

**Biotechnology Industry Organization (BIO) and the Bill and Melinda Gates Foundation -  
Lunch Plenary  
December 5, 2002**

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CARL: Thank you. We're about to begin our program. This is a bit like introducing a race horse that has already left the gate, but our next speaker directs the Bill and Melinda Gates Global Health Program. It was described at our luncheon yesterday as just another start-up, the type that we're quite familiar with in the biotech industry. Yeah, right.

The mission, put simply, is to improve health worldwide by funding initiatives ranging from preemptive food shortage relief, to the clinical development of new drugs and vaccines. That mission, seemingly daunting, is back with a 20 -- backed by a \$24 billion endowment, the world's largest for a philanthropic organization. Last year, the Gates Foundation dispensed \$856 million in global health grant awards, and more than \$1.1 billion in grants overall. This outfit's heart is clearly in the right place.

Dr. Richard Klausner shares the optimism of the Gates and the people in this room that such commitment of resources, combined with smart policy and superb science can reduce or eliminate illnesses that now claim millions of young and poor lives every year.

The former director of the National Cancer Institute came to the Gates Foundation seven months ago. He came extraordinarily well prepared for its truly unique demands. With a \$4.5 billion budget and 5,000 employees, NCI is the

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largest institute within the National Institutes of Health, and overseas, one of the largest clinical trial, drug development, and surveillance and epidemiology programs worldwide. NCI also administers the second largest HIV/AIDS programs worldwide.

While at NCI, Dr. Klausner, along with Tony Fauci, the director of the National Institute of Allergy and Infectious Diseases, oversaw the creation and development of the Vaccine Research Center. Rick Klausner is well known for his own scientific work, having served as the chief of the cell biology and metabolism branch of the National Institute of Child Health and Human Development.

He's the author of more than 280 scientific articles, several books. He has earned numerous awards and honors, including membership in the National Academy of Sciences and the Institute of Medicine. Rick has also served as the president of the American Society for Clinical Investigation, advisor to the presidents of the National Academies for Counterterrorism, and liaison to the White House, Office of Science and Technology Policy.

On a personal level, although I've just got to know him, we have a -- we do have a close mutual friend. According to that mutual friend, he's a geopolitician with an M.D. and a heart of gold, and a compassionate advisor to many people with cancer and other diseases. It's my pleasure to welcome Rick and thank him for joining us here.

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[ applause]

RICK KLAUSNER: Carl, thank you so much. And I am glad you were the one to interrupt everyone's eating. So I assume you finish while Carl was giving that very generous introduction.

Let me begin by just recognizing Carl. This meeting is a truly important event. It is a beginning. I am sure we all must leave here committed to this being a beginning. I don't need that yet. And I just really want to applaud Carl for his leadership of Bio and ringing with passion and a sense of tremendous personal commitment the critical ethics and ethos of global health, which represents all of our responsibilities.

What I want to talk about this afternoon is a sense of what innovation has and must bring to our attempts to solve some of the most challenging problems that are not only challenging, but of course, equally pressing. Those of the diseases, of the members of the global community who have often little or no access to this extraordinary world of innovation, invention, technology, and wealth that we take for granted.

The evolution of international public health, an area and field bravely carried by a relatively small group of people for too long very much in the funding backwater to global health parallels the emergence of the globalized world. The switch from an international public health perspective to one that we call global health, which is an extremely attractive

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phrase for which I don't think we have any clear or precise definition, but it reflects the switch from attending to problems by reaching across geopolitical boundaries to functioning within a world where geopolitical boundaries have become less and less relevant, although often extraordinarily problematic.

That we must deal with global health or with health as a global problem is demanded by three critical correlates of globalization. First, in a global community, it is a moral imperative to address the most pressing human problems not just of our nearest neighbors, but all of our global neighbors. Second, and Tony brought this up before, our own security reflects the blurring of geopolitical boundaries.

Now I mean security on many levels. As you all know, infectious diseases know no geopolitical boundaries. And the processes of globalization, travel, transportation and global commerce assure that we will certainly share disease if we fail to share improved health. The devastation of certain diseases, most notably AIDS, is likely and I think almost assuredly going to cause significant political and social destabilization in many parts of the world where profound effects will be no easier to contain than the infections themselves.

The safety of food in a world of globalized agricultural and food distribution will provide a series of growing problems about the transmission of disease across

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boundaries, as will the potential for the deliberate spread of emerging and re-emerging infections and to people at livestock and at crops. The third correlate of globalization that gives an imperative to global health is that the cornerstone of the global -- cornerstones of the global economy are healthy and growing markets that are global, and healthy and growing global economies that not only provide the markets, but contribute to all aspects of the world of commerce. Diseases such as malaria, parasites, and especially AIDS, and the huge inequities in child and women's health not only limit the growth of economies in markets, but can clearly be predicted to actually put fundamental constraints on any model of growth and a ceiling on achieving the promise of an expanding global economy and global commerce.

That disease limits human productivity has been a hallmark actually of all of human history. But in a global economy, disease becomes a global threat. Thus the agenda of global health is a moral, political, security, and economic imperative. It is a new agenda, and ought to be viewed as a new agenda, not out of any disrespect to -- for those who have toiled in this for a long time, but just the opposite, to build from it with new scale, new scope, and a new sense of approaches.

This new agenda, while recognizing and building on recognizes that we need to build and strengthen local and

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country specific health infrastructures, and that they will be essential to global health agenda is driven by a formulation of disease control and health aspirations that are strategic and independent of geopolitical boundaries, even as the implementation of solutions are via geopolitically contained systems.

The eradication of small pox and polio, the control of the AIDS pandemic, which will claim millions of lives this year, the control of malaria, neonatal tetanus, vaccine preventable diseases, on and on. All of these require global strategies and local solutions. Fundamentally, the phenomenon of global strategy and local solutions is a reasonable description of the scales that have to interact in a global economy.

The imperatives for global health that are moral, around security, and that are economic all provide the basis for the industries of health innovation to adopt global health that's central to their missions, which is why Carl's call to the biotech industry this summer is so important. The moral imperative, in fact, does and will provide motivation for the participation of creative and entrepreneurial people that will drive innovation.

It will also drive funding from institutions dedicated to the public good, be they public or philanthropic. The security imperative will push governments to incent both

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innovation and product development, and the economic imperative which I want to spend a little more time on, will markets even among the poor, markets that can grow, but will only grow with the success of global health innovations and access that assures the appropriate application of those innovations.

And so it is to innovation that I want to turn for the bulk of this talk. That is what this community here is about. If I can have the first slide? I want to talk about three aspects, each of which require innovation that will be required to both create new solutions, improve available solutions, and assure access to solutions to problems to achieve goals of global health.

The first is the access issue. And it requires an enormous amount of creativity and innovation, access to existing health technologies, such as basic vaccines, available drugs, and developing novel methods for the introduction of health technologies.

The second thing I'll refer to is to accelerate the evolution of available health technologies for resource poor settings by addressing the unique challenges of adaptability, usability, affordability and safety. Now before we talked, someone mentioned dual use. I think one of the most intriguing aspects of dual use in approaching technologies for the developing world is that the developing world should not, because it cannot afford poorly performing technologies that

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frankly our medical system often embraces.

The fact that a drug can be approved with the most minor of incremental advances in outcome, I don't actually want to criticize, but it ain't going to work for adoption in the developing world. Our acceptance in this very wealthy medical system, even though it was not doing that well, of diagnostic and detection technologies that fundamentally don't work very well, such as mammography, is not acceptable, and will not be adopted in the developing world. And I think there is this marvelous drive of dual use that we can contemplate, that the tools and technologies that we need to develop and those operating characteristics of those tools and technologies to be defensible in resource poor settings actually often will have to have operating characteristics that we ought to be demanding in the Western and developed world, but we will -- we must demand in addressing global health.

And I see that as providing a type of driving force of actually raising the standards, and being a sort of peculiar dual use approach to addressing global health problems. And finally, of course, there are problems for which we have no good solutions. Vaccines for HIV, malaria, successful vaccines for DB, new drugs, diagnostics that we don't have that will need to be created.

So let me look a little bit at these three areas. They involve a whole variety of global health -- of technologies,

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from vaccines to drugs to diagnostics devices, information and communication tools and other public health tools that relate to the environment of vector control nutrients, water and sanitation.

I will, however -- let me just correct a misperception. The Gates Foundation is extremely interested in vaccines. It is not only interested in vaccines, but the full range of these tools and technologies. I say that because I'm now going to use vaccines as an example of this first innovation part. And it is the innovation problem of how to find novel ways to both assure access to available technologies and create roots of access that pair us to introduce new technologies.

Fundamentally, the linkage of the pull and the push that we talked about this morning. So let me just review what most of you know of the challenges of vaccines and immunization. For the developing world, in many countries, in fact in virtually all developing countries, rates of immunization are inadequate. And in fact, the average rates that we support hide the fact that there are areas in the developing world in particular that are far below the reported average. In some countries, less than one in three children are immunized during their first year of life. And there are many reasons for this. And they all represent challenges as you can see.

They include the difficulty of the delivery systems,

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the governmental infrastructure, and the problems with knowing what needs are, in particular, for thinking about introducing new vaccines. From the recently released WHO, UNICEF, World Bank report on the states of the world's vaccination, I would just show -- I don't know if I have a -- but you can see the lowest white line represents the level of coverage over time. And this is just looking at the three doses of the most basic vaccine, DTP. And you can see that the overall coverage in Africa remains only about 50 -- sub Saharan Africa, about 50 percent.

What products are we talking about? There are four -- the -- for developing countries for the poorest of these developing countries, the hope and expectation now of the regular immunization with seven antigens, which should be growing with the introduction of HIV and Hepatitis B to nine. And you can see the distinction in the developed world wherein established markets, there are 12 currently regularly used antigens.

The challenges for manufacturing, which is an extremely important, could be a talk in and of itself, for all sorts of reasons. It's something we have to solve, but the challenge for manufacturing for providing access to available technologies, that is known vaccines, as I'm sure you all know, is both there and growing. The developing world only accounts for about 20 percent of the \$6 billion a year vaccine market,

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despite the fact that over 90 percent of the 133 million births a year take place in the developing world.

There is a growing problem of the divergence of the products that are made for the developed world, and the needs of, and the products that are desired in the developing world. There is, in fact, a global shortage of vaccines. There's been a shortage of vaccines domestically. Mergers between major pharmaceutical companies, decreasing number of manufacturers of vaccines, and this decreasing manufacturing base or low profit traditional vaccines.

It is, I think, an interesting phenomenon. Makes sense. The vaccines developed and are part of the pharmaceutical industry, but you have then this fundamental problem in big Pharma of vaccines in general representing an opportunity cost, even though they are, and certainly can be, profitable products.

This is what the market looks like. It's been growing at an annual average rate of 10 percent, up to currently 2000, about \$6 billion. This is driven by about half of it, an increase in the volume and about half an increase in the average price.

Here's where we begin to look at what are the markets we're talking about. And you see on the far left that of the \$6 billion, a little less than \$5 billion are generated in the developed world. The market now in the developing world, both

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middle income and low income, is about \$1.1 billion or that's the current vaccine market. It is not an insignificant market, but it is small when compared with the total global pharmaceutical market.

Financing gaps are a problem. Developing countries, which account for over 90 percent of the world's disease burden only has about 18 percent of the income and only represents about 10 percent of global spending on health. In terms of vaccines and immunization, it is important to recognize that there are multiple flows of money. And currently, over \$1.5 billion is provided for immunization to developing countries via multilateral and bilateral donors.

There are challenges with access that work and work to standards we expect. In an immunization, there are enormous issues with not only delivery, but safe delivery. And as you see here, surveys demonstrate that as much as half of injections given in developing countries are not sterile, and therefore not safe. And you see here, if you can read it, the extraordinary numbers, this is not just from vaccinations, this is from all use of injection, but that in developing countries unsafe injection practices has been associated and claim to be connected to at least eight million Hepatitis B infections, two million Hepatitis C infections, 75,000 cases of HIV/AIDS. And of course, you all know the problem probably should not be viewed as unsafe injection practices, but something much worse

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of what happened in China, resulting in probably a million cases of HIV/AIDS.

Vaccine quality and safety represent technological challenges which I'll come back to, that we have to address the delivery system is going to work well and efficiently and effectively. The issue of sensitivity of vaccines to heat is a huge problem, requiring the maintenance of a cold chain. I'll come back to this. And a large problem, not only for vaccines, but for all that we're talking about in this conference is the lack of national and perhaps better regional or international and standardized and rationalizable effective regulatory authorities that can assure quality and safety of domestically produced and imported products.

There are barriers to R & D. The major, major vaccine manufacturers are addressing more -- much more their work and their efforts at the developed world. And you can see why from those economic charts, than the needs of developing countries. And a major disincentive for vaccine manufacturers has been two things. One, the unpredictability of demand and price and the slow uptake of new vaccines in developing countries. And finally, the issue of what is an appropriate cost structure for what will be a relatively low price, but high volume product. And again, I will turn to that.

So let me give you one example of a picture of a system attempting to provide a solution to that. And that is the

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Global Alliance for Vaccines and Immunization and the vaccine funds. It is an example of the first issue of innovations related to access to available technologies and also pathways to the introduction of new technologies. As I'm sure this audience is familiar with, GAVI is an alliance between the public and private sector. And it has this one overarching goal of saving children's lives and improving people's health through the widespread use of vaccines.

It has a procurement on any funding on in the Vaccine Fund, which currently has about \$1.1 billion in it. The countries eligible are 75 in the world, who's gross national product annually is less than \$1,000 per capita. Now there's a variety of characteristics of how GAVI and the Vaccine Fund work, that I think is an important part of what I like to talk about as the ethos of global health sciences. And that is taking the best of the characteristics of science, and applying them to health programs.

There are a variety of those characteristics in that ethos. One is that decisionmaking should be evidence based and data driven. Evidence based, not politically based. That systems that are attempting to solve problems should be developed by expertise and be open to evaluation and independent and objective review. That the programs ought to be held to standards of performance and outcomes that are measurable, reportable, and believable through independent

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And all of these have been attempted to be put in place. And it's an ongoing process by GAVI. Countries have to apply right applications that demonstrate their commitment, their commitment to issues of safety and delivery, in order to be eligible for funding. The funding mechanism is an incentive one. And that is part of the dollars per child funded is given if the application is approved, but the rest of it is only given if the countries demonstrate that they can actually deliver the products.

Over the last few years, you can see, you can't read this, and I won't go through the details, of the different types of vaccines and the doses that have been delivered through GAVI up to last year 180 million doses. \$130 million were distributed last year, and \$900 million have so far been allocated that will spread out over the next five. And that can be spent out over eight years.

The impact calculated already from GAVI would be that expanded DTP3 coverage in 2001, and save an estimated 280,000 lives. If GAVI meets its five year coverage targets just for DTP3, HEPB and HIB, the calculation is that it will save over two million lives by 2007, but they're in fact a variety of other benefits, as listed here in terms of revitalization of [unintelligible] community, renewed focus on coverage, bringing together the private sector, for profit sector, the not for

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profit private sector, and the public sector. And I'm going to talk again a little bit more about that in a minute, as well as I believe being a testing ground for the types of processes that should define what we demand about accountable approaches to global health.

There are several components for that ethos of a science based approach to these sorts of public health problems. Within GAVI as a vaccine provision project, that is now being launched. It's up and running. It will be a work in evolution. The goal, however, is to provide over time a more and more sophisticated demand forecasting so that we can bring to companies and manufacturers a clarity of demand so that negotiation about price can be entered into with some reasonable volume pricing assumptions and expectations.

And this is really a critical part of the ethos of GAVI, figuring out what is the market and providing a mechanism that enables the gathering and communication of this information as a partnership across sectors and provides a buffer to assure that the procurement links with the demand forecasting.

Another aspect of the ethos I talked about is measurable outcomes. So GAVI has introduced a data quality audit. 18 countries will be completed by the end of the year. The pass rate is only 50 percent. That is demanding where the data, and this is done independently by techniques that I

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suspect again will evolve in terms of sample size and statistics, although the CEC recently did an evaluation, looks like that statistics are at least acceptable. And it means that 80 -- that there's 80 percent verification threshold for their immunization registries, as I said, in the first round about 50 percent of countries meet them. And then there is a process for assuring and figuring out the diagnostics about why it's not -- why they're not being met, and to somehow -- and to find ways to make sure that there is real quality of the data for immunizations that are being delivered.

And finally, GAVI is demanding that associated with the funding is the development of a long term country specific financial sustainability plan, bringing together ministers of finance and ministers of health from other sectors with technical assistance to develop projections, models of where the funding sources will come from as countries move and it will not be for many countries entirely. It is not self sufficiency that is being demanded, but a sustainable and multi year projection of how one is going to go about linking implementation plans with financing approaching and funding sources.

And that is both funding and financing. And as you can see, 13 countries have already completed their financial sustainability plans for many. This was the first time that long term multi year planning was linked for health -- for a

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health system between MOH, the ministers of health and ministers of finance and next year an additional 21 countries will submit their financial sustainability plans. Again, this is part of this issue about how especially manufacturers and developers have the confidence that there will be long term stability and the ability to project the nature of the markets and the nature of the products that will be demanded and where the financing of the resources will come from.

Innovation, this is one of the great challenges and one of the reasons GAVI was set up. And that is recognizing the extraordinary and unacceptable delay between the development of a new technology, such as a new vaccine, in the developed world and the several decade delay in introduction to the developing world. So what has been developed and -- are -- is a process calling ADIPS for Accelerated Development and Introduction Plans. And again, this represents a very specific type of public private partnership, gets us something we discussed this morning, to basically establish demand, establish demand justification, establish a reasonable estimate of demand and market, and to drive a strategic approach to late stage product development launch to execute effectively marketing initiatives that are appropriate for the various and challenging markets that we were talking about, so that there is fundamentally for new products a linkage of the pull mechanisms with the push mechanisms.

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And what do I mean by that? So first, we need to overcome demand uncertainty. And I'm sorry these colors don't show up. It just represents the incredible delay between the introduction of two vaccines, Hepatitis B and Mofluous [Misspelled?] Influenza B years from availability in the developed world to the uptake. And you see the inflection point that we're looking at for Hepatitis and for HID.

Now what are the issues here? The issues for an AIDA [Misspelled?] are to link and make the case for the necessity and the perception of the need and value of the introduction of a new product at the place where the products are going to be purchased, not by whom they're going to purchased, back to that, but where they're going to be purchased. And that's by the countries.

Therefore, the ADIPS are funded to do burden of disease studies in the developing world and late stage clinical trials to assure that there is the case made for the effectiveness value cost effectiveness of the product to build demand within the country. And to do that up front with the product manufacturers so that they are part of the process of this late stage developing world development that these monies that come from the Vaccine Fund will pay for.

The case for supply to industry we recognize in this must be made. And there are three issues here. There are the issues about projecting revenue. Again, this goes back to

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having a mechanism to get a better prediction of volume and what the revenue will be given a negotiated price. The issues of cost. And now here, this will be these monies for burden of disease and late stage clinical trials that, of course, are part of and an essential part of building demand, working up front by knowing the demand forecasting how to think about manufacturing needs and scale up, up front, what will be the registration problems, the issues for ongoing production, and to be able to work through the impact that this will have and the scaling might have on other aspects of the core business of the manufacturer.

The whole point of this is to try to create a virtuous cycle of predictable and lower and affordable prices, but predictable and hope for hopefully in that prediction the ability to predict the volume that provide revenue in the price volume discussion. That in this virtuous circle, cycle that to make predictable the demand, and to link that to make predictable for everyone the capacity for manufacturing, for delivery, etcetera.

Is it worth the cost of doing this? How do we think about the money flows? First of all, as we said, we need to build the public health case that relates to burden of disease, relates to effectiveness, and assures that this approach is a useful, useable and most effective approach that the countries recognize and then prioritize the introduction of these new

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vaccines. And of course, we're asking whether the accelerated introduction of any particular vaccine represents the best use of the -- this commodity fund.

So what this chart shows is a model for the transition from this commodity fund driven purchasing and funding through the expensive phase of introduction, expensive for a variety of reasons, not the least of which is the introduction phase does not involve large volumes. And so, the model we are using is in green is the donor support to a variety of sources, but particularly through the Vaccine Fund. And then what you see over time is based upon developing the demand, working with the countries to assure and establish that this will be their demand, that there be through the financial sustainability plan now linked now just with ongoing immunization, but with the introduction of new immunization linked into the overall immunization program, what you see in the green, is coming up with a long term purchasing where the price now is driven down, we hope, by two factors. One, the volume as now the introduction takes off. And two, what's in the dotted line is the hope for and the potential for technological shifts, cheaper manufacturing, cheaper approaches to the production of product.

Maybe going too long, so I will skip a few things. I won't go through all the details of market analysis. This was -- this work was very much led by Raj Shah. Amy Batsen

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[Misspelled?] and Raj is here from foundation. Amy Batsen [Misspelled?] from the World Bank. But in this, we are trying to create not only a rationalization for the introduction of new technology that is linked through the connection across sectors, the connection across donors, the connection across the country, the connection across the developers of the products, the manufacturers and developers with the solution of this particular global health problem.

I would -- we will have to, of course, see how well this works, but I will posit that something along this line, I believe provides a very intriguing model for multiple funds, the Global Fund, funds for drugs, for diagnostics, and for all of the technologies that then leverage where it is needed, the public and not for profit private funds for the expensive part of introduction while you work towards a sustainable both push and pull for product, for the nature of the product, the volume of the product, and the delivery and adoption of the product.

And what you see in the bottom here is in the blue line is the total market revenue. But in the space at the left is what is taken up by donor financing, which is what we see in this as a general model for these commodity process funds and then with the hope that financial sustainability, remember, not the same as poor countries self sufficiency. But we'll change over time. Some poor countries, hopefully and more and more become less poor countries and middle income countries,

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Skip this. The next aspect of innovation, as I said, is the accelerated evolution of available health technologies. And I was going to show some wonderful examples. I think they're all or most of them, Chris you can probably correct me, I think they were taken from Path, but they represent a variety of important technologies that make vaccines more usable appropriate and affordable for the developing world and I -- well, I want it to be an advertisement for all your stuff. I mean, I'm going to run through it. What I will instead is announce that one of the new parts of the foundation, which we're calling Global Health Initiatives, and this is Sally's part of the foundation, which will be the part of the foundation that will fund projects in cross cutting technologies, everything from vaccine technologies to drug development technologies, to a variety of cross cutting issues in epidemiology and information systems. It will be where we do policy work. And Raj Shah, economics. And where we support human capacity.

I'd like to tell this group is that in January, and watch our website, we will be announcing a \$50 million new funding initiative, which will come out as a request for proposals for novel vaccine technologies. Technologies that attempt to solve problems, such as mucosal administration, new types of bacterial and viral and other vectors, transcutaneous

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delivery, edible vaccines, immune enhancement, novel approaches to agitants, wanting innovative agitator presentation, agitators that move us towards the challenge of for any vaccine, single dose delivery. It is not clear to me that that is not achievable with some of the new things that new agitators can do to new cells that can be made to be unexpected presenting cells.

New ways to do combination and multi valence vaccines, new ways to avoid heat instability and delivery. So what I will take this as an opportunity to say over the next year, I would hope, that people will get used to more and more looking at our website. Don't look at it yet. It's not ready. You would just complain. For ongoing announcements of new initiatives emerging from the foundation as we move more towards a much more proactive approach to grant making, we will still accept applications through letters of intent, but in fact we are through the creation of a much more proactive strategic plan.

And particularly to watch in this area for this community the technology based funding mechanisms. And of course, that final aspect of innovation, and I only show a few examples, and of course they are foundation centric of things that the foundation has been helping to support, and many of these public private partnerships aimed at doing that critical third aspect of innovation, and that is creating tools and

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technologies that we wish we had but we don't have.

Let me just end by talking a little bit about the argument for the biotech industry rising to Carl's challenge to address the needs of the global community and global health. Others at this conference have made the point that I don't need to re-emphasize that there are many aspects, many characteristics of the nimble, entrepreneurial, creative niche seeking biotech industry that are extraordinarily well aligned to the possibilities of the types of problems that need to be solved and the types of markets available in the developing world, both for low income and middle income countries.

That has been made. And simply, we emphasize that I cannot imagine us achieving as a community, as a world, our goals of global health without the international biotech communities being an absolutely essential part of it. This community ought to set for itself a high level of its total activity that should be directed at global health. They will have, I am sure, extraordinary, as I said before, dual use blow back into the developed world.

The developing world includes real markets. The PAHO [Misspelled?] countries spend almost \$20 billion a year in pharmaceutical products, nearly five percent of the global total. There is, of course, an entering the developing world a segmentation and a complexity of the markets, including a growing middle class. In India, in 2001, \$25 billion was spent

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on health, 5.2 percent of the GDP. And the private sector spending represented almost \$22 of the that \$25 billion.

In China, today spends almost three percent of GDP on health with a total of over \$30 billion. The fact is there is money in the most impoverished parts of the world. How is that money spent? It has been estimated that the total purchasing power parity of countries with per capita incomes of over \$25,000 per year is only one-quarter of the total purchasing power of all countries in which individuals earn less than \$2,000 a year.

Products are purchased as has been written by Desoto, by Prahalad and others, there is wealth in poverty. There are huge challenges in how to create delivery and marketing approaches to provide products and especially products of value and products make a difference -- that make a difference to these enormous potential markets. But to access those markets are going to require new ways of approaching and thinking about strategic aspects of marketing and delivery, about shaping products that are -- that fit the market, that meet the consumer needs.

The markets also need to be shaped by engaging marketing activities with the countries with Ministries of Health with many individuals who are the consumers, who need and want these products. There need to be novel ways of thinking about shaping marketing and distribution organizations

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for creating revenues driven by volume, rather than unit price. The volume is there and the total of the dollars is potentially there. I am not saying this is going to be easy, but this seems to me is the type of innovative marketing approach perfectly suited to an emerging industry of innovation, production, and such as the biotech industry.

We need to learn from friends that have done well in the developing world. This may not be under doing well and doing good. I shouldn't make any judgments here, but you know, there are companies that sell to the most impoverished. Coca Cola, it's recognized. I think one needs to think about whether the only approach to the marketing of health products are the approaches developed by the pharmaceutical industry in the United States, which is different than in Europe and in either of those, is a challenge, but the numbers are not impossible.

Added to that is as far as any of us can see, a growing agenda for the world at the political level, and at the level of private philanthropy to add to both the dollar flow and the enhancement of processes to make global health a reality. I certainly hope - many of us hope, as Tony said this morning, that in this world that is beginning more and more to feel more and more dangerous to the most wealthy and formally most secure, that one aspect of our way of looking at the world will be to recognize ourselves as fundamentally and inextricably a

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part of the global health community.

So let me thank you again for not only participating in this historic meeting, but for what I will just assume by your being here and having eaten lunch that the price of that is that when you walk away, you don't walk away from the commitment that being here represents. We look forward to working with Bio, with all sectors on this really quite extraordinary and historic vision of global health for a global community.

Thank you.

[ applause]

SIMON BEST: Thank you again, Dr. Klausner. Good afternoon. I'm Simon Best. I'm a member of the Bio board and the chair of its bioethics committee. So I'm particularly delighted and honored to have been asked by Carl to introduce our second speaker this afternoon.

I think we've all been struck during this very stimulating couple of days by the significance of Secretary of State Colin Powell's remarks earlier this week about the overarching scale of the global threat of the HIV/AIDS pandemic, even compared to that of global terrorism. So we're therefore particularly delighted to have as our second speaker today, Alan Larson, Secretary Powell's senior economic advisor.

Alan began his career in the foreign service almost 30 years ago. And in 1999 became the first foreign service

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officer to be appointed Undersecretary of State for economic, business and agricultural affairs. In his current role, he's actually been actively involved in many other areas of interest to Bio. So his plate this year has included intellectual property reforms in India, the Ampass [Misspelled?] of Biotech food approvals in Europe, as well as U.S., Pakistan agricultural cooperation, the financing of terrorism, the reconstruction of Afghanistan, strategies for maintaining oil security if war breaks out with Iraq, and U.S., Mexico bilateral relations.

So more than ever, you know, his range of activities illustrates how U.S. economic and national security hinges on the well being of other nations. Mr. Larson is on the front lines of that issue in the Middle East, in Europe, Latin America, and Asia. He first joined the State Department in 1973. And his current leadership role follows senior positions dealing with economics, trade, finance, energy, sanctions, transportation and telecommunications.

From 1990 to 1993, Mr. Larson was U.S. ambassador to the OECD in Paris. He's also served in the economic sections of U.S. embassies in Jamaica, Zaire, and Sierra Leone. He has a Ph.D. in economics from the University of Iowa. And please join me and welcome him this afternoon.

[applause]

ALAN LARSON: Good afternoon. I really want to thank

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Bio and the Bill and Melinda Gates Foundation for sponsoring this innovative conference and being kind enough to ask me to come and join you for part of it.

As was just said, Secretary Powell has made clear his view that HIV/AIDS and similar infectious diseases are among our biggest foreign policy problems. And on Monday on the occasion of World AIDS Day, he said that HIV/AIDS doesn't just destroy immune systems, it also undermines the social, economic and political systems that underpin entire nations and regions. And the disease spreads fast as in places under stress, weakening already fragile support systems beyond the breaking point, causing whole societies to begin to shudder and reach the edge of collapse.

That's why we're so pleased that such a group of dynamic and creative people are meeting to discuss these issues this week. We understand that history is full of examples of cases where epidemic diseases have spread across the globe, altering the social and economic and political fabrics of societies and continents. We also understand that in a globalized world, infectious diseases respect no boundaries that are geographic or political or socio-economic.

And it's telling to me as an economist that when we search for a way to describe the way that financial crisis in Asia can have an effect on Latin America, we talk about contagion. People understand at the very gut level that we are

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in this together, and that unless we find common solutions, we are as we just said, going to share common diseases.

I also think it is important to recognize, and I've seen this as I lived in some of the poorest societies on the face of the earth like Sierra Leone, that no matter how rich or poor you are, health is something you can't get enough of. And no matter how rich or poor a country is, we are all struggling to meet the demands of, and pay for the demands of our citizens to have better healthcare.

We believe it is very important for all of our best minds to be engaged in the search for solutions to the international or global health problems, including those afflicting the poorest countries, and those that involve the neglected diseases. One of the ways that the United States is trying to show leadership is through the Global Fund on Infectious Diseases, through which we have been the largest contributor, as well through our bilateral programs to tackle infectious diseases.

But we also recognize that governments can't do this alone. We think it's very important to work cooperatively with the private sector. We think it's very important to find the incentives that can harness the managerial skills, the technology and the know-how of the private sector. Now today, the vast majority of the medical research and development capabilities are in the hands of the private sector. And

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that's why the ideas that emerge from this conference will be so important in forging the policies.

I happen to be one who believes that the protection of intellectual property rights is one part of this incentive equation. I was recently in India. And I met this absolutely dynamite group of Indian scientists and researchers, who believe that stronger protection of intellectual property rights in India would be one of the best ways, not only to attract investment, but to tackle the health needs of India, because it could provide the capability to have a research and development oriented industry that could do clinical trials at much lower costs than in places like the United States, and be able to attack some of the diseases that plague India.

Shortly after my trip to India, Bill Gates came by for a trip that I must say got somewhat greater publicity in part because he not only had a good message, but he had several zeroes behind his message. We were very pleased that the Gates Foundation committed \$100 million the India AIDS initiative to slow the spread of HIV/AIDS, to combat the social stigma that is associated with it, and to increase awareness and leadership through communication, and advocacy.

Another part of the incentive equation is developing trust between the public and private sectors. It is important to work with governments and developing countries, so that they can prioritize and develop long range plans. And we heard a

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little bit about this in the case of vaccines and the work of GAVI. Because in doing this, and helping countries do this sort of planning, it does provide a foundation for cooperative interaction with the private sector.

I also want to comment briefly about cooperation between multilateral -- multinational corporations, excuse me, and smaller local emerging producers in the developing world. This holds a lot of promise. And we've heard a little bit about how GAVI is developing joint projects to develop vaccines for developing countries. And we're very encouraged by the results that we are seeing, and that you've seen the charts, and the philosophy that is underlying the work of GAVI.

I think it's also important to recognize that American businesses overseas are using their know how to tackle these problems. Coca Cola is putting to work its knowledge about distribution in helping the fight against HIV/AIDS in Africa. Companies like Daimler-Chrysler and Ford South Africa have won awards for their leadership in addressing this problem.

I think it's also worthwhile, and I won't go into detail on this because you all know about it, but U.S. pharmaceutical companies are doing many, many important initiatives around the world, participating for example in the accelerating access initiative, as working to bring drugs to some 36 countries, most of them in Africa at significantly reduced prices, offering antiretrovirals to more than 60

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developing countries at no profit. Some companies are offering testing kits for HIV/AIDS. I think all of these initiatives are very, very important and should be expanded wherever they can be effectively used.

To be truly effective, or fully effective in fighting disease and improving health in the poor countries, it is going to be important to focus on new health technology, as we just heard. For me, biotechnology does hold almost unparalleled potential to address food security, nutrition problems in developing countries, as well as to help the development of new medicines.

I've worked very hard to help build stronger understanding in Europe of the potential and promise of biotechnology. At a conference that we helped organize in Rome in June of this year, we had Dr. Norman Borlog [Misspelled?] kick off a discussion of this issue. But I must say, even as an Iowan who's a strong proponent and supporter and admirer of Dr. Borlog [Misspelled?], I think the person who stole the show is a Chinese researcher named Dr. Hwang, who illustrated with a few simple charts and graphs how biotech cotton in China was saving lives because farmers were no longer exposed to excess pesticides as a result of their practices of cultivation.

We've also all heard a lot about the nutritional values that are just coming through the pipeline of things of like golden rice. The United States is working with other countries

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through something called the African Agricultural Technology Foundation supported by USAID, to help African countries develop new biotech crops that are adapted to their particular needs. It's just been launched, but the results so far are very promising.

And I think we ought to be considering whether there are similar approaches that could bring the power of biotechnology and other pharmaceutical know how in support of the search for new treatments and fears for neglected diseases.

When I was in India, I also got to meet one of your conference participants, Dr. Venalpaul [Misspelled?], who runs an institute in Geneva called the Medicines for Malaria Venture. Now I'm not here to advocate for any particular approach, but I was intrigued at the approach that he is developing. And it was the passion and enthusiasm that he brought to me as he was lobbying me on the airplane flight from Delhi to Mumbai is the same type of passion and enthusiasm I've heard all around this room, as people have been talking about the ideas that they would like to bring forward, to harness the initiative and know how of the private sector in support of developing new technologies, new health technologies, than can help address the needs of developing countries.

I do think that the biotech industry has a particularly important role to play as someone who's worked very hard to overcome what I think are very, very uninformed and prejudiced

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views about biotechnology in Europe, I think it is important to show that this is a technology that has great potential to help poor people in poor countries. I'm convinced that that's the case in agriculture, because I've seen it. And I believe it is likely to be the case in the area of pharmaceuticals and health technologies as well.

Finally, I'd like to make one point, one last point about the importance of the private sector. I've been talking a lot about things that I think that -- where the private sector and the public sector and the philanthropic sector can work together in support of socially beneficial developments. But I do understand, and I do believe that the most important single thing for developing countries to become more prosperous is for them to grow, for them to attract investment, for them to have foreign companies invest in them. And yes, make profits in that because that's what creates jobs. That's what creates economic growth. And that's what we'll pay the taxes that will help supply the revenues that are going to pay for these vaccines, once you get beyond the stage when the Bill and Melinda Gates Foundation is helping to pay for them and the World Bank is helping to pay for them.

So I think it's very important to recognize as well the powerful role of private sector investment in developing countries in support of their own growth and development. I do want to, as my last word, again congratulate Bio and the Bill

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and Melinda Gates Foundation for having this conference on such an important issue. I am convinced that you are on to work that is very, very important. And we will look forward to hearing the full account of it when the week is done. And I completely agree with the comment that we may walk away from the table, but we cannot walk away from this issue.

Thank you very much.

[ applause ]