National Institute of Allergy and Infectious Diseases
2004 Summit on the State of Anti-Infective Development

August 16-17, 2004
Bethesda, Maryland

Meeting Summary

This report is dedicated to the memory of
John R. La Montagne, Ph.D., 1943 - 2004
NIAID Deputy Director

National Institute of Allergy and Infectious Diseases
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Introduction

The National Institute of Allergy and Infectious Diseases (NIAID) sponsored the 2004 Summit on the State of Anti-Infective Development to gain a better understanding of the current state of anti-infective development, identify potential roles for NIAID, and optimize future opportunities for the Institute to contribute to the development process. The 2004 conference built on the Summit on the Development of Infectious Disease Therapeutics, which was held in September 2000. This report presents highlights of the 2004 summit and summarizes recommendations for NIAID and other organizations.

Speakers and summit participants included representatives from pharmaceutical companies, biotechnology companies, academia, public-private partnerships (PPPs), NIAID, the World Health Organization (WHO), Infectious Diseases Society of America (IDSA), Centers for Disease Control and Prevention (CDC), U.S. Food and Drug Administration (FDA), Department of Defense (DOD), Department of Health and Human Services (DHHS), and the NIH Office of Technology Transfer. The agenda is provided in the appendix.

Presentation and panel discussion topics included: demand and supply of anti-infectives; perspectives on scientific and strategic opportunities, challenges, barriers and risks to anti-infective discovery and development; regulatory issues; and the potential role for NIAID in addressing the problem of anti-infective development. NIAID Director Dr. Anthony S. Fauci provided brief introductory remarks in which he emphasized the dynamic nature of the field of infectious disease, and the need for unique partnerships to address ongoing microbial threats.

Demand and Supply

Session speakers presented background information on several overarching issues affecting the demand and supply of anti-infectives, including the need for new medicines in the United States; the need for new medicines for neglected diseases; and issues impeding the discovery, development, and commercialization of new antimicrobials.

The Need for New Medicines in the U.S.

Dr. John Bartlett, representing the Infectious Diseases Society of America (IDSA), briefly summarized the recent IDSA report, Bad Bugs, No Drugs, As Antibiotic Discovery Stagnates…A Public Health Crisis Brews (www.idsociety.org/pa/IDSA_Paper4_final_web.pdf). The report, which was prepared by the IDSA Taskforce on Antimicrobial Availability, outlines the problems of antimicrobial resistance in the United States and the lack of new antibiotics in the pipeline to treat resistant infections. Dr. Bartlett noted that since the 1980's there has been a significant increase in the rates of antimicrobial resistance that are of public health concern. Resistant bacteria are found not only in the nosocomial situation, but also in the community, with the types of resistant organisms continually evolving.

The Need for New Medicines for Neglected Diseases

Dr. Janis Lazdins-Helds of the World Health Organization described the '10/90 gap' -- the fact that approximately 10 percent of annual funding for health research is spent on health problems that account for 90 percent of the global disease burden. The gap was first highlighted in 1990 by the Commission on Health Research for Development. Since then, the NIH budget has doubled and the balance in how health research funds are spent has improved. The case remains, however, that only a fraction of new chemical entities registered by western health authorities are specifically indicated for tropical diseases. Underserved diseases that affect large numbers of individuals worldwide include lower respiratory tract infections, which should be preventable; high disability diseases, such as filariasis and nematode infections; and those diseases causing long term, major organ system consequences such as Chagas' disease (cardiovascular) and schistosomiasis (liver).

Dr. Lazdins-Helds also noted that the recent entry of new research partners (such as the Gates Foundation and The Global Fund to Fight AIDS, Tuberculosis and Malaria) into this environment has made the situation both more promising and more complex. These entities now play a role in enhancing research activities, delivering products and services, and developing targeted initiatives such as the International AIDS Vaccine Initiative (www.iavi.org), Medicines for Malaria Venture (www.mmv.org), and Drugs for Neglected Diseases Initiative (www.dndi.org).

Issues Impeding the Discovery, Development and Commercialization of New Antibacterials

Dr. Martin Rosenberg, who has extensive experience working with and advising both large pharmaceutical companies and biotechnology companies and serves as a consultant to NIAID on drug development issues, addressed corporate issues that impact decisions about pursuing anti-infective development. Dr. Rosenberg emphasized the following points that provide disincentives for companies to invest in new antibacterials:

- corporate resources are allocated to areas providing the best commercial opportunities, which recently has not included development of antibiotics;
- most bacterial infections can be effectively controlled using current antibiotics;
- laboratory detected susceptibility to the antimicrobial does not necessarily equate with the ability of a drug to be effective clinically;
- new products are often not that different from current antibiotics in both clinical and commercial experience;
- there has been a poor success rate in developing novel broad spectrum antibiotics;
- narrow spectrum agents do not provide sufficient return on investment;
- regulatory hurdles, including restricted labeling and the number of trials required to cover multiple indications; and
- the need for large, expensive safety studies prior to approval by FDA as well as the clinical trial requirements needed to demonstrate non-inferiority.

Scientific and Strategic Opportunities and Challenges

Speakers in this session, representing pharmaceutical companies, biotechnology companies, and public-private partnerships, provided their perspectives on the current state of anti-infective development, perceived markets, barriers to success, and future directions and opportunities. (See appendix for a list of speakers.)

Part I: Perspectives from Large Pharmaceutical Companies

Unmet Expectations for Developing New Antibiotics. Early antibiotics were discovered serendipitously and were natural products. Initial genomic approaches to developing new antibiotics showed great promise for target identification. There was anticipation that genomic sequencing would help fill the pipeline, as well as expectations for unprecedented rates of identification, selection and validation of novel potential targets. Genomics showed promise for unparalleled understanding of the infection process, and rapid screening technologies. To date, however, results have fallen short of expectations and no major new classes of antibiotic drugs have been identified in more than 20 years. Participants reflected on the possible reasons for this that are summarized in the following sections.

Economic Issues Affecting Industry Decisions. Return on investment is a key element driving the extent of industry involvement in the development of new anti-infectives. Within any corporate structure, there are limited funds and thus, decisions to move toward a particular product result in lost opportunities in other therapeutic areas. Lack of clarity with respect to medical need, technical feasibility, and commercial attractiveness can prevent a company from making a commitment to go forward. Other disincentives for developing new antibiotics include success in achieving incremental advances in existing classes of drugs, difficulty in achieving both clinical and commercial differentiation with new products when evaluated for equivalence; the dearth of resistant organisms in clinical trials; and the fact that microbial resistance *in vitro* does not necessarily equate to failure of the drug to be effective clinically.

Overall, the development of antibacterials has become riskier, longer, more expensive and less profitable resulting in few products in the pipeline. The search for 'blockbuster drugs' during the last decade has been largely unsuccessful as new broad-spectrum, mass-market antibiotics have not been found. Chronic suppressive therapies such as antivirals and antifungals are valued higher than acute, curative therapies. Furthermore, it has not been possible to make niche markets lucrative by targeting problem organisms. Unlike other areas of drug development, societal concerns for resistance lead to restrictions in use of new drugs. Other economic disincentives include many competitors in the market, public cost containment in industrialized countries, short courses of treatment, and the fact that resistance is not yet perceived as rampant or unmanageable.

Scientific Barriers and Other Impediments. There are also scientific barriers at both the discovery and developmental stages for new antibiotics. While genomic-based discovery continues to provide potential targets, the lack of quality lead compounds hinders further progress. Identification of targets is relatively easy -- the challenge is to identify key genes that are amenable to attack by antimicrobials. From 100 new targets, only 4-5 leads are typically developed. While the reasons for this low hit-rate are not understood, it has discouraged industry from committing resources to this area.

Clinical trials and regulatory issues also act as barriers to the development of new anti-infectives. Conducting clinical trials of adequate statistical power is complicated because of limited patient populations and resistant organisms. In addition, some industry representatives perceive the FDA to have a low tolerance for risk. For example, very large safety studies are needed by the FDA prior to approval,

rather than post approval. Industry representatives also expressed concern about restricted labelling, clinical trial requirements for demonstrating non-inferiority, the number of trials required to cover multiple indications, and additional requirements for combination therapies despite the fact that additive empiric therapy is commonly practiced in hospital and outpatient settings.

Despite these impediments, participants described a number of reasons to continue the search for new antibiotics. These include unmet medical needs; advances in technology (preclinical toxicology filters are more advanced and predictive, high-throughput screening and genome-based technologies have matured); and more sophisticated, modular synthetic chemistry. Moreover, anti-infectives have a higher success rate *in vivo* than *in vitro*. About one-third of anti-infectives that enter clinical trials make it to the market, in contrast to the industry standard of approximately 20 percent. The reasons for this higher success rate may be that safety issues are well-defined for many anti-infective drug classes, and that pharmacokinetic and/or pharmacodynamic models that are well-established and predictive for optimal efficacy, provide guidance for appropriate dose selection.

Part II: Perspectives from Public-Private Partnerships and Biotechnology Companies

Perspective from Public Private Partnerships. Public-private partnerships for health can be defined as arrangements that innovatively combine skills and resources from institutions in the public and private sectors to address persistent global health problems. Representatives from two successful PPPs, Medicines for Malaria Venture (MMV) and Global Alliance for TB Drug Development (GATB), summarized their goals and activities and provided examples of how PPPs can help advance drug development. (See appendix for a list of speakers.)

MMV is a non-profit foundation created to discover, develop and deliver new, affordable antimalarial drugs through effective public-private partnerships. MMV's main objective is to bring public and private sector partners together to fund and provide managerial and logistical support for discovering and developing new medicines to treat and prevent malaria. These medicines should be affordable and appropriate for use by target populations in developing countries. Using public and philanthropic funds, MMV manages a portfolio of drug development and discovery projects that are conducted by academic and pharmaceutical partners. MMV's portfolio management provides value by lowering risks and creating knowledge and cost efficiency across projects. The pharmaceutical companies provide chemistry, toxicology, management and technology. In return, MMV gets intellectual property rights in endemic areas (countries), drug supplies, and a return on sales in non-endemic areas; industry gets rights in non-endemic areas (countries), as well as public and human relations benefits.

The Global Alliance for TB Drug Development is a not-for-profit enterprise established to accelerate the discovery and development of faster-acting and affordable drugs to fight tuberculosis. GATB is building a portfolio of drug candidates by acquiring, in-licensing or co-developing promising compounds. The GATB portfolio contains a number of drugs at various stages of development from lead identification through lead optimization to preclinical and clinical studies. The development of these drug candidates is outsourced to public and private partners who receive funding and expert scientific and management guidance from GATB. GATB has also made investments in platforms, such as a database of TB compounds, and related technologies, murine models, and clinical trials capacity development. GATB designs innovative agreements to leverage intellectual property and ensure the affordability of developed drugs, especially in poorer, high-endemic countries. Other mechanisms used by GATB include upfront fees, royalty sharing, grant-back options, and manufacturing rights. Using many of these mechanisms, GATB is developing the anti-TB compound, PA-824. The technology for PA-824 was developed by Pathogenesis, Inc. and was acquired by Chiron when they bought Pathogenesis.

Perspective from Biotechnology Companies. Representatives of several biotechnology companies (see appendix for list of speakers) described factors influencing their ability to become involved in developing anti-infectives. First, the biotechnology industry perceives itself as willing to take more risks than are large pharmaceutical companies. Biotechnology companies also have a lower threshold for return on investment than do large pharmaceutical companies, and can focus on smaller niche markets. However, the biotechnology industry generally has limited funding, which decreases the magnitude of the resources they can devote to discovery. Additionally, there are limited resources available within the biotechnology industry for large programs or Phase III trials, and biotechnology companies cannot usually field the large, primary-care sales forces that are common for large pharmaceutical companies.

Participants explained that there are biotechnology companies that view niche products as a cost-effective strategy to employ focused, targeted, drug discovery. For small companies, these drugs present opportunities for in-licensing. Markets of $200 - $500 million are attractive, mainly because large pharmaceutical companies do not allocate discovery and pre-clinical development efforts in this area. Fully integrated data management systems allow for full tracking of samples from gene to crystal with integration of chemistry, biology and structural data. This allows for improved decision making during lead optimization with smaller, focused discovery teams in shorter time.

Case Studies

The objective of this session was to use multiple examples to illustrate corporate decision-making processes that weigh risks, available resources, commercial feasibility, and scientific opportunities to determine whether to proceed with developing particular anti-infectives.

Antivirals. In the first example, Dr. Amy Patick from Pfizer, Inc. described the collaborative efforts of Pfizer, NIAID and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) to ascertain whether antivirals developed for human rhinoviruses would be active against SARS. Successful progress in these efforts was impeded by limitations in corporate resources and the inability to capitalize on the iterative nature of the structure-activity relationship.

Dr. Mitch Hitchcock from Gilead discussed the discovery challenges, financial rationale, and marketing strategies of developing an influenza antiviral. He highlighted multiple commercial issues for a common clinical indication such as influenza. In spite of clear perceptions of a potential market with an unmet medical need, influenza offers several marketing challenges: 1) a short season with considerable year to year variability; 2) potentially large numbers of prescribers that will increase marketing costs; 3) uncertainty regarding drug usage versus vaccination; and 4) a needed paradigm shift by organized medicine to use influenza antivirals.

Antibacterials. In the second set of case studies, Dr. Francis Tally of Cubist Pharmaceuticals described the development of a first-in-class antibacterial (Daptomycin IV). The company in-licensed the drug from a large pharmaceutical company. The regulatory process (IND and NDA) proceeded rapidly. For some indications, it has been difficult and very costly to set up or complete the required trials. However, Cubist received licensure for a single indication, the profits from which could support development of this drug for other indications. In another example, Dr. Steve Projan of Wyeth presented animal data on an antibacterial candidate with an excellent profile against resistant pathogens that was nevertheless shelved due to concerns about toxicity.

Antifungals. Dr. Donald Buell from Fujisawa HealthCare, Inc. outlined the challenges in the development of an antifungal agent for use in neonatal candidiasis. The challenges include an extremely medically fragile patient population; a relatively rare disease requiring the need for multiple centers for rapid enrollment; off-label use of several antifungal agents despite lack of comparative, controlled data to support informed decisions; and lack of data on the incidence and nature of toxicity for the standard of care, Amphotericin B. Despite these challenges, the medical need for treatment options in a disease of high morbidity and mortality, the opportunity to validate a newer class of antifungal agent with favorable safety profile, and the opportunity to gather new data on the current, but older standard of treatment make this a good example of a case with potential for public health benefit.

Antiparasitics. In the last case study, the development of a new antimalarial drug was described by Dr. Brian Wynne of GlaxoSmithKline. This drug was discovered at the Walter Reed Army Institute of Research and is being developed under an NIAID cooperative agreement/challenge grant. The difficulties of bringing a drug to market for use in the developing world against a vector-borne disease were discussed. These include the inability to control the vector, the unpredictability of weather/seasons in potential trial sites, and the ethics of developing and testing drugs in countries that may ultimately not be able to afford them.

Intellectual Property (IP) Issues

In response to comments from company representatives regarding the government's role and procedures with respect to intellectual property arising under federally funded research and development contracts and grants, several issues were clarified through presentations and discussions during the meeting. These included the Bayh-Dole Act, which is codified at 35 U.S.C. Chapter 18 §§ 200-212 (1980), the government use license and the government's march-in rights under the Bayh-Dole Act, and the authorization and consent clause in government contracts.

Regulatory Issues

Dr. Janet Woodcock, Director, Center for Drug Evaluation and Research, FDA, spoke about the FDA's Critical Path Initiative (www.fda.gov/cdrh/ocd/criticalpath.html). This initiative calls for collaboration between government, research institutions and manufacturers to modernize the medical product development process and make it more predictable and less costly. The focus of the critical path is to update the evaluative tools currently used to assess safety and efficacy of new medical products. Examples of evaluative tools include the use of Bayseian statistics, validation of biomarkers for use in clinical trial patient selection and/or as surrogate endpoints, use of computer simulation to predict device failures, and improved post-market reporting of implanted device adverse events to assist in developing more focused premarket trials. One unique aspect of anti-infective development is that safety assessment is generally more generic than for other types of therapeutics, because anti-infectives are directed at the pathogen and not the human host. In addition, increased use of preclinical, pharmacokinetic, and pharmacodynamic information, novel clinical trial designs, use of surrogate endpoints, extrapolation of efficacy evidence, and better diagnostics could positively affect future development of antimicrobials.

NIAID Activities Past and Present

In providing an overview of NIAID's activities in anti-infective development, Dr. Carole Heilman, Director of NIAID's Division of Microbiology and Infectious Diseases, stressed that the Institute's role in product development has traditionally focused on providing critical data to support decision making about issues of great public health importance. NIAID has also undertaken risky research in areas in which the government is uniquely positioned to move products forward. NIAID's efforts are guided by a complex priority-setting process, which can include input from multiple sources at multiple stages. The development of specific initiatives can be guided by program reviews, blue ribbon panels, patient advocacy groups, advisory subcommittees, and focus groups, as well as by the NIAID Advisory Council.

A recent example of NIAID's targeted support of drug development is the Innovative Approaches for Combating Antimicrobial Resistance initiative. NIAID has also developed new mechanisms for collaborating with industry, such as Challenge Grants and Partnerships for development of biodefense products. The number of NIAID grant awards to industry has increased from 160 in FY1999 to an estimated 325 in FY2004.

NIAID has provided long-standing support for a number of drug development resources. For most pathogens, there are resources for target identification and validation, and for assay development. For selected pathogens such as TB, hepatitis B and C, and NIAID Priority Pathogens, there are additional resources for acquiring compounds, conducting screening, performing *in vitro* and *in vivo* assays, evaluating animal efficacy and preliminary drug exposure studies, and performing safety testing and pharmacokinetic/pharmacodynamic analyses.

Potential Roles for NIAID and Models to Optimize NIAID's Contribution

Two panels consisting of a cross-section of summit participants were convened to examine potential roles for NIAID in the process of anti-infective development and to determine how NIAID activities can be focused to be most effective. (See appendix for a list of panel participants.) Questions addressed included how the Institute might set priorities for using limited resources; how the Institute should interact with industry at various stages of anti-infective development; how to maximize contributions of academic researchers, and whether to pursue compounds that have been abandoned for economic or technical reasons. The recommendations of the panels as well as those made during the meeting are included below.

Summit Wrap-Up and Closing Remarks

Dr. John LaMontagne, Deputy Director of NIAID, closed the meeting with an indication of NIAID's long-standing commitment to developing anti-infectives and the Institute's continuing involvement and support for this area. He highlighted the importance of understanding the underlying mechanisms of resistance and the need for basic investigations into crucial areas such as microbial membrane biophysics. He also emphasized that the Institute would continue to promote and facilitate interactions among industry, academia, public-private partnerships, and government to advance product development. He reiterated NIAID's commitment to maintain and even increase support for all phases of product development, and use targeted initiatives to focus efforts on areas of highest priority for public health.

Recommendations for NIAID

Basic Research

- Continue strong support of basic research including focused emphasis on mechanisms of antimicrobial resistance and microbial membrane biophysics.
- Continue support for basic discovery research including target identification and development of assays and diagnostic tools for more rapid, earlier detection of antimicrobial resistance.
- Expand support for preclinical toxicology (e.g., in vitro toxicology; animal toxicology) and drug metabolism studies.
- Continue strong support of genomics research including proteomics capabilities and protein structure analysis.
- Support the involvement of medicinal chemists and molecular biophysicists in research on anti-infectives.

Translational Research

- For NIAID's investment in product development to be fully realized, NIAID should establish a prioritization process for allocating limited resources. Criteria could include public health priorities; feasibility of scientific and clinical research paths to product licensure; feasibility of product production; and feasibility of product distribution. The use of external advisors to review progress is encouraged.
- Support resources for developing models for pharmacokinetic and/or pharmacodynamic analysis and developing non-murine animal models.
- Provide resources for medicinal chemistry and formulation methodologies.
- Provide support for developing new statistical tools for analyzing clinical trial data.
- Support the conduct of early phase clinical trials, including pharmacokinetic studies in special populations, in low incidence diseases, or difficult indications.
- Provide support for assessing the impact of the use of diagnostics on drug resistance.
- Support development of improved methodologies, including statistical tools, to allow more efficient use of clinical trial resources.
- Collaborate with FDA and industry to evaluate possible alternative clinical endpoints for prospective clinical trials.
- Promote the evaluation of drugs not developed as anti-infectives for use as anti-infectives and discontinued candidates for potential niche indications.

Training

- Support training of investigators in scientific fields relevant to drug discovery and drug development, such as medicinal chemistry, microbial membrane biophysics, microbial physiology, and systems biology. NIAID should provide incentives for maintaining a cadre of investigators in these fields.
- Support postdoctoral training in interdisciplinary sciences related to drug development.
- Provide training for academic investigators in the preclinical drug development process.
- Support training of academic investigators in industrial settings through mechanisms that could include sabbatical and exchange programs.
- Provide support for training of scientists as well as technical staff in the use of BSL-3 and BSL-4 facilities.

Partnerships

- Foster the development and expansion of public-private partnership models for product development and manufacturing as well as late-stage clinical development.
- Continue to support the improvement of clinical trial infrastructure in developing countries.

Recommendations for Other Organizations

- Explore the use of patient advocacy groups to raise public awareness of the problem of antimicrobial resistance.
- Conduct better analysis and oversight of the medical use of anti-infectives with the goal of delaying the emergence of clinical resistance using currently available therapies.
- Encourage the development of new anti-infectives by implementing novel intellectual property incentives for industry (e.g., tax credits, liability protection, patent extension).
- Examine and reevaluate the required clinical trials for regulatory approval of clinical indications.

Appendix: Summit Agenda
The State of Anti-Infective Development

Monday, August 16, 2004

Introduction and General Remarks
Dr. Anthony S. Fauci, Director, NIAID

Demand and Supply

The Need for New Medicines in the United States
Dr. John G. Bartlett, Chair, Antimicrobial Availability Taskforce, Infectious Diseases Society of America

The Need for New Medicines for Neglected Diseases
Dr. Janis Lazdins-Helds, Coordinator, Product Research and Development, Tropical Disease Research, World Health Organization

Issues Impeding the Discovery, Development, and Commercialization of New Antibacterials
Dr. Martin Rosenberg, NIAID Anti-Infective Development Consultant

Scientific and Strategic Opportunities and Challenges

Part I: Perspectives from Large Pharmaceutical Companies

Session Chair: Dr. Gail Cassell, Vice President for Scientific Affairs and Distinguished Lilly Research Scholar for Infectious Diseases, Eli Lilly and Company

Pfizer, Inc.-- Dr. Michael Dunne, Vice President, Therapeutic Area Development Leader, Infectious Diseases

Merck -- Dr. Dennis Schmatz, Vice President, Infectious Disease Research

Bristol-Myers Squibb Company -- Dr. Claude Nicaise, Vice President for Regulatory Strategy

Johnson & Johnson Pharmaceutical Research and Development -- Dr. Karen Bush, Distinguished Research Fellow and Biology Team Leader, Antimicrobial Agents Drug Discovery

AstraZeneca -- Dr. John Rex, Vice President and Medical Director for Infection

Novartis -- Dr. Harald Reinhart, Global Section Head, Tropical and Infectious Diseases, Department of Clinical Development and Medical Affairs

GlaxoSmithKline -- Dr. David Cocchetto, Vice President, Anti-Viral/ Anti-Infectious Regulatory Affairs

Part II: Perspectives from Public-Private Partnerships and Biotechnology Companies

Session Chair: Dr. George Miller, Chief Scientific Officer, Blanca Pharmaceuticals

Public-Private Partnerships:

- **Medicines for Malaria Venture** -- Dr. J. Carl Craft, Chief Scientific Officer
- **Global Alliance for TB Drug Development** -- Dr. Maria Freire, Chief Executive Officer

Biotechnology Companies:

- **Rib-X Pharmaceuticals, Inc.–** Dr. Joyce Sutcliffe, Vice President for Biochemistry and Molecular Biology
- **Idenix Pharmaceuticals –** Dr. David Shlaes, Executive Vice President, Research and Development
- **Affinium Pharmaceuticals --** Dr. Nachum Kaplan, Director of Molecular, Cell, and Microbiology

Case Studies

Session Co-Chairs: Dr. Todd Weber, Director, Office of Antimicrobial Resistance, National Center for Infectious Diseases, CDC, and Dr. Dennis Dixon, Chief, Bacteriology and Mycology Branch (BMB), Division of Microbiology and Infectious Diseases (DMID), NIAID

Antivirals:

- **SARS Therapeutics** -- Dr. Amy Patick, Head of Virology, Pfizer, Inc.
- **Neuraminidase Inhibitors** -- Dr. Michael Hitchcock, Vice President for Medical Affairs, Gilead Sciences, Inc.

Antibacterials:

- **C98-6446 --** Dr. Steven Projan, Associate Director, Infectious Disease Discovery Research, Wyeth
- **Daptomycin** -- Dr. Francis Tally, Senior Vice President for Scientific Affairs, Cubist Pharmaceuticals

Session Chair: Dr. Dennis Dixon, Branch Chief, BMB, DMID, NIAID

Antifungals:

- **Micafungi** -- Dr. Donald Buell, Fujisawa HealthCare, Inc.

Antimalarials:

- **Tafenoquin** -- Dr. Brian Wynne, Senior Director, Anti-Infectives, GlaxoSmithKline

Regulatory Issues

The Critical Path Initiative: What Impact will it have on Anti-Infectives Development? Dr. Janet Woodcock, Director, Center for Drug Evaluation and Research, FDA

Tuesday, August 17, 2004

NIAID Activities Past and Present -- Dr. Carole Heilman, Director, DMID, NIAID

Potential Roles for NIAID

- How the Institute might set priorities for use of limited resources
- How the Institute should interact with industry at various stages of anti-infective development
- How the contributions of academic researchers might be maximized
- How the Institute can assist in bringing forward compounds that have been shelved for economic or technical reasons

Moderated panel chaired by Dr. Martin Rosenberg
Participants:

- **Blanca Pharmaceuticals** -- Dr. George Miller
- **Global Alliance for TB Drug Development** -- Dr. Maria Freire,
- **ViroDefense** -- Dr. Marc Collett,
- **Johnson & Johnson –** Dr. Karen Bush
- **Notre Dame University** -- Dr. Shahriar Mobashery, Navari Family Professor in Life Sciences

Models To Optimize NIAID's Contribution

Moderated panel chaired by Dr. Catherine Laughlin, Chief, VB, DMID, NIAID and Dr. Sandy Lehrman, Director, Therapeutics Research Program, DAIDS, NIAID
Participants:

- **Eli Lilly and Company** -- Dr. Gail Cassell,
- **GlaxoSmithKline** -- Dr. Martin Steiner, Senior Director,
- **AstraZeneca** -- Dr. John Rex
- **Rib-X Pharmaceuticals, Inc.** -- Dr. Joyce Sutcliffe
- **Harbor-UCLA Medical Center** -- Dr. John Edwards, Jr., Chief, Division of Infectious Diseases

Summit Wrap-up and Closing Remarks -- Dr. John LaMontagne, Deputy Director, NIAID