September 6, 2011

Ms. Adriana Velazquez-Berumen,
Acting Director of Essential Health Technologies
Diagnostic Imaging and Medical Devices
World Health Organization
Avenue Appia 20
1211 Geneva 27
Switzerland

Dear Ms. Velazquez:

On behalf of the Global Medical Technology Alliance (GMTA), and as foreseen in our June 28, 2011 letter, we are providing our ideas for possible joint work with the WHO. We appreciate the increasingly constructive dialogue to date and hope this identification of areas of common interest and work, within the bounds of WHO rules, will be discussed in our upcoming October 12, 2011 meeting.

The GMTA is a new and growing body. We can offer diverse experience in a wide range of technologies, knowledge and experience with different regulatory and reimbursement systems, and expertise in training and product development and delivery. However, our resources are limited.

We propose initial work in selected areas. We believe the proposed work items reflect several areas of shared interests. The Essential Health Technologies (EHT) group may find that some of the topics would also help focus on specific issues for consideration at the planned Second Global Forum on Medical Devices. As these initial coordination efforts succeed and the GMTA grows, we hope to be able to expand our joint efforts

The GMTA looks forward to working collaboratively and constructively with WHO and other stakeholders, as appropriate, to contribute to saving lives, reducing disabilities, promoting quality of life, and creating sustainable health care systems. We welcome Director General Chan's stated interest in finding synergies with the private sector and other stakeholders to work with WHO to achieve its goals.

The medical technology industry has a successful history of working to develop sustainable solutions to improve healthcare infrastructures around the world –

and these efforts are increasing. We hope you will view the GMTA as a resource as the WHO develops its many projects related to medical technology.

Our facilitator in Geneva, Ms. Tatjana Sachse of Sidley Austin LLP, remains ready and available to contact us at any time with requests or questions you may have. Her contact information is: tel. (022) 308 00 80 and email: tsachse@sidley.com.

Sincerely,

Ralph Ives
GMTA Co-Chair

John Wilkinson
GMTA Co-Chair

PROPOSED SHARED INTERESTS
FOR THE DEVELOPMENT OF A WORKPLAN
FOR COOPERATIVE EFFORTS BETWEEN
THE WORLD HEALTH ORGANIZATION
AND THE GLOBAL MEDICAL TECHNOLOGY ALLIANCE

Overall Shared Interests

The Global Medical Technology Alliance (GMTA) shares many common goals with the World Health Organization (WHO). We note that the WHO's agenda in 2011 identifies six broad priority areas, which include ways to promote the development and strengthening of health systems. Health technologies are one of the six building blocks identified by WHO as essential for all health systems (along with financing, health workforce, information, service delivery and leadership/governance). Members of the GMTA support the objectives of providing safe, effective and innovative medical technology that saves and enhances lives, benefiting people and society. We believe we can meaningfully contribute to the WHO's agenda in this field.

In addition, the WHO Office of Essential Health Technologies listed the "4 As" -- availability, accessibility, appropriateness and affordability -- as key components of its agenda. The First Global Forum on Medical Devices considered a number of recommendations to advance this agenda, some of which are already being acted upon.

Taking into account these important WHO objectives, the GMTA suggests the following set of "shared interests" and activities for an initial work program:

- Ensuring patient and healthcare professionals' safety;
- Delivering Quality Medical Technologies To Patients; and
- Encouraging Ethical Business Practices

The shared interests proposed below should be viewed as interrelated factors, each reinforcing the other. For example, improving ethical business practices would focus on purchasing medical technology based on the best value and safest high quality products, instead of improper inducements to government officials and others. At the same time, medical technology is only one of the

building blocks of effective health care delivery systems, and must be considered in relation to the overall needs and resources of a particular society.

Proposed Shared Interests

1. Ensuring Patient and Healthcare Professionals' Safety

All stakeholders share an interest in ensuring that patient safety is the highest priority in the selection and use of diagnostic and therapeutic medical technologies across all health systems. At the same time, protection of healthcare workers from avoidable occupational risks is also essential to health systems – especially with many developing countries facing a severe shortage of trained healthcare personnel. Training of health care workers on medical technology appropriate for each patient is essential. Adopting sound regulatory requirements and practices, including pre-market assessment and post-market vigilance, provides greater assurances of patient safety. Regulatory systems based on harmonized international guidance and standards improve the attractiveness of a country's market by reducing compliance costs, which are reflected in prices -- thereby enhancing accessibility with greater patient choice, and affordability with lower prices. In addition, measures to reduce the incidence of healthcare associated infections (HAIs) – by patients and by healthcare professionals, who are exposed to infectious diseases -- improve safety and address affordability through a substantial reduction of healthcare costs by reducing morbidity and mortality from avoidable infections.

The GMTA suggests the following activities to promote patient safety related to medical technologies.

A. **Training:** Member companies of the associations represented by the GMTA already provide considerable training to healthcare workers on the use of medical devices and diagnostics. The GMTA would welcome a structured discussion with the WHO on:

    - ways to expand and improve training on medical technology in developing countries; and
    - development of information on the impact of HAIs and best practices to reduce the spread of this very preventable problem (including our ongoing work in the field of injection safety and infection control through the WHO SIGN initiative).

B. **Regulatory Systems:** Sound regulatory requirements and practices promote patient safety through clear, appropriate, efficient, and internationally consistent regulations covering those who develop, produce and place medical technologies on the market. At the same time, we urge that governments should establish regulations in line with their abilities and resources to implement and sustain them. Also, as governments develop

regulations, they should ensure that they are harmonized with international guidance. Such an approach helps reduce costs and enhances the accessibility of appropriate medical technology. Some of the steps that the GMTA could take in cooperation with WHO are:

- Expand the use and understanding of labelling based on internationally recognized standard symbols for some medical devices;
- Develop and encourage alternative methods and formats for the acceptance of labelling (e.g., electronic, streaming, etc);
- Promote understanding of a structured approach to implementing medical technology regulations based on Global Harmonization Task Force (GHTF) guidance;
- Work with WHO and member states to promote broader acceptance and greater use of internationally harmonized regulatory practices; and
- Develop regulatory training programs, possibly in conjunction with on-going efforts in other multilateral fora, such as APEC.

2. Delivering Quality Medical Technologies To Patients

Developing and delivering appropriate, affordable and reliable medical technologies to patients depend not only on determining patients' needs but also on research and development (R&D), a functioning supply chain, and fair and transparent procurement practices. Likewise, the supply chain – from manufacturer to the patient – should be better understood as part of any consideration of prices and distribution, especially in an age where lean systems are deployed widely as a means to drive down costs. Finally, appropriate methods of purchasing medical technology are critically important to minimize costs and to ensure patients receive the best quality care.

The GMTA recommends working with the WHO on the following activities to promote a better understanding of, and improvements in, the delivery of quality medical technologies to patients.

A. **Supply chain:** Development and manufacturing of medical technology is only part of the challenge of patient accessibility. Delivery, technical support, and servicing of the products are also essential. The GMTA offers to present to the WHO an analysis of the various components of the supply chain. Such an analysis would contribute to the WHO's project on "Definition of a methodology to measure price components and affordability on medical devices." We would then welcome a discussion of elements of the supply chain.

B. **Purchasing:** There is a variety of methods used by the private sector and governments in different countries in the purchase of medical technology.

There is also a wide range of medical devices and diagnostics currently on the market at affordable prices in developing countries or being developed for different income levels. We assume the EHT group would be most interested in helping Member States develop government capacity for the sound procurement of medical technology. One method governments use is public tendering, however, this often presents challenges of determining quality, evaluating appropriateness, and avoiding discrimination and corruption. The GMTA is prepared to present studies and recommendations on:

- Best practices in tendering systems, including quality criteria;
- Appropriate use of health technology assessment in medical technology procurement decisions; and
- Steps being taken by industry to develop "market appropriate" solutions to medical technology needs, which would contribute to WHO work on "Assessment of the World's Needs for Health Technologies."

3. Encouraging Ethical Business Practices

In order to promote health development and equitable access to appropriate and affordable technologies for patients, it is necessary to eliminate unethical and corrupt practices in procurement. Efforts to do so should be made in the development, manufacturing, promotion, procurement, management, or use of medical technologies. This objective deserves the WHO's attention in its own right. In addition, eliminating such practices reduces costs to patients and industry. Studies by Transparency International (TI) and the Organisation for Economic Co-operation and Development (OECD) show that unethical and corrupt practices have the most severe impact on the most vulnerable societies. Eliminating corrupt practices is integral to the sustainability of health care systems to ensure the availability and supply of safe and appropriate medical technology for health care providers and patients. Addressing corruption will become increasingly important as the geographic origin of medical technology becomes even more diverse. We would welcome the opportunity to work with the WHO in the following areas.

A. **Education:** Experience suggests that corrupt business practices exist, probably more widely in countries with weak governance systems GMTA associations have on-going programs to educate member companies – including through various committees and conferences – to promote adherence to our codes' principles. Adherence to the codes applies not just in the associations' home countries but on a global basis. We recommend that the WHO convene experts from appropriate institutions (e.g. OECD) and NGOs (e.g., TI) to provide their views and assessments of this problem. The GMTA could contribute with our ideas.

B. **Code Principles:** A condition for membership in the GMTA is to have a code of ethical business practices. In addition, individual members of GMTA

are working with countries on harmonized principles of business conduct. For example, this work was memorialized within APEC as the “Kuala Lumpur Principles” earlier this year. We recommend that the GMTA work with the WHO to promote an understanding, and expanded adoption, of code principles.