



Community Life Improvement Program

In Association with the
Alliance of Minority Medical Associations

The Global Alliance for Better Health

Issues of Concern:

1. Solutions to Global Disease Trends- How Do We Help?
2. Role of Medical Innovation & Technology to Solve Disease Dilemmas in Public Health
3. Role of Intellectual Property in Medical Innovation—Threats to Intellectual Property in Medical Innovation
4. Role of Government- Role of Markets
5. Global Solutions to Eliminating Health Disparities
6. Medical Solutions to Eliminating Health Disparities
7. Global Poverty- Long Term Solutions
8. Research & Innovation & Access

Thoughts to consider

A.” We need to establish a measurable global health baseline; this will be comparable to the minimum wage index. We will strive to attain, and to exceed, this status for every individual citizen of the world”.

B. “The world, as led by the dominant G8 nations, must decide if it desires to strive toward Global optimum health and take on this problem of reducing global health disparities”.

C. “It is in our collective (The entire world) self interest to address global health issues.”

D. “We must determine, and be aware of the threat to the survival our own lifestyle and culture, if we fail to address these problems. With today’s global economy, travel, and exposure, we are all at risk if any population is unhealthy and untreated.”

E. “The G8 nations, partnered with the WHO, and Phrma, might be the ideal vehicle to create and organize and manage this effort against global health issues.”

Solutions to Global Disease Trends and protection of intellectual property

I am writing on behalf of the Global Alliance for Better Health, a collaborative effort of the Community Life Improvement Project and the Alliance of Minority Medical Associations. This coalition was formed because of the need to better address the mounting evidence-based data that highlights the significant disparities in health care treatment outcomes that occur among many underserved populations within the United States and globally. Our global alliance of physicians, scholars, healthcare executives, providers, and policy experts, focuses on healthcare of the underserved. We represent a coalition of community based thought leaders, and organizations joined in purpose with the major national minority medical associations. We believe more individualized and targeted strategies are needed to improve disease management and treatment outcomes in these high-risk populations and groups.

We write to express concerns that we have regarding important issues that will be placed before the Intergovernmental Working Group on public health and Intellectual Property in an approaching hearing. There are plans by some that would remove the protection of patents that protect the production of medicines. We do not support the proposals that would seek to ignore intellectual property (IP) rights, and therefore, threaten the world wide benefits that come as a result of market driven innovation. The current efforts as represented by the Public Intellectual Property proponents are short sighted and bear potential negative down stream effects. Although as leaders of healthcare operations, and direct providers of health care in world wide locations, everyday we witness the consequences that occur with of lack of access to proper healthcare, and efficacious medicines. Too often we see that these consequences include premature, and excess, death. Although the proponents of cutting IP rights probably have good intentions these outcomes are neither satisfactory nor indicative of a good solution. People suffer from disease or die as much from inadequate care, as they do from no care at all. If we do not have continued access to innovative new medications and treatments, we will pay an ever escalating price economically, and in terms of an increase in global health risk and human suffering. A major corollary is that not only do we need access to innovative pharmaceuticals, but they must also be designed and produced in a manner that takes into account the variability of human response. This again requires strong incentives for quality research and development and not just mass production of pharmaceuticals solely on cost concerns. We have the view that the foundation for research, development, and distribution of new drugs should be patient centered (efficacious) first, followed by issues of cost. The use of generic drugs while beneficial in some cases must be demonstrated to be effective on a specific product basis and not approved on a presumed but not proven class effect. This is particularly important in diverse ethnic populations. Pharmaceutical products must have been developed including broad based and diverse populations in their research. The failure to follow this principle may have a disproportionate negative impact on poor and underserved people around the world. A significant percentage of these will be people of color.

2. Global Health Trends

Global health trends are influenced by a diverse set of exigencies, including, geographic location, environmental factors, cultural norms, political climate, and socioeconomic issues. Poverty is an incubator for disease burden and a multiplier of health disparities. Trends change over time with new understanding of disease and best practices.

In the not too distant past, infectious disease, famine, and drought were the major focus and concern in the public health arena. Today, this list is expanded by the increased occurrence of chronic diseases world wide. The World Health Assembly recognized in a recent resolution that:

There is a growing burden of diseases and conditions that disproportionately affect developing countries, particularly women and children. Reducing the very high incidence of communicable diseases in those countries is of continuing priority. At the same time, they noted it is important to ensure that the increasing prevalence of noncommunicable diseases in those countries is recognized and addressed. This means that the focus of global disease prevention and therapies must be broadened.

The causes previously thought of as the leading contributors to worldwide morbidity such as infectious disease, have now been joined by chronic diseases. Illnesses such as heart disease, diabetes, cardiovascular disease, and cancer have become even more prominent in terms of global morbidity and mortality, thereby adding to the list of major public health issues that must be urgently addressed. This is in part due to the longer life expectancy of the post “antibiotic” world, and in part due to the fact that many populations have developed sedentary and dietary lifestyles consistent with increased risk of chronic disease. This improved life expectancy may enable the negative manifestation of genetic polymorphisms in ethnic groups, that lead to disproportionate onset of chronic disease. The ravages of chronic disease are seen in greater concentrations in underserved, impoverished populations of color. These effects are further influenced by environment, nutrition, lifestyle, and poor access to efficacious medicines. The trend of disease tends to be reflective of a region’s or nation’s relative position in the world economic order. These trends are also affected by the priorities of local governments.

It may be difficult for a government to focus on a particular disease problem if there is famine, or if the area is a war zone. Where there is a lack of public infrastructure, an inadequate public health system, or an underdeveloped medical manufacturing, research and development (R&D) capability, the negative impact on health will be magnified. In this situation, acute disease processes may tend to be regarded as more urgent than the manifestations of chronic disease. Focus may be on short term solutions and survival, rather than on issues that will manifest in future morbidity, mortality, and damaging economic consequences.

Research-based pharmaceutical firms are today investing considerable effort and resources in the R&D of new treatments and vaccines for communicable diseases such as malaria, tuberculosis, rotavirus, and HIV/AIDS that are endemic in many poor countries. Pharmaceutical innovations by private research-based companies have led to the development and mass distribution of antibiotics and anti-retroviral medicines to treat infectious diseases widespread in developing countries. Because people in these developing countries increasingly now also suffer from, non-communicable diseases that were traditionally associated with the developed world also stand to benefit from pharmaceutical advances that impact chronic diseases. In addition, patients worldwide need medicines to treat not only potentially life-threatening diseases, but also debilitating conditions that undermine quality of life. For the relatively rare cases in which adequate market incentives are lacking for private-sector development of medicines for diseases that primarily affect poor countries, governments should consider creating incentives through mechanisms such as advance purchase commitments, voluntary licenses, “orphan drug” legislation, and public-private partnerships.

A number of organizations such as the WIPO, OECD, and other independent global institutions cite the lack of Intellectual Property as key factor behind low rates of economic growth and persistent poverty. IP development stimulates economic development which may lead to a better environment for improved health.

There are various approaches to address the issues of global health disparities, one method would establish a measurable “global health baseline”; this will be like the minimum wage index. We will strive to not only to attain, but to be above this measure for every individual citizen of the world. A crucial commitment must be made by the “haves” to the “have nots” so that all nations become “engaged stake-holders” in the planning process and each is held accountable for their duty and role in the accord. A consortium made up of the G8 nations, partnered with the W.H.O. and Pharma, might be the ideal vehicle to create, organize, and manage this effort to more effectively address global health issues. This global strategy would effectively declare war on disease worldwide, and would provide the initial framework and plan for achieving global optimum health. With today’s global economy, travel, and exposure, we are all at risk if any population is unhealthy and untreated. The threat of disease and poor health to any human is a threat to every human.

Successful medical innovation is crucial to everyone. In recent years governments, the pharmaceutical industry, charitable foundations, and non-governmental organizations have made progress by 1) funding initiatives to develop new products against diseases affecting developing countries, and 2) increasing access to existing products. However, these initiatives have proved inadequate to completely surmount the challenges that stand in the way of significantly improving global health. Much more must be done to decrease the avoidable suffering and mortality. Of all the methods employed, those of private enterprise R&D have proven to be the most successful. Advances in biomedical science have provided opportunities to develop new, affordable health products, and in particular to meet public health needs in developing countries. Examples include;

1. Advance Market Commitments (AMC): A contract between potential purchasers and R&D-based companies whereby the purchaser promises the company a set price and volume for a product if/when the product is fully developed.

2. Tropical Disease Fund: A fund for tropical diseases is similar to the Global Fund¹ in that it ensures that necessary finances are available to purchase medicines for neglected diseases.

3. Tropical Disease Acts: Similar to Orphan Drug Acts, this is a legislative package that provides research and market incentives to increase R&D for diseases of the developing world.

4. Strengthening Public-Private Sector Partnerships (PPPs): PPPs have proven to be an effective way to bring public and private sectors and academic research institutions together however finding sustainable funding sources has been a challenge. More funding is needed from bilateral and multilateral donors and governments. It should be a priority of multilaterals donors to implement policies to strengthen PPPs and promote funding.

Evidence shows that increased foreign investment is important to most governments and their progress. An increased level of intellectual property protection in developing countries leads to increased foreign investment. Higher standards of IP protection internationally leads to greater innovation worldwide. IP protection is a linchpin of continued and improved global health development. Opportunities of this type must be harnessed more effectively and more urgently.

In urgent medical situations that involve large numbers of affected people, an effective system of triage must be established in order to achieve health care success for the largest number of people. Triage starts with assessing and prioritizing available resources and the acute needs of the affected population. This is made difficult by the large disparities of health and healthcare that exist throughout the world. These problems are often exacerbated by local corruption that prevents resources from reaching those most in need. This type of issue could be better addressed from within an accord such as has been proposed.

For true success, the world, as led by the dominant G8 nations, must strive toward Global optimum health and take on this problem of reducing global health disparities. As members of global community, it is in our collective self interest to address global health issues. We must determine, and be aware of the threat to the survival of our own lifestyle and culture if we fail to address these problems.

The aim of the proposed global strategy for public health is to provide a medium-term framework for sustainable needs-driven, essential research and development program relevant to diseases disproportionately affecting developing countries.

Creating solutions to global disease trends requires determining their root causes, which may vary based upon geographical, political, socioeconomic and environmental locations.

The initial significant help that we can facilitate is to encourage each nation (both developed and undeveloped) to become engaged as a stakeholder in this process. Medical innovation and technology can and does play a key role in public health, but it must be calibrated to the needs, beliefs, and sensitivities of the people it is meant to help. We must demonstrate to each stakeholder nation that continued access to new pharmaceuticals and technology requires continued participation by our R&D companies.

The evidence is clear that successful medical innovation and respect of intellectual property go hand in hand. Ideally everything on earth should be free and available to everyone else, however, the practical implications of that idea, make it any thing but pragmatic. Businesses can only afford to distribute what they are being paid to produce.

Pharmaceutical innovation based on the current private –sector model has produced massive benefits for patients’ world wide. The success of this model is because of the existence of patent protection, which plays an important role in each step of the innovation process. The profit made by way of the patents allows these R&D companies to continue to under take their research and develop new knowledge.

If adequate incentives for drug creation aren’t there, schemes for distributing them will have no meaning. Without the current private sector model and their patents none of our modern drugs would have been developed, even for patients in the western markets.

Given the evolving nature of infectious disease and the magnitude of chronic disease, major continued innovations, and R&D will be needed. Research and development is fueled by investment of capital. This capital investment is driven by the potential of return on that investment. Unfortunately if these investments dry up because these ventures do not provide enough financial return to allow future investment, innovation will be hindered. What is missing on the global stage is that the interests of the various stake holders are not aligned. For the investor the primary interest is in growing the value of their equity share. The medical consumer on the otherhand, especially those in developing countries, are usually strictly consumers that have no economic stake or concern about the survival of the resource, they only want to receive successful treatment. Both of these view points need to be combined. We all are in the same boat if research and development fail to meet our joint needs of continual creation of products and cures. We all suffer if the companies stop all innovation. We have to create methods to give the consumers and the producers more points of alignment than they currently have. It should be clear that the entire world is at risk if an epidemic such as SARS or the bird flu reaches critical mass. Therefore we protect ourselves by making sure that there is no population that is unprotected.

There was a proposal sent to CIPH² advocated that governments set aside a fixed percentage of national output to finance pharmaceutical R&D, and abolish patents, to allow drugs to be produced by anyone. Governments would determine research priorities and the pharmaceutical companies would become contractors of the state. State-driven R&D has not proven to be effective in producing new medical therapies. It would be extremely expensive and inefficient for governments to develop capacity to conduct clinical trials. In addition the overall impetus for market competition would be removed. The R&D treaty is wrought with operational problems, one of which is the system's difficulty to govern and enforce. Another problem the treaty faces is that few countries currently contribute to fixed R&D costs and those countries not contributing would have little incentive to enter.

A mechanism should be developed wherein all countries, based upon a sliding scale or means test, would become equity shareholders in the pharmaceutical and health industry. This would trigger a self financed way to earn discounts on medications. The approach to eliminate health disparities should be setting a goal and a plan to obtain optimal health for all. This goal alone is the best approach to eliminate health disparities regarding medications and the protection of intellectual property. Having all nations as shareholders and stakeholders.

The role of most governments is to provide a framework and an infrastructure that facilitates the life activities of its citizens. Thus, a government should be a tool used by its people to accomplish together what they could not accomplish alone. The government should make sure its population has access to the best possible care and therapeutics. This can be done by investing in a vehicle that funds on their behalf into research and development companies. As these research and development companies become profitable, the countries can receive cash, or therapy, or both.

In the same way that countries don't like anyone to violate their sovereignty, these countries should be the first to respect Intellectual property rights. Nations of the world should seek, by the rule of law and sovereignty, to work with the research and development manufacturers towards a win-win situation that would directly benefit their government as well as their people.

Global Solutions

The global R&D-based pharmaceutical industry, by way of its past performance, is committed to meeting global health needs – both in the developed and developing world. The pharmaceutical industry, has developed the drugs used to successfully treat the greatest percentage of diseases worldwide, specifically:

- 1) All drugs in 8 different classes of cardiovascular drugs,
- 2) all of the most effective cancer drugs in 8 classes,
- 3) All recent and effective antibiotics for respiratory infections,

- 4) All 21 anti-retroviral drugs in 4 different classes, and
- 5) All recent drugs in 4 different classes to treat depression.

A possible way to approach global solutions to health issues, as mentioned before, is with a public private partnership that would be anchored by the G8, the W.H.O., and Pharma. These G8 nations have the greatest financial means and are also incentivized by their own risk in global health issues. Less fortunate and developing countries could benefit from this partnership for life and health. Together we could do more than any of us could do alone. In essence we would establish a virtual “super world department of health and human services” and a massive healthcare data base. This health vehicle would have two major arms:

- 1) WHO a health care data base.
 - A. Research and & development validity with Return on investment available to all participating countries.
- 2) Via the G8
 - A. Joint investment mechanisms allowing investment via financial aide credits. The intention is that all therapeutics should go through this mechanism at an agreed upon fair price.

Medical Solutions

Medical solutions are best, and least costly, when approached from a preventative standpoint. This would include providing health education, and risk reduction efforts, in the framework of proven best practices. Approaches and methods must be employed that will yield maximum patient compliance.

Global Poverty

Poverty on a global scale remains a challenge, but will best be helped by international cooperation on economic and health issues. Long term solutions will require major effort, goodwill and planning.

Research

Successful research and innovation require economic incentives. Historically societies that allow innovation to be financially rewarded have performed in a superior manner to those that do not. This is an important lesson for the future.

Although there are still many decisions to be made regarding the future course of action, systems that have the long term interest of global patients at heart must be preferred over short sighted solutions that destroy the hope of coming generations. We advocate that by protecting intellectual property rights, and honoring the patent process, we will engage the companies that lead R&D to remain positively and productively involved in solving

Global health issues .In order to maintain the protection of medical innovation it is imperative keep in place the positive incentives that protection of patents bring.

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Bibliography

1. Thailand's Compulsory Licensing on Drugs, Good Step for Public Health or Bad Precedent for Intellectual Property: Ronald A. Cass: March 2007
2. Commission on Intellectual Property Rights, Innovation and Public Health: WHA 56.27; 10th Plenary Meeting (CIPIH): May 2003
3. Intergovernmental Working Group to implement recommendations of the CIPIH Report; WHA 59.24; May 2003
4. Elements of a Global Strategy and Plan of Action: IGWG; Annex 1. Annex 2:
5. Commission on Health Research and Development
6. Second Class Medicine: Randall W. Maxey, M.D., Ph.D.: Health Disparities in African Americans: August 2007
7. Established in 2002, The Global Fund is the largest international funder of programs designed to combat malaria and tuberculosis, providing two-thirds of all financing, and provides 20% of all international funding to combat HIV/AIDS