4. Reach a conclusion as to whether the two systems are redundant or complementary, both in current configuration and potential "enhanced" configuration. The analysis shall include a comparison of the effectiveness of the potential “enhanced” national surveillance system with the current and planned BioWatch approach.
5. Prepare an interim report to outline the progress to date on addressing the major issues under consideration by the committee including the types of information that have been collected for assessment and any obstacles to addressing items in the task. The interim report will also provide any conclusions reached by that date.
6. Utilize the results obtained in items 1 through 4 to compile a comprehensive final report of the study. The final report shall include all findings and results concerning the effectiveness of BioWatch. The contractor shall present and brief the final report to OHA senior management prior to its public release in prepublication form and dissemination according to the regular

practices of the National Academies. The publication process for the final report will be completed following its public release.

The members of the committee bring to the study expertise in areas that include biological threat assessments, evaluation of biological detection systems, environmental monitoring technologies, biological assays, microbiology, virology, epidemiology, syndromic surveillance, health information technology, the U.S. public health sector, hospital systems, emergency medicine, laboratory operations, statistical methods, systems engineering, operations research, and economic analysis.

The committee has interpreted its task as focusing on detection of serious disease threats, especially those from bioterrorism, through means that include (a) environmental monitoring technologies used by the BioWatch program, including Generations 2.0, 2.5, and 3.0; (b) reporting from clinical settings to public health systems; and (c) syndromic surveillance systems that use various types of data (e.g., outpatient visits, pharmacy sales, absenteeism) to identify unusual patterns that may signal disease outbreaks. The committee will take into account assessments of biological threats and the implications of surveillance and detection for response to disease outbreaks and expected outcomes, but it is not attempting to evaluate threat assessments or response plans.

STUDY PROCESS

The committee is gathering information for this study through presentations at meetings, committee and staff discussions with federal officials and subject matter experts, a review of publicly available reports and peer-reviewed literature, and a review of other relevant information provided by DHS and other federal agencies.

At the time this interim report was prepared for review, the committee had held three information-gathering meetings: July 2008, September 2008, and November 2008. (See Appendix A for the agendas of information-gathering sessions open to the public.) These meetings provided an opportunity for the committee to learn about the origins and objectives of the study; the BioWatch technology currently in use (Generation 2.0) and planned for deployment within the next few years (Generation 2.5 and Generation 3.0); the analysis underlying the deployment of BioWatch monitoring units; the intersection of the BioWatch program with state and local public health departments, including public health laboratories and the Laboratory Response Network; the use of traditional and syndromic surveillance by health departments to detect disease outbreaks; tools intended to improve diagnosis of diseases of concern in emergency departments and other clinical settings; and organizational and technological challenges in communication and information sharing. Two additional committee meetings will be held.

STATUS OF THE COMMITTEE'S INVESTIGATIONS

The issues before the committee are complex and require careful consideration of many different matters. Among these are the technological characteristics and capabilities of the devices being used in the BioWatch program, the prospects for the network of deployed monitoring devices to detect an aerosolized biological agent, and the implications of current and anticipated timeliness of data from BioWatch devices for response to a disease threat and mitigation of adverse outcomes.

Also challenging is understanding the clinical context in which disease detection and reporting occurs and the factors that shape the decision-making process for the state and local public health officials who must interpret data generated by the BioWatch system as well as that from syndromic surveillance or traditional disease reporting. The issues are not only ones of understanding the health implications of the data, but also of sorting out the responsibilities, authorities, and expectations of a complicated mix of federal, state, and local participants. Failure to respond quickly in the face of a significant biological threat may have dire consequences, but initiating an unnecessary response on the basis of misleading information would have its own adverse results.

Furthermore, the committee has been asked to consider features of an "enhanced national surveillance system" that relies on hospitals and the public health system. This task demands thoughtful consideration of both the desirable and the feasible. The committee must also understand the costs associated with biosurveillance. This is likely to prove challenging for the BioWatch program, which is new and operates primarily under the aegis of a single federal department but requires planning and involvement from each of the more than 30 localities where BioWatch is deployed. For public health and health care, however, the challenge will be much greater because of the need to understand the implications of biodefense-related surveillance for systems that must meet a broad array of other health surveillance needs.

The task given to the committee touches on many subject areas and requires collection and review of a substantial body of information from not only the published peer-reviewed scientific and policy literature but also rapidly evolving policy and technical documents from federal agencies active in biodefense programs. The committee recognizes that information requests to agencies to obtain essential and up-to-date information impose additional burdens and appreciates efforts being made to respond to its requests.

The committee is in the midst of its review of information and deliberations. As a result, it does not yet have an adequate basis for presenting any findings or recommendations in this interim report. At the conclusion of its review and deliberations, the committee looks forward to providing a final report that presents constructive findings and recommendations regarding the roles of the BioWatch program and the public health and health care systems in biosurveillance and disease detection for biodefense.

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Appendix A

Agendas for Data-Gathering Sessions Open to the Public

Meeting 1

July 30–31, 2008

The Keck Center of the National Academies
500 Fifth Street, N.W.
Washington, DC

Wednesday, July 30, 2008

1:00 p.m.	Introductory remarks *Bernard Goldstein, M.D., Chair* *Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System*
	Introductions by committee members and meeting attendees
1:15	Study Context and Goals: Congressional Perspective *Representative David Price (D-N.C.)* *Chairman, Homeland Security Subcommittee of the House Appropriations Committee*
	Discussion
1:45	Study Context and Goals: Sponsor Perspective *Jeffrey Runge, M.D.* *Assistant Secretary and Chief Medical Officer* *Department of Homeland Security*
	Discussion
2:15	Introduction to the BioWatch Program and Its Technology *Robert Hooks* *Deputy Assistant Secretary for WMD and Biodefense*

Office of Health Affairs
Department of Homeland Security

Discussion

3:00 Introduction to Public Health Surveillance Activities at the Federal Level: Public Health Information Network (PHIN), BioSense, and Related Surveillance Tools
Daniel Sosin, M.D.
Coordinating Office for Terrorism Preparedness and Emergency Response
Centers for Disease Control and Prevention

Discussion

3:45 DoD Pentagon Shield
Paul Benda
Director, CBRNE Directorate
Pentagon Force Protection Agency

Discussion

4:30 Introduction to the GAO Review of Biosurveillance Across the Federal Government
William O. Jenkins, Jr.
Director, Homeland Security and Justice
U.S. Government Accountability Office (GAO)

Discussion

5:00 Adjourn Open Session

Meeting 2
September 22–24, 2008

Conference Center, Venable LLP
575 Seventh Street, N.W.
Washington, DC

Monday, September 22, 2008

4:30–5:00 p.m. Intersection of Environmental Detection and Public Health Surveillance
Michael Osterholm, Ph.D., M.P.H.
Center for Infectious Disease Research and Policy, University of Minnesota

Tuesday, September 23, 2008

9:15 a.m. Introductory remarks
Bernard Goldstein, M.D., Chair
Joseph DeSimone, Ph.D., Vice Chair

Introductions by committee members and meeting attendees

9:30–11:00 Panel: Perspectives on BioWatch Detection Events: Experience and Lessons Learned
Session Moderator: *Marci Layton*
Chevelle Glymph, M.P.H., District of Columbia Department of Health
Denise Sockwell, M.S.P.H., Virginia Department of Health
Debora Boyle, D.V.M., Ph.D., Center for Infectious Disease Research and Policy, University of Minnesota
Pamela Diaz, M.D., Centers for Disease Control and Prevention

11:00–12:30 Panel: Surveillance in Public Health and Health Care
Session Moderator: *Jim Buehler*
Atar Baer, Ph.D., Public Health, Seattle-King County, WA [by phone]
Joe Gibson, Ph.D., Marion County Health Department, IN [by phone]
Alana Deyneka, M.D., North Carolina Division of Public Health
Richard S. Hopkins, M.D., M.S.P.H., Florida Department of Health
Jerry Tokars, M.D., M.P.H., Centers for Disease Control and Prevention
David Buckeridge, M.D., Ph.D., McGill University

12:30 p.m. Working Lunch

1:30–3:00 Panel: Laboratory Roles in BioWatch and Surveillance in Public Health and Health Care
Session Moderator: *Norman Crouch*
Vickie Baselski, Ph.D., University of Tennessee
Hawazin Faruki, Dr.P.H., Laboratory Corporation of America
Mary Gilchrist, Ph.D., Massachusetts Department of Public Health
Harvey Holmes, Ph.D., Centers for Disease Control and Prevention
Sudha Pottumarthy, Ph.D., Houston Public Health Laboratory [by phone]
Mary Shaffran, M.P.A., Association of Public Health Laboratories

Meeting 3

November 3–5, 2008

The Keck Center of the National Academies
500 Fifth Street, N.W.
Washington, DC

Monday, November 3, 2008

9:20 a.m. Introductory remarks
Bernard Goldstein, Chair
Joseph DeSimone, Vice Chair

Introductions by committee members and meeting attendees

9:30 a.m. Thoughts on Biosurveillance
Tara O'Toole, M.D., M.P.H.
CEO and Director

Center for Biosecurity of the University of Pittsburgh Medical Center

10:15–12:15 Panel: Critical Information Needs for Decision Makers
Moderator: *Calvin Johnson*
James Hadler, M.D., M.P.H., New Haven, Connecticut
Jeffrey Engel, M.D., North Carolina State Epidemiologist
Herminia Palacio, M.D., M.P.H., Harris County Public Health and Environmental Services, Texas
Martin Fenstersheib, M.D., M.P.H., Santa Clara County Health Department, California [by phone]

12:15 p.m. Working Lunch

12:45–1:15 *Amy Altman, Ph.D.*
Director, Extramural Research Office
Luminex Corporation

1:15–3:00 Panel: Index Case Recognition: Current Realities/Future Opportunities
Moderator: *Art Kellermann*
Kate Heilpern, M.D., Emory University
Michael Bullard, M.D., University of Alberta, Edmonton
Art Papier, M.D., Logical Images, Inc.
Barry Rhodes, Ph.D., National Center for Public Health Informatics, CDC

3:15–5:00 Panel: Point-of-Care Diagnostics: Current Realities/Future Opportunities
Moderator: *Jerome Schultz*
Stephen Quake, D.Phil., Stanford [by phone]
Frances Ligler, D.Phil., D.Sc., Naval Research Laboratory
Gerald Kost, M.D., Ph.D., UC Davis and Lawrence Livermore National Laboratory
Amy Altman, Ph.D., Luminex Corporation

5:00 p.m. Adjourn Open Session

Tuesday, November 4, 2008

1:45–3:15 p.m. Other Operational Approaches to Environmental Monitoring for Bioterrorism

1:45 DoD Joint Program Guardian Installation Protection Program
COL Mark Malatesta
Joint Project Manager–Guardian
Joint Program Executive Office for Chemical and Biological Defense, DoD

2:30 Postal Service Biohazard Detection System
Patrick Mendonca
Senior Director, Policy and Planning
U.S. Postal Service

3:15 Adjourn Open Session

Appendix B

Biographical Sketches of Committee Members

Bernard D. Goldstein (*Chair*) is a professor in the Department of Environmental and Occupational Health at the University of Pittsburgh Graduate School of Public Health, where he previously served as dean. Before coming to Pittsburgh, he was the director of the Environmental and Occupational Health Sciences Institute, a joint program of Rutgers, The State University of New Jersey, and the University of Medicine and Dentistry of New Jersey (UMDNJ)–Robert Wood Johnson Medical School. Dr. Goldstein was assistant administrator for research and development, U.S. Environmental Protection Agency, 1983–1985. His past activities include serving as a member and chairman of the NIH Toxicology Study Section and EPA's Clear Air Scientific Advisory Committee. He is a member of the IOM, where he has co-chaired the section on Public Health, Biostatistics, and Epidemiology and is current head of the Environmental and Occupational Health and Toxicology Interest Section. He is also chair of the NRC Standing Committee on Risk Assessment Issues and Review. Dr. Goldstein is a fellow of the American Association for the Advancement of Science, American College of Physicians, American College of Preventive Medicine, and the Academy of Toxicological Sciences. He is the past recipient of the Robert A. Kehoe Award of Merit of the American College of Occupational and Environmental Medicine, the Katherine Boucot Sturgis award from the American College of Preventive Medicine, the Distinguished Service Award from the American College of Toxicology, and the Distinguished Achievement Award from the Society for Risk Analysis. He received an M.D. from New York University School of Medicine, and is board certified in internal medicine, hematology, and toxicology.

Joseph M. DeSimone (*Vice Chair*) is the Chancellor's Eminent Professor of Chemistry at the University of North Carolina at Chapel Hill and the W.R. Kenan, Jr. Professor of Chemical Engineering at North Carolina State University. He also serves as director of the National Science Foundation Science and Technology Center for Environmentally Responsible Solvents and Processes and is co-principal investigator for the Carolina Center for Cancer Nanotechnology Excellence. He is also the director of the Institute for Advanced Materials, Nanoscience, and Technology at UNC-CH. Among Dr. DeSimone's notable inventions is an environmentally friendly manufacturing process that relies on supercritical carbon dioxide for the creation of fluoropolymers, such as Teflon®. More recently, he worked with a team to design a polymer-based, fully bioabsorbable, drug-eluting stent, which helps keep a blocked blood vessel open after a balloon-angioplasty and is absorbed by the body within 18 months. Dr.

DeSimone's current interests are focused on applied fabrication technologies from the microelectronics industry to make nanocarriers for use in medicine. Dr. DeSimone holds more than 115 issued patents with more than 70 new patent applications pending, and he has published more than 240 peer-reviewed scientific articles. In 2005, Dr. DeSimone was elected into both the National Academy of Engineering and the American Academy of Arts and Sciences. DeSimone has received numerous awards and recognition, including the Lemelson-MIT Prize, Presidential Green Chemistry Challenge Award (1997), the Engineering Excellence Award by DuPont (2002), and the American Chemical Society Award for Creative Invention (2005). He is the cofounder of Liquidia Technologies, Inc., and a cofounder of BioStent which was sold to Guidant (now Abbott Vascular). He has served on the DELS Board on Chemical Sciences and Technology. Dr. DeSimone earned his B.S. in chemistry from Ursinus College and his Ph.D. in chemistry from the Virginia Polytechnic Institute and State University.

Michael S. Ascher is the Senior Medical Advisor to the California Emergency Management Agency (CALEMA) and a visiting researcher in the Department of Medicine and Epidemiology, University of California (Davis) School of Veterinary Medicine. Previously, he has been the lead for biological defense activities in the California Department of Health Services and principal investigator of the CDC grant to the state for preparedness and response. Other past positions include chief of the Viral and Rickettsial Laboratory, Division of Communicable Disease Control, at the California Department of Health Services. He also served in the U.S. Army as chief of medicine and in the Bacteriology Division at U.S. Army Medical Research Institute of Infectious Disease. In the area of biological defense, he has served on the Armed Forces Epidemiological Board and an interagency advisory panel on Biological Warfare Preparedness for the 21st Century and has consulted for the Department of Defense, Centers for Disease Control and Prevention, MITRE Corporation, the National Domestic Preparedness Office of the FBI, and others. Dr. Ascher's research interests include mechanisms of protective immunogenicity of microbial vaccines and advanced methods for diagnosis of infectious diseases. He currently serves on the National Academies Standing Committee on Biodefense at the U.S. Department of Defense. Dr. Ascher received his M.D. from Harvard Medical School.

James W. Buehler is a Research Professor in the Department of Epidemiology and a member of the Center for Public Health Preparedness and Research at the Rollins School of Public Health at Emory University. Prior to joining the Emory faculty in 2002, he served for 21 years in the U.S. Public Health Service as a medical epidemiologist at the Centers for Disease Control and Prevention (CDC), where he worked in the areas of general field epidemiology, maternal and child health, HIV/AIDS, and, for a brief period in 2001, anthrax. His work in public health surveillance—population health monitoring—has spanned analysis, development, management, application of surveillance information to programs and policies, and ethics. Dr. Buehler's applied research interests center on improving public health capacity to detect and respond to epidemics and other community health emergencies and on improving the use of epidemiology in public health systems and practice.

Karen S. Cook is the Ray Lyman Wilbur Professor of Sociology at Stanford University, chair of the Department of Sociology, and director of the Institute for Research in the Social Sciences (IRISS). She joined the faculty of the Department of Sociology in academic year 1998–1999. Before coming to Stanford she was on the faculties of the University of Washington and of Duke

University. Professor Cook was elected vice president of the American Sociological Association in 1994–1995. She also has served as vice-president of the International Institute of Sociology and as chair of Research Committee 42 (social psychology) in the International Sociological Association. In 1996, she was elected to the American Academy of Arts and Sciences, and in 1998–1999, she was a fellow at the Center for Advanced Study in the Behavioral Sciences. In 2004, she received the Cooley-Mead Award for career contributions to social psychology from the American Sociological Association. She was elected to the National Academy of Sciences in 2007. Professor Cook has a long-standing interest in social exchange, bargaining, and social justice and is currently involved in a large interdisciplinary project focusing on trust in social relations. She is a co-author of *Cooperation Without Trust?* (2005) and her edited or jointly edited books include *The Limits of Rationality* (1990), *Sociological Perspectives on Social Psychology* (1995), *Trust in Society* (2001), and *Trust and Distrust in Organizations* (2004). Currently she also serves as co-editor of the *Annual Review of Sociology*. In the past, she has served on many editorial boards and as editor of *Social Psychology Quarterly* (1988–1992). Her research has been supported by the National Science Foundation and the Russell Sage Foundation, and articles based on this work have appeared in the *American Journal of Sociology*, the *American Sociological Review*, *Social Psychology Quarterly*, and other journals in sociology. Professor Cook received her B.A., M.A., and Ph.D. from Stanford University.

Norman A. Crouch is assistant commissioner at the Minnesota Department of Health. In this position he is responsible for overseeing the department's Health Protection Bureau, which includes the Office of Emergency Preparedness and Response, as well as the Divisions of Environmental Health, Infectious Disease Epidemiology, Prevention and Control, and the Public Health Laboratory. Previously, he was director of the department's Public Health Laboratory Division. Prior to his current involvement in the practice of public health at the state level, with interest in the development of emergency response networks to detect and respond to emerging biological and chemical health threats, Dr. Crouch was on the faculty in the Department of Microbiology at the University of Iowa and the Department of Biomedical Sciences at the University of Illinois College of Medicine in Rockford, Illinois. He has served as a member of the Board of Directors and as president of the Association of Public Health Laboratories (APHL). He currently serves on several APHL committees, which includes being chairman of the APHL Emergency Preparedness and Response Committee and member of the APHL Finance Committee. In addition, he serves on the APHL subcommittee for Continuity of Operations Planning and the steering committee for Laboratory Performance Standards. He is board certified in medical and public health virology by the American Board of Medical Microbiology. Dr. Crouch received his B.S. degree in bacteriology from the University of Wisconsin–Madison, and his Ph.D. in medical microbiology also from the University of Wisconsin. He conducted post-doctoral studies at the Baylor College of Medicine in Houston, the Pennsylvania State University College of Medicine in Hershey, and the Mayo Clinic in Rochester, Minnesota.

Francis J. Doyle III holds the Duncan and Suzanne Mellichamp Chair in Process Control in the Department of Chemical Engineering at the University of California, Santa Barbara (UCSB), as well as appointments in the Electrical Engineering Department and the Biomolecular Science and Engineering Program. He is the associate director of the Institute for Collaborative Biotechnologies. Prior to his appointment at UCSB, he held faculty appointments at Purdue University and the University of Delaware, and he held visiting positions at DuPont,

Weyerhaeuser, and Stuttgart University. Dr. Doyle's research interests are in systems biology, network science, modeling and analysis of circadian rhythms, drug delivery for diabetes, model-based control, and control of particulate processes. He is currently the editor-in-chief of the *IEEE Transactions on Control Systems Technology*, and holds associate editor positions with the *Journal of Process Control*, the *SIAM Journal on Applied Dynamical Systems*, and *Interface*. In 2005, he was awarded the Computing in Chemical Engineering Award from the American Institute of Chemical Engineers for his innovative work in systems biology. He received his B.S.E. from Princeton, Certificate of Post-graduate Studies from Cambridge, and Ph.D. from California Institute of Technology, all in chemical engineering.

Seth Foldy is State Health Officer and Administrator of the Division of Public Health for the State of Wisconsin. Until recently, he served as an associate professor in the Department of Family and Community Medicine at the Medical College of Wisconsin and principal of health.e.volution consulting. He also cofounded and served as chief medical officer of the Wisconsin Health Information Exchange, which recently began supplying public health agencies with real-time hospital and clinic data. In addition, he assisted the Argonne National Laboratory Decision and Information Sciences division on emergency public health response exercises, trainings, modeling, and information fusion systems. Dr. Foldy was previously Commissioner of Health in Milwaukee, Wisconsin, and had earlier practiced and taught urban family medicine in Worcester, Massachusetts, and Cleveland, Ohio. He helped create the SURVNET, a 14-jurisdiction communicable disease surveillance network; the SARS Surveillance Network, which deployed syndromic surveillance rapidly across four states; and a regional emergency medicine internet for surveillance and clinician alerting. He led the local elimination of monkeypox at the center of its first hemispheric appearance in 2003, and participated in a joint health task force responding to the 2005 Indian Ocean tsunami. He chaired the National Association of County and City Health Officials' Information Technology Committee and served on the board of the eHealth Initiative Foundation, the Centers for Disease Control Information Council, and facilitated the formation of the Joint Public Health Informatics Taskforce. Dr. Foldy holds degrees from Stanford University, Case Western Reserve University, and the Medical College of Wisconsin, board certifications in Family and Preventive Medicine, and the Roemer Prize for Creative Local Public Health Work.

Elin A. Gursky is a fellow and principal deputy for Biodefense, National Strategies Support at ANSER. She has held various senior-level government and private sector positions. As Director of Epidemiology and Communicable Disease Control (1987–1995) for Prince Georges County, Maryland, Dr. Gursky addressed and helped reverse epidemic rates of communicable diseases, including infectious and congenital syphilis, enteric pathogens, and multidrug-resistant tuberculosis. Dr. Gursky subsequently served as deputy health commissioner for New Jersey (1995–1998), building and leading the Public Health Protection and Prevention Programs. She designed and implemented a statewide interactive electronic communication system to improve the accuracy and timeliness of disease reporting, surveillance, and response. She developed a fax-based Health Alert system for immediate dissemination of urgent infectious disease information to the medical community. She also instituted a comprehensive review and re-writing of practice standards for the state's 117 local health departments to rebuild the state's public health infrastructure. Dr. Gursky has also served as Vice President for Public Health for a

10-hospital system and as a private consultant on hospital business strategies. She received a D.Sc. from Johns Hopkins University in 1985.

Sandra Hoffmann is a fellow at Resources for the Future. Before joining Resources for the Future she served on the faculty of the University of Wisconsin–Madison LaFollette School of Public Affairs. She also practiced law with the DC office of McKenna, Conner, and Cuneo, specializing in chemical and pesticide regulatory law. Dr. Hoffmann's research focuses on the economics of health and environmental risk management, in particular, health valuation and integration of economics and health risk assessment. Her research on health valuation includes studies assessing the social cost of environmental pollution in China, assessments of the social cost of foodborne illness in the United States and a series of studies on parental decision making affecting children's risk of developmental harm from environmental neurotoxins. She has advised the EPA and the OECD on improving regulatory economic analysis related to children's environmental health. A significant body of her work has focused enhancing the usefulness of foodborne illness disease surveillance to public health decision makers. She has testified on this issue before USDA and FDA. She is co-editor with Michael Taylor of *Toward Safer Food: Perspectives on Risk and Priority Setting*, which sets out a systematic structure for designing a more science/risk-based approach to food safety regulation in the United States. Dr. Hoffmann received a Ph.D. in Agricultural and Resource Economics from the University of California, Berkeley, and a J.D. from the University of Michigan Law School.

Calvin B. Johnson is vice president and chief medical officer of the Temple University Health System in Philadelphia. Previously he was secretary of the Pennsylvania Department of Health, a position he held from 2003 to 2008. He is a board-certified pediatrician. Before his appointment at the Department of Health, Dr. Johnson was a physician in the Pediatric Emergency Department at the Temple University Children's Medical Center in Philadelphia and an assistant professor of pediatrics at the Temple University School of Medicine. In Philadelphia, he served on the board of directors of the Philadelphia Health Management Corporation. He has also served as medical director of the Division of Family Health Services in the New York City Department of Health. Dr. Johnson was a commissioned officer in the Medical Corps of the U.S. Army Reserve/National Guard, achieving the rank of major. Dr. Johnson received his undergraduate degree from Morehouse College, his M.D. from the Johns Hopkins University School of Medicine, and an M.P.H. from the Johns Hopkins University School of Hygiene and Public Health.

Paul Keim holds the Cowden Endowed Chair in Microbiology and is the Arizona Regents Professor at Northern Arizona University (NAU). He is the director of NAU's Microbial Genetics and Genomics Center. He also directs the Pathogen Genomics Division at the Translational Genomics Research Institute (TGen), a nonprofit research institute. He maintains his Laboratory Affiliate at Los Alamos National Laboratory in the Division of Biosciences. Dr. Keim's current research interests include genomic analysis of bacterial pathogens and the application of genomic technology to clinical diagnostic problems. He currently serves as principal investigator or co-principal investigator for three projects unrelated to the BioWatch program that are funded by the Homeland Security Advanced Research Projects Agency (HSARPA): (1) Microbial Forensic Signatures on the TIGR system, (2) Forensic Assays for the Analysis of *Ricinus communis*, and (3) High Resolution Forensic Assays–Phase II award. Dr.

Keim's laboratory has developed high-resolution strain-typing analysis methods for the forensic analysis of *B. anthracis*, *Y. pestis*, and *F. tularensis*. He has participated in collaborative projects with scientists from the former Soviet Union to understand the ecology and epidemiology of these pathogens. Dr. Keim has served on grant review panels for USDA and NIH; on advisory groups for the FBI, GAO, and HHS; and on three previous NRC committees. He is currently a member of the FBI's Scientific Working Group on Forensic Analysis of Chemical, Biological, Radiological and Nuclear Terrorism, the National Science Advisory Board for Biodefense, and the executive advisory committee for the Pacific Southwest Regional Center for Biodefense. He is a fellow of the American Academy of Microbiology. Dr. Keim received a B.S. in biology and chemistry from Northern Arizona University and a Ph.D. in botany from the University of Kansas. He has done post-doctoral work in genetics, genomics, and biotechnology.

Arthur L. Kellermann is professor in the Department of Emergency Medicine and associate dean for Health Policy at Emory University School of Medicine. He also holds an appointment as a professor in Department of Environmental and Occupational Health at the Rollins School of Public Health, Emory University. He has conducted landmark research on prehospital cardiac care, use of diagnostic technology in emergency departments, and health care for the poor. His papers have been published in many of the nation's leading medical journals. He is a recipient of the Hal Jayne Academic Excellence Award from the Society for Academic Emergency Medicine, the Excellence in Science award from the Injury Control and Emergency Health Services Section of the American Public Health Association and the Scholar/Teacher Award from Emory University. He was a Robert Wood Johnson Health Policy Fellow at the Institute of Medicine (IOM) for 2006–2007. Dr. Kellermann is a member of the Institute of Medicine. He has served as co-chair of the IOM Committee on the Consequences of Uninsurance and as a member of the IOM Committee on the Future of Emergency Care in the United States Health System.

Kenneth P. Kleinman is associate professor of Ambulatory Care and Prevention at Harvard Medical School and Harvard Pilgrim Health Care. Before joining the faculty of the Harvard Medical School in 2000, Dr. Kleinman was an associate research scientist at the New England Research Institutes, Watertown, Massachusetts. His research focuses on public health surveillance, particularly the statistical identification of aberrations that signal the onset of events of public health significance, and evaluating such statistical methods, including syndromic surveillance. He serves as director of the statistical core of a CDC program grant for a Center for Excellence in Public Health Informatics. He earned his B.A. in sociology and anthropology from Oberlin College, and his S.M. and Sc.D. in biostatistics from the Harvard School of Public Health.

Marcelle Layton is the assistant commissioner for the Bureau of Communicable Disease at the New York City Department of Health and Mental Hygiene. The bureau is responsible for the surveillance and control of 71 infectious diseases and conditions reportable under the New York City Health Code. Current areas of concern include antibiotic resistance; foodborne, waterborne, and tickborne diseases; hepatitis C; and biological disaster planning for the potential threats of bioterrorism and pandemic influenza. She completed an internal medicine residency at the University Health Science Center in Syracuse, New York, and an infectious disease fellowship at Yale University. In addition, Dr. Layton spent 2 years with the Centers for Disease Control and

Prevention as a fellow in the Epidemic Intelligence Service, where she was assigned to the New York City Department of Health. In the past, she has volunteered or worked with the Indian Health Service, the Alaskan Native Health Service, and clinics in northwestern Thailand and central Nepal. She has previously served on the IOM Forum on Microbial Threats. Dr. Layton received her medical degree from Duke University.

Eva K. Lee is an associate professor in the H. Milton Stewart School of Industrial and Systems Engineering at Georgia Institute of Technology, and director of the Center for Operations Research in Medicine and HealthCare. She is also a senior research professor at the Atlanta VA Medical Center. Dr. Lee earned a Ph.D. at Rice University in the Department of Computational and Applied Mathematics, and received her undergraduate degree in Mathematics from Hong Kong Baptist University, where she graduated with Highest Distinction. Dr. Lee was awarded a NSF/NATO postdoctoral fellowship on Scientific Computing, and a postdoctoral fellowship from Konrad-Zuse-Zentrum Informationstechnik Berlin in 1995 for Parallel Computation. Dr. Lee works in the area of mathematical programming and large-scale computational algorithms with a primary emphasis on medical/healthcare decision analysis and logistics operations management. She tackles challenging problems in health systems and biomedicine through systems modeling, algorithm and software design, and decision theory analysis. Specific research areas include health risk prediction, early disease prediction and diagnosis, optimal treatment strategies and drug delivery, healthcare outcome analysis and treatment prediction, public health and medical preparedness, large-scale healthcare/medical decision analysis and quality improvement. Dr. Lee's research in logistics focuses on large-scale optimization and algorithmic advances for optimal operations planning and resource allocation. She has developed decision support systems for inventory control; large-scale truck dispatching, scheduling, and transportation logistics; telecommunications; portfolio investment; and emergency treatment response and facility layout and planning.

Shane D. Mayor is a research professor in the Department of Geological and Environmental Sciences at California State University, Chico. From 2003 to 2008, he served as scientist at the Earth Observing Laboratory at the National Center for Atmospheric Research (NCAR), Boulder, Colorado. Dr. Mayor completed his Ph.D. at the University of Wisconsin–Madison in 2001 with a focus on using volume image lidar (VIL) data to improve fine-scale numerical simulations of atmospheric boundary layer turbulence. After completing his Ph.D., Dr. Mayor worked at NCAR through the Advanced Studies Program and the Atmospheric Technology Division to develop REAL—an eye-safe version of the Wisconsin VIL. Through a technology-transfer effort, commercial versions of REAL now operate for urban aerosol surveillance and at a military test range. Prior to his years at Wisconsin, Dr. Mayor worked at NASA Langley on differential absorption lidars, and at NCAR on heterodyne Doppler lidars. Dr. Mayor previously served on the NRC Committee on Testing and Evaluation of Biological Stand-off Detection Systems.

Timothy F. Moshier is senior principal scientist in the Environmental Science Center of Syracuse Research Corporation. Previously, he was staff member in the Biodefense Systems Group at the MIT Lincoln Laboratory. Other former positions were with tactical and research, development, and acquisition (RD&A) organizations for the U.S. Army. Mr. Moshier also served 6 months with the United Nations Special Commission (UNSCOM) in 1995, investigating Iraq's biological weapons program. Among his RD&A assignments, Mr. Moshier has served at U.S.

Army Dugway Proving Ground (Installation Biological Safety Officer and Operations Officer), the Joint Program Office for Biological Defense (Detection Project Officer and Manager for the Critical Reagents Program), and as the Project Manager for the Joint Biological Point Detection System. Mr. Moshier has also worked for SPARTA, Inc., as Chief, Homeland Security Division, where he was responsible for the daily operation of an organization consisting of threat and international relations specialists; chemical, biological, and nuclear defense experts, and a group of explosive ordnance disposal experts. He has served on three NRC committees: Biodefense at the U.S. Department of Defense, Testing and Evaluation of Biological Standoff Detection Systems, and Committee on Review of Testing and Evaluation Methodology for Biological Point Detectors. He received a B.A. in biology from the State University of New York College at Oswego, an M.S. in biology from Syracuse University, and a Masters in Military Art and Science from the U.S. Army Command and General Staff College.

Frederick A. Murphy is professor, Department of Pathology, University of Texas Medical Branch (UTMB) at Galveston. At UTMB he is also a member of the Institute for Human Infections and Immunity, the Galveston National Laboratory, the Center for Biodefense and Emerging Diseases, and the McLaughlin Endowment Program. Previously, he served as dean and distinguished professor, School of Veterinary Medicine, and distinguished professor, Department of Internal Medicine, School of Medicine, University of California, Davis. Dr. Murphy received a B.S. and D.V.M. from Cornell University and a Ph.D. from the University of California, Davis. He served as chief, Viral Pathology Branch, then director of the Division of Viral and Rickettsial Diseases, and later director of the National Center for Infectious Diseases of the Centers for Disease Control and Prevention. His honors include elected membership in the Institute of Medicine, the Presidential Rank Award from the U.S. government, membership in the German Academy of Natural Sciences and the USSR Academy of Medical Sciences. Recently he has served as a member of the U.S. Department of Health and Human Services Secretary's Council on Public Health Preparedness. Currently he serves on the NRC/IOM Committee on Biodefense at the U.S. Department of Defense. He also has been co-chair of the NRC Committee on Occupational Health and Safety in the Care and Use of Nonhuman Primates, and a member of the IOM Committee on Microbial Threats; the NRC Committee on Public Health, Agriculture, Basic Research, Counter-terrorism and Non-proliferation Activities in Russia; and the IOM Committee on Transmissible Spongiform Encephalopathies.

Royce W. Murray is Kenan Professor of Chemistry at the University of North Carolina at Chapel Hill (UNC-CH). He was educated at Birmingham Southern College (B.S., 1957) and Northwestern University (Ph.D., analytical chemistry, 1960), joined the University of North Carolina faculty in 1960 and became Kenan Professor of Chemistry in 1980. He served as Chemistry Department chairman 1980–1985. Dr. Murray has been colleague to nearly 150 graduate and post-graduate students, with whom he has published over 425 papers. Among his many awards are the Olin Palladium Medal (The Electrochemical Society), the Charles N. Reilley Award (Society for Electroanalytical Chemistry), the Faraday Medal (Royal Society of Chemistry, UK), Breyer Medal (Royal Australian Chemical Institute), American Chemical Society Award in Analytical Chemistry, the North Carolina Award in Science, the Pittsburgh Analytical Chemistry Award, and the Luigi Galvani Medal of the Italian Chemical Society. He is an elected member of the National Academy of Sciences and of the American Academy of Arts and Sciences. He has served since 1991 as editor-in-chief of the journal *Analytical Chemistry*.

Dr. Murray's research interests include electroanalytical methods, the molecular design of electrode surfaces and nanoparticles, electrochemically reactive semi-solid media, mass transport and electron transfer dynamics, electrocatalysis, and voltammetry in extreme media.

Douglas K. Owens is a general internist; a senior investigator at the VA Palo Alto Health Care System; a professor of medicine and, by courtesy, of health research and policy at the Stanford School of Medicine; and a core faculty member at the Center for Health Policy/Primary Care and Outcomes Research (CHP/PCOR). He directs the Stanford–UCSF Evidence-based Practice Center; the Program on Clinical Decision Making and Guideline Development at PCOR; the Palo Alto VA's Postdoctoral Informatics Fellowship Program; and the Palo Alto VA's Health Services Research Fellowship Program. Owens' research focuses on technology assessment, cost-effectiveness analysis, evidence synthesis, biodefense, and methods for clinical decision making. Dr. Owens received a B.S. and an M.S. from Stanford University and an M.D. from the University of California, San Francisco. Dr. Owens is chair of the Clinical Efficacy Assessment Subcommittee of the American College of Physicians. He is past-president of the Society for Medical Decision Making, and was elected to the American Society for Clinical Investigation, and the Association of American Physicians. He received the Under Secretary's Award for Outstanding Achievement in Health Services Research from the Department of Veterans Affairs.

Stephen M. Pollock is Herrick Emeritus Professor of Manufacturing and Professor Emeritus of Industrial and Operations Engineering at the University of Michigan. He has been involved in applying operations research and decision analysis methods to understand and influence a variety of operational phenomena, including military search and detection, criminal recidivism, manufacturing process monitoring, sequential allocation of resources, predictive and proactive maintenance, networks of queues, the stochastic behavior of infectious disease epidemics, and the optimization of radiation oncology plans. He has authored over 60 technical papers, co-edited two books, and has served as a consultant to over 30 industrial, governmental and service organizations. Professor Pollock was associate editor and area editor of *Operations Research*, senior editor of *IIE Transactions*, associate editor of *Management Science*, and on the editorial boards of other journals. He has served on various advisory boards for the National Science Foundation and on the Army Science Board. He was president of the Operations Research Society of America in 1986 and awarded the 2001 INFORMS Kimball Medal for contributions to operations research and the management sciences. He a fellow of INFORMS and the AAAS and is a member of the National Academy of Engineering. He was a member of the NRC's Committee on Applied and Theoretical Statistics. Among other NRC activities, he chaired the CNSTAT panel on Operational Test Design and Evaluation of the Interim Armored Vehicle, served on the panel on Statistical Methods for Testing and Evaluating Defense Systems, the Committee on Technologies to Deter Currency Counterfeiting, and the Panel on Methodological Improvements to the DHS Biological Agent Risk Analysis.

I. Gary Resnick is the Bioscience Division Leader at Los Alamos National Laboratory. He is an internationally recognized scientist in the area of chemical and biological defense, with extensive leadership and management experience. His scientific and technical accomplishment encompasses all aspects of research, development, and testing of chemical warfare agents and chemical/biological defense systems. In addition, he has been an active member of the interagency and international chemical and biological arms control communities. His previous

positions include: Associate Center Director for Chemical and Biological (CB) Defense, Center for Homeland Security at Los Alamos National Laboratory; Director of CB Defense, Defense Threat Reduction Agency; Director of Research and Technology, Edgewood Chemical and Biological Center; Technical Director, U.S. Army Dugway Proving Ground; and staff scientist at the U.S. Environmental Protection Agency. He holds a B.S. from Cornell University, an M.S. from Long Island University, and a Ph.D. in microbiology from the University of Rhode Island.

R. Paul Schaudies is president and CEO of GenArraytion, a company that is developing products and services for rapid diagnosis of infectious disease agents, including those underlying sepsis and hospital-acquired infections. Previously, he founded and managed the Biological and Chemical Defense Division at Science Applications International Corporation (SAIC). His expertise is in biotechnology and nanotechnology. Dr. Schaudies spent 4 years with the Defense Intelligence Agency as collections manager for biological and chemical defense technologies. As such, he initiated numerous intra-agency collaborations that resulted in accelerated product development in the area of biological warfare agent detection and identification. He has served on advisory panels for the Defense Intelligence Agency, the Defense Advanced Research Projects Agency, and the Department of Energy. He has bench research experience managing laboratories at Walter Reed, Walter Reed Army Institute of Research, and as a visiting scientist at the National Cancer Institute. Dr. Schaudies was the science advisor to the EPA on-scene coordinator and incident commander at the anthrax incident in Washington, DC. He received a B.S. in chemistry from Wake Forest University and a Ph.D. from Temple University School of Medicine in the department of biochemistry. Dr. Schaudies is currently a member of the NRC/IOM Committee on Biodefense Analysis and Countermeasures and has served on the NRC Committee on Protecting Occupants of DOD Buildings from Chemical or Biological Release and the NRC Committee on Materials and Manufacturing Processes for Advanced Sensors.

Jerome S. Schultz is on the faculty at the University of California, Riverside, where he is Distinguished Professor in the Bourns College of Engineering, chair of the Bioengineering Department, and director of the Center for Bioengineering Research. He founded the Department of Bioengineering when he joined the UC Riverside faculty in 2004. Dr. Schultz began his career in the pharmaceutical industry (Lederle Laboratories) and then joined the University of Michigan, where he was chairman of the Department of Chemical Engineering. He spent 2 years at the National Science Foundation as deputy director of the Engineering Centers Program. In 1987, he joined the University of Pittsburgh as director of the Center for Biotechnology and Bioengineering, and was the Founding Chairman of the Department of Bioengineering. He recently spent a year at NASA's Ames Research Center as a senior scientist in their Fundamental Biology Program. He is a member of the National Academy of Engineering, a Fellow of the Biomedical Engineering Society, and was a founding Fellow and President of the American Institute for Medical and Biological Engineering. Dr. Schultz received his B.S. and M.S in Chemical Engineering from Columbia University, and his Ph.D. in Biochemistry from the University of Wisconsin.