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United States General Accounting Office

Report to Congressional Requesters

March 2000

GLOBAL HEALTH

Summary of Conference on Immunization in Developing Countries



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Abbreviations

Hib	Haemophilus influenzae type B
WHO	World Health Organization



United States General Accounting Office
Washington, D.C. 20548

National Security and
International Affairs Division

B-284673

March 1, 2000

The Honorable Mitch McConnell
Chairman
The Honorable Patrick Leahy
Ranking Minority Member
Subcommittee on Foreign Operations
Committee on Appropriations
United States Senate

While international initiatives have increased the percentage of children immunized against six serious diseases¹ to a global average of 80 percent, many countries have immunization rates far below the global average. In addition, many have not expanded their immunization programs to include newer vaccines that the World Health Organization (WHO) now recommends for use in developing countries. These shortfalls have severe consequences—WHO estimates that at least 4 million deaths each year among children in developing countries can be linked to these children's lack of access to vaccines.

In response to your concern about these shortfalls, we recently issued a report entitled *Global Health: Factors Contributing to Low Vaccination Rates in Developing Countries* (GAO/NSIAD-00-4, Oct. 15, 1999). In that report, we identified a number of factors that limit access to vaccines for children in developing countries, including (1) shifting donor priorities, (2) inadequate infrastructure and insufficient information for decision-making, and (3) the relatively high cost of newer vaccines.

¹The diseases in question are diphtheria, measles, pertussis, polio, tetanus, and tuberculosis.

On November 19, 1999, we convened a conference in Washington, D.C., on "Global Health: Addressing Immunization Shortfalls in Developing Countries" to provide you and other concerned Members of Congress with informed discussion about actions that could be taken to address these limiting factors. The conference agenda is reproduced in appendix I. A variety of public and private sector experts participated, including representatives from multilateral organizations, the U.S. government, private foundations, and the pharmaceutical industry.² This report summarizes the views expressed at the conference.

Achieving a Heightened Commitment to Immunization

In the broadest sense, the conference participants agreed that the shortfalls described in our October report could be attributed to the absence of a meaningful, coordinated, worldwide commitment to immunizing children in poor countries. Conferees observed that developing country governments and their partners in the donor community have consistently undervalued immunization relative to other competing health sector priorities, despite the fact that immunization is one of the most cost-effective health investments. Conferees agreed that funding from all sources, including developing countries themselves, has not been adequate to ensure that children in these countries receive the vaccines recommended by WHO. In addition, it was noted that donor assistance to national programs has been inconsistent and poorly coordinated.³

The conferees suggested that the United States work with other bilateral donors, multilateral agencies, and developing country governments to create and sustain a heightened worldwide commitment to ensuring access to vaccines for children in developing countries. To bring about such a commitment, participants stressed the need for advocacy aimed at convincing decisionmakers in donor agencies and developing countries alike to assign a higher priority to immunization, accompanied and reinforced by allocation of increased resources to improve and expand immunization performance.

²Appendix I includes profiles of the conference participants.

³We noted in our October report that United Nations Children's Fund and U.S. Agency for International Development funding for routine immunization has declined since 1990 and that total annual bilateral contributions for immunization fluctuated significantly through the 1990s.

Participants suggested a number of actions that could be taken to elevate the priority assigned to immunization. For example, immunization performance could be identified as a key concern in health sector strategies for developing countries that the donor community, including the United States, agrees to support. Future donor funding levels could be linked, in part, to performance in this area. Several conferees suggested that debt relief negotiations under the Heavily Indebted Poor Countries Debt Initiative be employed as a vehicle for focusing increased attention on immunization and that funds made available through this initiative be targeted to improving performance in this area.⁴

To ensure that heightened commitments are translated into effective and sustained programs of action, the conferees suggested that donor agencies and developing country governments work together to prepare and carry out coordinated, country-specific strategies for addressing immunization shortfalls. National immunization coordinating committees could be created in individual countries to provide focal points for all concerned parties, including government agencies and donor organizations, to work together in identifying needs, agreeing on measures that should be taken to address these needs, and assigning responsibility for carrying out the resulting plans. To illustrate the benefits of this approach, one participant described an ongoing effort to improve immunization performance in Bolivia that is being sponsored by the World Bank and the Pan American Health Organization, with support from several other donor organizations.⁵ Prior to this effort, donor assistance to immunization in Bolivia was uncoordinated and limited in scope and had done little to correct the national system's declining performance. Through the current effort, the donor community has worked with the Bolivian government to develop an integrated approach to reversing this decline. A medium-term plan for improving national performance has been adopted, with clear targets and efforts to improve management capability. The Bolivian Ministry of Finance has significantly increased domestic spending on immunization and has committed to additional substantial increases as the project proceeds.

⁴The World Bank and the International Monetary Fund developed the Heavily Indebted Poor Countries Debt Initiative to provide a comprehensive approach to the debt problems of many of the world's poorest countries. Resources released through the initiative may be directed toward reducing poverty in beneficiary countries. Improved immunization performance is one of many competing priorities that beneficiary countries may choose to fund with the resources freed up through the initiative.

⁵Others providing support include the U.S. Agency for International Development, the governments of Japan and Belgium, and the United Nations Children's Fund.

Strengthening National Immunization Systems and Generating Better Information

The conferees observed that inadequacies in national vaccine procurement and distribution systems have been a major impediment to achieving higher immunization rates in developing countries and that investments are required in a variety of areas to ensure that these systems can function effectively. For example, developing countries need help in ensuring that personnel charged with immunizing children can do their jobs safely and effectively, and in repairing gaps in the vaccine "cold chain."⁶ Additional investments are also needed to provide the management expertise needed to forecast vaccine needs, procure supplies, and distribute them throughout the country in an efficient and timely manner.

The conferees generally agreed that initiatives aimed at improving access to vaccines must include measures designed to fill these critical infrastructure and health system management gaps. Conference participants cautioned, however, that efforts to repair these gaps should not be too narrowly targeted. To function effectively, immunization systems rely upon competent national public health systems. Therefore, donor agencies should, when appropriate, focus on strengthening underlying national public health capacities, rather than confining themselves to immunization-specific interventions.

Several conferees observed that these efforts should include measures designed to generate the information that decisionmakers need to allocate resources for immunization and to manage these resources in an effective and efficient manner. Effective national immunization programs must be based on reliable information about the incidence of specific vaccine-preventable diseases, the efficacy of vaccines in preventing these diseases, and the performance of the national systems designed to deliver these vaccines. Uncertainty about whether to introduce new vaccines, in particular, can be fueled by doubts about the prevalence of targeted diseases in individual countries and the consequent cost-effectiveness of allocating scarce resources to procuring vaccines aimed at their prevention. Similarly, effective management of national immunization programs is difficult in the absence of accurate information on vaccine coverage levels actually being achieved through current efforts and their impact on the incidence of disease.

⁶Most vaccines must be kept refrigerated or frozen. The "cold chain" refers to the storage and transportation equipment required for keeping vaccines cold from the time they are manufactured to the time they are actually administered.

Staging efficacy trials for new vaccines in developing countries can provide clear information on actual disease burdens and the potential impact of candidate vaccines in reducing these burdens.⁷ Given the lack of equipment and skilled personnel in developing countries and vaccine companies' focus on industrialized country markets, efficacy trials are seldom conducted in developing countries. One conference participant suggested that donors direct additional resources toward improving medical capabilities in selected developing countries so that these countries could more readily participate in such trials. Given the expense involved in conducting such trials, several participants cautioned that such efforts should be accompanied by initiatives aimed at ensuring that multiple countries in a given region accept the results.

Several participants observed that the international community has invested substantial resources in building surveillance capacity in the developing world to support the worldwide campaign to eradicate polio. They suggested that the systems created in support of polio eradication be retained and expanded to focus on other priority diseases.

One participant observed that improvements in vaccine technology could provide a major boost to efforts to improve immunization programs in developing countries. For example, heat-stable versions of current vaccines would eliminate the need for maintaining the vaccine cold chain. Technologies for creating heat-stable versions of currently available vaccines are already understood in principle, though additional development is required. Another participant agreed but pointed out that because of the lack of paying markets in the developing world, private companies do not have any market incentive to develop these technologies.⁸

⁷Efficacy trials involve the administration of new vaccines to test populations as a means of establishing their effectiveness in preventing disease.

⁸Unlike their counterparts in developing countries, consumers in industrialized countries have the resources to pay extra for heat-stable vaccines. However, since industrialized country health systems have no difficulty keeping vaccines refrigerated, consumers in these countries have no reason to pay a premium for heat stability.

Making Newer Vaccines Affordable

Over the past 25 years, WHO's recommendations for developing country immunization programs have been expanded beyond the six original vaccines to include vaccines against hepatitis B and *Haemophilus influenzae* type b (Hib).⁹ Despite the fact that these vaccines are now available at a fraction of the price at which they were originally offered, they remain absent from national immunization programs in most developing countries.¹⁰

The participants generally viewed the continued absence of these newer vaccines from many national immunization programs as one consequence of the widespread undervaluation of vaccines among decisionmakers in both donor agencies and developing country governments themselves. While the cost of procuring these vaccines is clearly an obstacle for the world's poorest countries, conferees identified decision-makers' continued preference for supporting other priorities as the primary factor limiting their adoption.

To address the ongoing absence of these newer vaccines from many national immunization schedules, conference participants recommended that advocacy on behalf of a heightened worldwide commitment to immunization include efforts directed specifically at clarifying the cost-effectiveness of expanding immunization to include these newer vaccines. Participants suggested that the donor community support this advocacy by providing funds for the specific purpose of assisting the world's poorest countries in procuring these vaccines. These funds could be contributed to a vaccine fund already established under the auspices of the Global Alliance for Vaccines and Immunization.¹¹

⁹A vaccine against the Hib bacterium, which causes meningitis and pneumonia, was recommended by WHO for countries that have sufficient disease burden and infrastructure capability to warrant introduction.

¹⁰Hib vaccine is now available to developing countries at about \$2 per dose, while hepatitis B vaccine can be obtained for under \$1 per dose. Both require three doses to be effective.

¹¹The Global Alliance for Vaccines and Immunization was launched in January 2000 to coordinate international efforts aimed at improving immunization in developing countries. Participants include WHO, the World Bank, the United Nations Children's Fund, vaccine companies, private foundations and bilateral donors, including the U.S. Agency for International Development.

Vaccines that are just entering the market present a greater challenge. Conference participants noted that vaccines against a number of additional diseases—including diarrheal and respiratory infections that are major causes of death among children in developing countries—are expected to become available within the next few years. These vaccines can be expected to appear initially at prices that will make them inaccessible to most developing countries.¹² As in the past, these prices can be expected to decline over time as producers improve their manufacturing processes and competitors introduce alternative products. Conferees observed, however, that in the interim children in industrialized countries will gain access to these vaccines while children in developing countries will continue to do without.

Several conferees said that market segmentation—selling new vaccines to low-income countries at prices substantially lower than those charged in high-income countries—should be employed as one element of a strategy for accelerating widespread introduction of newer vaccines. Vaccine company representatives expressed their willingness to charge a low price to consumers in the world's poorest countries. However, they added that wealthy consumers (that is, industrialized country governments, health care institutions, and individuals) would continue to be charged higher prices to ensure a profit and to recover research and development costs. Because they have been severely criticized for employing such pricing arrangements in the past, U.S. companies may be reluctant to employ them in the future. Several participants suggested that Congress counter this reluctance by supporting U.S. companies in offering new vaccines to low-income countries at substantially reduced prices.

Increased use of group purchasing arrangements was also raised as another approach to accelerating developing country access to new products. One participant observed that through combining the market demand of its member countries in Latin America, the Pan American Health Organization has purchased vaccines at lower prices and increased use of hepatitis B and Hib vaccines in the region.

¹²For example, a vaccine against rotavirus, which causes the most severe forms of diarrhea, was introduced in the United States at a price of over \$100 for a three-dose series. This product was subsequently withdrawn due to safety concerns, but industry is continuing to work on alternative anti-rotavirus vaccines.

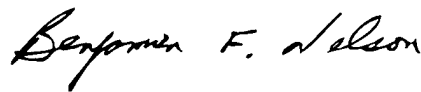
Scope and Methodology

This report was prepared from a transcript of our conference proceedings of November 19, 1999, supplemented by copies of formal statements submitted by a number of the panelists. Though assigned specific topics, all of the panels at the conference engaged in broader discussions, touching upon multiple aspects of the issue at hand. This summary reflects the totality of the day's discussion.

We gratefully acknowledge the contributions made to the proceedings by each of the panelists, with a special thank you to Dr. John LaMontagne of the National Institute of Allergies and Infectious Diseases for moderating much of the day's discussion.

We are sending copies of this report to appropriate congressional Committees; the Honorable Lawrence F. Summers, Secretary of the Treasury; the Honorable Madeleine K. Albright, Secretary of State; the Honorable Donna Shalala, Secretary of Health and Human Services; the Honorable J. Brady Anderson, Administrator of the U.S. Agency for International Development; and other interested parties. We will also make copies available to others upon request.

If you or your staff have any questions about this report or wish to discuss these issues further, please contact me at (202) 512-4128. Other GAO contacts and staff acknowledgments are listed in appendix II.



Benjamin F. Nelson
Director, International Relations
and Trade Issues

Conference Agenda and Profiles of Participants

Agenda

8:30	Registration
9:00	Welcome David M. Walker Comptroller General of the United States
9:10	Opening Remarks Senator Patrick Leahy (D-VT)
9:20	Panel 1: MAKING VACCINES AFFORDABLE Reducing the Price Barrier for Developing Countries Moderator's Introduction (5 minutes) John LaMontagne Deputy Director, National Institute of Allergy and Infectious Diseases Panelist Presentations (20 minutes in total) David Alnwick Director, Health Section, United Nations Children's Fund David Brandling-Bennett Deputy Director, Pan-American Health Organization Mark Kane Director, Bill and Melinda Gates Children's Vaccine Program Adel A.F. Mahmoud ¹ President, Merck Vaccines Jacques-François Martin President, Parteurop Consultants Panel Discussion (30 minutes) Audience Questions (20 minutes)

¹Dr. Mahmoud was unable to attend.

10:35	Mid-Morning Break
10:50	Panel 2: GENERATING INFORMATION FOR DECISION-MAKING Obtaining Adequate Data for Deciding Whether to Incorporate Additional Vaccines in National Immunization Programs Moderator's Introduction (5 minutes) Dr. LaMontagne Panelist Presentations (20 minutes in total) Claire Broome Senior Advisor to the Director for Integrated Health Information Systems, U.S. Centers for Disease Control and Prevention Amie Batson Health Specialist, The World Bank Ariel Pablos-Mendez Scientific Advisor, Health Sciences Division, Rockefeller Foundation Kevin Reilly President, Wyeth Vaccines & Nutrition Walter Vandersmissen Government Affairs Director, SmithKline Beecham Biologicals Panel Discussion (30 minutes) Audience Questions (20 minutes)
12:05	Lunch Break
1:15	Panel 3: IMPROVING DELIVERY SYSTEMS Developing Strategies to Improve Developing Country Immunization Systems Moderator's Introduction (5 minutes) Dr. LaMontagne

**Appendix I
Conference Agenda and Profiles of
Participants**

Panelist Presentations (20 minutes in total)

Daniel Cotlear
Senior Economist, The World Bank

Nils Daulaire
President, Global Health Council

Bjorn Melgaard
Director, Department of Vaccines and Biologicals, World Health
Organization

Joy Riggs-Perla
Director, Health Office, U.S. Agency for International Development

Panel Discussion (30 minutes)

Audience Questions (20 minutes)

2:30

Mid-Afternoon Break

2:45

Panel 4: DEVELOPING A U.S. STRATEGY

Implications of Today's Discussion for U.S. Policies and Programs

Moderator's Introduction (5 minutes)

Lynne Holloway
Assistant Director, National Security and International Affairs Division,
U.S. General Accounting Office

Panelist Comments (20 minutes in total)

Dr. LaMontagne
Dr. Broome
Dr. Mahmoud²
Ms. Riggs-Perla

Panel Discussion (30 minutes)

Audience Questions (20 minutes)

4:00

Adjournment

²Mr. Vandersmissen took Dr. Mahmoud's place in this discussion.

Participant Profiles

Mr. David Alnwick is Chief of the Health Section in the Programme Division of the United Nations Children's Fund (UNICEF). He has served UNICEF in a number of health and nutrition-related positions in Uganda and Kenya as well as at Fund headquarters in New York. Before joining UNICEF, Mr. Alnwick taught chemistry and physics at the Cameroon College of Art, Science and Technology; held research positions with British Drug Houses Ltd., the London School of Hygiene and Tropical Medicine, and the Medical Research Council (U.K.); and worked in Africa for the U.K. Overseas Development Administration. He holds an Honours Degree in Chemistry from the University of Leeds and a Master of Science in Human Nutrition from the London School of Hygiene and Tropical Medicine.

Ms. Amie Batson coordinates vaccine issues for the World Bank's Health, Nutrition, and Population group. Ms. Batson co-chairs the Bank's task force on mechanisms for accelerating the development of an HIV/AIDS vaccine and the Task Force on Financing of the Global Alliance for Vaccines and Immunization. She holds a Master's degree in Public and Private Management from Yale University. Prior to joining the Bank, she was a technical officer in the Global Programme for Vaccines and Immunization of the World Health Organization (WHO), where she focused on public-private partnerships and the economics of vaccine manufacturing.

Dr. David Brandling-Bennett is Deputy Director of the Pan-American Health Organization (PAHO). Prior to being appointed to this position, he directed PAHO's Division of Communicable Disease Prevention and Control. He has spent much of his professional career in developing countries in Central America, Asia, and Africa, where he was involved in research and control of tropical and vaccine-preventable diseases and in training epidemiologists. Dr. Brandling-Bennett obtained his undergraduate and medical degrees from Harvard University and completed additional studies at Harvard, Stanford University, the U.S. Centers for Disease Control and Prevention, and the London School of Hygiene and Tropical Medicine.

Dr. Claire Broome is Senior Advisor to the Director for Integrated Health Information Systems at the U.S. Centers for Disease Control and Prevention (CDC), in which capacity she oversees CDC's National Electronic Disease Surveillance System. Prior to accepting this position, Dr. Broome served CDC in a number of other capacities, including Deputy Director, Associate Director for Science, and Chief of the Special Pathogens Branch in the National Center for Infectious Diseases.

Dr. Broome received her undergraduate and medical degrees from Harvard University and completed additional studies at the University of California (San Francisco) and Massachusetts General Hospital. She is an Assistant Surgeon General in the Commissioned Corps of the U.S. Public Health Service, and a member of the Institute of Medicine of the National Academy of Sciences.

Dr. Daniel Cotlear is a senior economist in the World Bank's Regional Office for Latin America and the Caribbean, where he is responsible for health sector project and analytical work in Argentina, Bolivia, and Peru. He holds a Ph.D. in economics from the University of Oxford and an M.Phil. from the University of Cambridge. Before joining the Bank, he was Director of Economic Analysis at the Ministry of Agriculture in Peru and Associate Professor of Economics at the Catholic University of Peru, and has also served as an independent consultant on agricultural economics and labor markets in Latin America.

Dr. Nils Daulaire is President and CEO of the Global Health Council—the world's largest membership alliance dedicated to global health. Before assuming the leadership of the Council, Dr. Daulaire was Senior Health Advisor to the U.S. Agency for International Development and the Clinton administration's leading international health expert. A Phi Beta Kappa and summa cum laude graduate of Harvard University, Dr. Daulaire received his M.D. at Harvard Medical School and his Master's in Public Health from The Johns Hopkins University. Dr. Daulaire has devoted more than 2 decades to field work in the developing world and speaks seven languages. He has testified before Congress on numerous occasions and has appeared widely in the press and on television and radio.

Ms. Lynne Holloway is Assistant Director responsible for international health issues in the National Security and International Affairs Division of the U.S. General Accounting Office (GAO). Prior to joining GAO, she was a consultant on urban economics for the Organization for Economic Cooperation and Development in Paris and worked for several U.S. consulting firms. She holds a Master's degree in Economics from the London School of Economics.

Dr. Mark A. Kane is Director of the Bill and Melinda Gates Children's Vaccine Program, which is housed at the Program for Appropriate Technology in Health. Previously, he was Medical Officer responsible for viral hepatitis and the introduction of new vaccines with WHO's Global Programme for Vaccines and Immunization, and spent 10 years in

epidemiological positions with the CDC. Dr. Kane has been an active participant in negotiations leading to the creation of the Global Alliance for Vaccines and Immunization.

Dr. John LaMontagne is Deputy Director of the National Institute of Allergy and Infectious Diseases (NIAID), one of the U.S. National Institutes of Health. Prior to accepting his current position, he held a number of other positions at NIAID, including Program Officer for Viral Vaccines and Director of the AIDS Program. Dr. LaMontagne has been an active contributor to national and international efforts against infectious disease. For example, he played a central role in organizing the Multilateral Initiative on Malaria, is a member of WHO's Scientific Advisory Group on Vaccines and Biologicals, chairs the Task Force on Strategic Planning of the Children's Vaccine Initiative, and advises PAHO on its vaccine research programs. Dr. LaMontagne earned his Ph.D. from Tulane University.

Dr. Adel A.F. Mahmoud is President, Merck Vaccines Division of Merck & Company, Inc. Previously, he was Chairman of Medicine and Physician-in-Chief at Case Western Reserve University and University Hospitals of Cleveland. Dr. Mahmoud's academic career focused on the epidemiology and immunology of parasitic and infectious diseases. He serves on multiple advisory boards for the WHO, the National Institutes of Health, and the CDC, and in 1987 he was elected to the Institute of Medicine of the National Academy of Sciences.

Mr. Jacques-François Martin is founder and President of Parteurop, a consulting company in Lyon, France, that works with biotechnology firms and other elements of the vaccine industry. He holds an M.B.A. from the Ecole des Hautes Etudes Commerciales in Paris, and was formerly President of Pasteur Merieux Connaught, a major vaccine producer headquartered in Lyon. He has served as chairman of the Biologicals Committee of the International Federation of Pharmaceutical Manufacturers Associations, and is currently a member of the Board of Directors for both the International AIDS Vaccine Initiative and the Bill and Melinda Gates Children's Vaccine Program.

Dr. Bjorn Melgaard is Director of the Department of Vaccines and Biologicals at the WHO. Previously, he was Chief of WHO's Expanded Programme on Immunization and Executive Secretary of the Children's Vaccine Initiative. Dr. Melgaard qualified as a medical doctor and received his doctorate from Copenhagen University. Early in his career, Dr. Melgaard was Programme Manager for the Kenyan national immunization program,

and he has accumulated more than 12 years of experience in developing countries in Africa and Asia, including holding health sector advisory positions in the governments of Tanzania and Bhutan.

Dr. Ariel Pablos-Mendez is Assistant Professor of Public Health at Columbia University, where he specializes in epidemiology, and Health Sciences Advisor at the Rockefeller Foundation. He holds an M.D. degree from the University of Guadalajara (Mexico) and a Master's in Public Health from Columbia. Prior to joining the faculty at Columbia, he was Director of Graduate Education in the Health Sciences at the University of Guadalajara. He has also worked with the New York City Bureau of Tuberculosis Control and was coordinator of WHO's Global Surveillance Project on Anti-tuberculosis Drug Resistance.

Mr. Kevin Reilly is President of Wyeth Vaccines and Nutrition, a division of Wyeth-Ayerst Global Pharmaceuticals. He has over 25 years of experience in the U.S. and international health care and pharmaceutical industries, including 10 years managing vaccine business activities. Mr. Reilly joined Wyeth-Ayerst in 1984 in Canada and has subsequently held regional management responsibilities for Asia and global responsibilities for infant nutrition and now vaccines. Prior to joining Wyeth-Ayerst, he held a senior executive position with the parent company of Connaught Laboratories.

Ms. Joy Riggs-Perla is Director of the U.S. Agency for International Development's (USAID) Office of Health and Nutrition. During her 23 years of service with USAID and the Peace Corps, she has developed and managed health and population programs in a variety of developing countries, including Egypt, Indonesia, Swaziland, and the Philippines. Ms. Riggs-Perla holds an M.P.H. degree in Health Services Administration and speaks several Asian languages.

Mr. Walter Vandersmissen is Director for Government Affairs at SmithKline Beecham Biologicals. He is a long-time SmithKline employee, having held responsibility for international vaccine marketing, business development, and technology transfer before assuming his current position. Mr. Vandersmissen holds a degree in Romance Philology from the University of Ghent and pursued an academic career before joining SmithKline. He is the current president of the European Vaccine Manufacturers.

GAO Contacts and Staff Acknowledgments

GAO Contact

Lynne Holloway, (202) 512-4612

Acknowledgments

In addition to Ms. Holloway, Ann Baker, Terri White, Thomas Laetz, Douglas Manor, Michael McAtee, and Rona Mendelsohn made key contributions to this report.

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