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Promoting and Protecting Your (Global) Health
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My first words must be ones of thanks to Dr. Hamburg for her very gracious invitation to deliver one of the Commissioner's Global Health Lectures. I confess to being secretly pleased to be asked to speak here, in part because of my appreciation and admiration of the work you do and what you represent. From the distance this institution appears as a mighty rock standing firm, as it is buffeted from time to time by an unknowing public which criticizes for being too deliberate and simultaneously criticizes for delaying the availability of the latest life-saving medication or device. The buffeting winds and waves do not come only from the public, but sectors of industry regard it sometimes with suspicion and on occasion even less generously. Too infrequently are there public plaudits for the work you do or the tremendous national resource you represent. But I suppose that is the lot of public institutions. I also wish to thank my many friends for attending and particularly Ms. Lou Valdez who provided me with considerable amount of background material. In her invitation letter Dr. Hamburg asked me to address essentially three issues:

- The role of the agency as an integral part of the international public health and global health diplomacy community;
- The critical functions of regulatory systems and regulatory science that contribute to improved public health outcomes;
- The integration and strategic engagement of FDA in the international regulatory public health agenda and its possible leadership role.

I must congratulate the Commissioner on a lecture series on global health at an institution whose pristine function is to safeguard the health of the American people. I regard this as an acceptance of the verity that global health is very much about there being shared responsibility among global actors. But I should first explain my own take on the meaning and relevance of global health today and make the firm distinction between it and international health before positing any need for diplomacy or the role of the agency in that area. Global health is very much in fashion today and there must be

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very few health academic or other institutions which do not boast a program or department of global health. But much of what is called global health today is the former international health in new wineskins and that approach to health was rarely international anyway, in the sense of there being action between and among nations to improve health. I take global health as the field of research and practice directed towards addressing the health of all the world's people and particularly with reducing health inequities globally. We are concerned with the health of the poor, but it is of equal or greater concern that there is such a health gap between the rich and the poor within countries and between countries. The only way we can truly address these health inequities that are the nub and the pith of global health is through cooperative action among nations. International public health must therefore be the collaborative activities carried out among nations to address global health. I am always careful to make the distinction between the nation state and the government. The government is only one –albeit the most powerful one of the actors within the nation state, the others being civil society and the private sector. We must note that there is also a growing tendency for collective, cooperative action between these other non-government state actors in addressing major global health problems.

There are several myths about the major challenges in global health. One such is that the noncommunicable diseases (NCD)-(cardio-vascular disease, diabetes, cancer and chronic respiratory disease) represent a problem of the rich developed countries of the north and incidentally for that reason were not included in the Millennium Development Goals (MDGs) which were crafted in terms of the problems that affected the health and development of the poor. Another is that because life expectancy is less in the developing countries, they are not likely to experience a high burden of NCD, they are diseases of the elderly. The poor countries of the south should only be concerned with the communicable diseases. Luckily these and other myths are being dispelled and the low and middle income countries have to contend with the communicable as well as the noncommunicable diseases. The Secretary General of the United Nations said recently: *“The NCDs have emerged relatively unnoticed in the developing world and are now becoming a global epidemic”*. The data are now clear that NCD deaths account for two thirds of the 57 million deaths that occur annually and 80% of these NCD deaths occur in the poorest countries. The majority of these deaths from NCD occur in adults below the age of 70 years and three quarters of all adult deaths are due to NCD. They constitute a major economic burden for poor countries and the evidence is clear that we will not achieve the MDGs unless we prevent and control NCD.

What does this have to do with the FDA? There has been a successful political movement, endorsed by virtually all countries of the world to convene a United Nations High Level Meeting on the prevention and control of NCD with the participation of Heads of State and Government in New York in September this year. It is proposed that the Heads of State and Government be asked to address the four major risk factors for this diseases-tobacco, diet, physical inactivity and the harmful use of alcohol. The regulation of tobacco is certainly central to your remit and parenthetically, let me congratulate you on your work on the labeling of cigarette packages. I am sure the issue of healthy and unhealthy foods, the nutrient content and labeling of foods must also be within your area of action. In addition, the Heads are being asked to ensure the provision

of essential medicines and technologies for the treatment of these diseases. This could call for a major global effort to produce and assure the quality of existing products as well as developing new ones to treat these diseases. FDA has an enviable record in this field.

The global health diplomacy in which FDA would play a role must be seen as a special branch of diplomacy, which is usually considered to be the art and practice of conducting negotiations between accredited persons representing nations or groups within nations. Traditional diplomacy concerned itself with protecting the territorial integrity of the nation state, and to the extent that health issues affect the security of the nation, then there has to be a role for diplomacy. We must remember that the first modern negotiations on health agreements between nations, with the express purpose of controlling the spread of infectious disease-primarily cholera, was carried out by diplomats, and not by health officials. Apparently doctors did not have the temperament for the norms and niceties of diplomatic negotiation. It is worthwhile noting that there is a growing tendency for countries to be represented at international health fora by their diplomats and sometimes I wonder whether the essential health issues are not submerged beneath other diplomatic interests.

FDA is primarily a domestic agency and I believe that for it to play a substantive role in global health diplomacy, it must do this directly as a negotiator in the diplomatic sense with like entities in other countries, with the authority of its own government, or it must do so through supplying information to its own government diplomats or representatives as they negotiate agreements that influence the health of the world and reduce health inequities-the essence of global health. I know from experience that this agency has a long tradition of the latter, and I have no doubt that this country's positions on issues within your competence are informed by your advice. I will refer later to the role of FDA as a negotiator in its own right with its homologues around issues related to ensuring better health globally.

There was a time when health did not figure in international politics and the expertise of FDA might not have had the salience and relevance it has at this time. But this role of health has changed remarkably in the past few years for essentially two reasons.

First, there is the growing realization that health can affect national security. I do not mean national security in the sense of protection of territorial integrity, but in terms of contributing to human security and social stability. The HIV/AIDS pandemic and the potential of the recent H1N1 influenza epidemic are examples of how this fear of general contagion can affect national interests including the economic aspect of national life. The recent outbreak of E. coli infection in Europe and the reactions of governments at the highest levels is another example of a problem that appeared to have its beginning as a health issue but entered into the realm of foreign policy.

Countries are being forced to consider health within their foreign policy agendas. Indeed in December 2010 the United Nations addressed the issue and urged its Member

States to continue to consider health issues in the formulation of foreign policy. The Resolution A/65/L.27: *Encourages Member States to consider the close relationship between foreign policy and global health and to recognize that global health challenges require concerted and sustained efforts in order to further promote a global policy environment supportive of global health*; and further: *Encourages Member States, the UN System, academic institutions and networks to further increase their capacity for the training of diplomats and health officials, in particular those from developing countries, on global health and foreign policy, by developing best practices and guidelines for training and open source information and education and training resources for this purpose.*

But there is yet another and perhaps more important reason for countries to engage in global health diplomacy and for their key agencies to be involved. I am attracted to the notion of soft power being an important tool of diplomacy as advocated by Joseph Nye. This country is unparalleled in its capacity to use hard power as an instrument for negotiation, or perhaps instead of negotiation and FDA has no role there. But areas such as health and culture are instruments of soft power and present immense opportunities for exerting influence. Joseph Nye refers to soft power co-opting rather than coercing people. It is the ability to entice and attract which he says can lead to acquiescence or imitation. Every country in the world would say amen to the charge given to the FDA of *“protecting the public health by ensuring the safety, effectiveness, and security of human and veterinary drugs, biological products, and medical devices; ensuring the safety of foods, cosmetics, and radiation-emitting products; and regulating tobacco products.”* Your government through you and your competencies has an immense source of soft power which can be used to tremendous advantage.

But let us be clear that this engagement in international public health and global health diplomacy has two aspects. There is both altruism as well as self-interest. I assume that this country and its health agencies have a deep and abiding concern for reducing the health inequities that exist and therefore engage in global health. It does so principally by engaging in intergovernmental activities and fora and it is a major contributor to and adviser for the World Health Organization and similar agencies as the places in which there is the best chance for developing intergovernmental action. But there is also the aspect of self-interest and global health diplomacy has to consider the negotiations that lead to benefit for this country. The fact that the benefit is shared does not make it any less important to oneself.

FDA is famous as a regulatory agency, and I am impressed by the efforts to focus on regulatory science as a fundamental aspect of improving the public's health. The concept and practice of regulation as an essential part of public health has intrigued me for some time. I have often told the story that at the beginning of my second term as Director of the Pan American Health Organization (PAHO), I was very conscious of the Henry Ford's "we have arrived" syndrome and as was articulated by James Collins and Jerry Porras in their book "Built to Last", I thought of BHAGs-"big hairy audacious goals". These move and shake organizations. One BHAG was to focus the organization's attention on the essential public health functions. This was, I suppose somewhat

reductionist, but I thought we could distill into some manageable number the essential functions that needed to be carried out if societies were to be organized to address the health of their populations. It should be no surprise that one of the critical essential public health functions was that of regulation. Among the most critical powers a government has at its disposal for modulating societal action are legislation, taxation and regulation, and while the first two of these are usually functions of a central authority, regulation finds a place centrally as well as sectorally. Every good health system must embrace this regulatory function.

In its description of the essential functions of the health system, WHO regards stewardship as the most important one and identifies the basic tasks that fall under this rubric. They are first, formulating health policy-defining the vision and direction; second, exerting influence—approaches to regulation and third, collecting and using intelligence. There are clearly a wide range of areas to be regulated but they must be few more critical to maintaining the health of the population than those which come under the purview of FDA. Thus there is good basis for the claim that FDA is a public health agency and it its work critical to the public's health.

But I have to confess to a minor disquiet I have always had in terms of the methods necessary to ensure the safety of the sanitary and social measures necessary to protect the public's health—which is in essence the role of FDA. The nature of science is such that there is never absolute certainty. There may well be a black swan. What is the level of acceptable risk and who determines that level? One often has the impression from the popular press and the litigation that attends bad health outcomes that no level of risk is acceptable and there can indeed be perfection. There must be a great deal written about this in the context of regulatory science, and I imagine that this must be an area that engenders considerable debate among you. Of course this is not new to science and I wonder if the continuous development of more sophisticated statistical methods increases our comfort level about uncertainty.

The definition of regulatory science as espoused by Dr. Hamburg and her colleagues is very clear, but I have wondered whether the science lies in the selection and development of the appropriate tools or predominantly in the tools themselves, as there is an almost inexhaustible panoply of scientific information that can be assembled for assessing the safety, efficacy, quality and performance of the products regulated by FDA. The rate of growth of much of the science employed by FDA has been vertiginous and especially so in the field of information and informatics. This has revolutionized our concept of the integrity of the nation state and has changed the information asymmetry that was so dominant a feature of health practice. I have learnt that the social culture of organizations changes much more slowly than the technology and it must be interesting to learn how the culture of an organization such as yours, initially with a limited number of tools and a strictly domestic focus has changed its bureaucracy and internal culture as you have adapted to the new vision of the agency and the vastly increased scientific armamentarium at your disposal.

Of course you strive for perfection and a level of oversight and regulation that reduces risk to some minimum. This recalls a passage from de Tocqueville's account of democracy in America, written just about 100 years before I was born. It seemed to me to be so relevant to much of what we strive to achieve in many fields of human endeavor including science. He speaks of human perfectibility.

"In proportion as castes disappear and the classes of society approximate-as manners, customs and laws vary, from the tumultuous intercourse of men-as new facts arise-as new truths are brought to light-as ancient opinions are dissipated, and others take their place-the image of an ideal but always fugitive perfection presents itself to the human mind. Continual changes are then every instant occurring under the observation of every man: the position of some is rendered worse; and he learns but too well that no people and no individual how enlightened soever they may be, can lay claim to infallibility. It can hardly be believed how many facts naturally flow from the philosophical theory of the indefinite perfectibility of man....".

I read the eloquent presentation given by Dr. Hamburg to the IOM Committee on regulatory systems harmonization in developing countries and doubtless the Committee will make recommendations on the practicability and feasibility of a global regulatory system. The arguments advanced by Dr. Hamburg were compelling as regards the impact of globalization on the movement of the substances for which FDA has a regulatory responsibility. It is necessary to ensure the quality and safety of those products before they reach the United States and this clearly involves having regulatory capacity in which there is confidence in the countries of origin of these products.

My experience with this issue was refreshed when I was named Chair of a WHO Expert Working Group charged to address current financing of research and development, coordination of research and development and make proposals for new innovative sources of financing to stimulate research and development. Our report concluded that one of the possible mechanisms for reducing the cost of developing and marketing new products was through regulatory harmonization and that it should be possible to align the regulatory requirements of a number of developing countries, more particularly those with greater production capacity. What was striking was the tremendous variation in the efforts at regulatory harmonization in the different parts of the world. In the Americas, the Pan American Network for drug regulatory harmonization grew out of the Pan American Conference on Drug Regulatory Harmonization which took place in 1999. The different national legislative frameworks present a major obstacle and it was felt that countries might not have enough trust to agree to a regionally harmonized system. It was suggested that the reluctance of countries to lose income from regulatory fees also constituted a barrier to any regional or global approach.

There is no doubt that FDA has a role in integrating itself into the efforts to develop international regulatory practice. But I am sure you recognize that this is a

tortuous and incredibly slow process that touches on the nerve of national sovereignty in which your diplomatic skills and patience will be tried. After all, it has taken Europe 45 years to reach the stage of committing to pharmacovigilance legislation. Your leadership role in the International Conference on Harmonization must surely stand you in good stead and I can only encourage you to continue to play a role in the regional and global schemes, but at the same time engage directly those countries with more advanced regulatory frameworks and practices and which are of more importance to you because of the bilateral flows of products in which you have interest. The mutuality of interest that is the prerequisite of fruitful cooperation is present, and I am sure you are aware of the fine line between exerting leadership and partnering with others for mutual benefit. Believe me that this is not unique to regulatory harmonization.

Ladies and gentlemen, I have tried to address the three issues with which Dr. Hamburg charged me, and I am sure that much of what I have said has occupied the attention of this agency over the years although some issues have assumed greater relevance especially since the rapid increase in interconnectedness has changed our society forever. Fortunately what has not changed for men and women of goodwill is a basic appreciation of our shared humanity and the need to reach out and help one another. As John Donne wrote about 400 years ago: "No man is an island of itself" and as Bob Marley sang almost 40 years ago in similar vein: "When the rain fall, it don't fall on one man's housetop".

I wish you good luck and trust that the image of the rock which I drew initially will continue to be an appropriate one for you.

I thank you for your attention.