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RE: Draft Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines (Medicines Guidelines or Draft)

Dear Dr. Khosla:

Thank you for soliciting broad consultation on the Medicines Guidelines. I am a community advisory board member in the U.S. National Institutes of Health (NIH) networks that conduct domestic and international clinical trials dedicated to research for the treatment and prevention of HIV/AIDS. I served as a community representative peer reviewer in the University of California HIV/AIDS Program grant awards and as a working group member for the NIH Office of AIDS Research FY 2009 Trans-NIH Plan for HIV-Related Research, section on natural history and epidemiology. Other advocacy efforts for those affected by HIV and participants in research also provide occasion to take great interest in the Medicines Guidelines.

These comments offer reasons why the Medicines Guidelines may be expanded to address additional human rights values along with those in the Draft. Attached to these narrative comments, a redline markup proposes edits that could incorporate those ideas; the suggested edits are indicated in ***bold italic underline***.

## EXPANSION OF MEDICINES GUIDELINES:

### Other Norms and Standards

The materials mention the benefit from identification of relevant human rights laws, norms and standards to support the Medicines Guidelines.[1] For that purpose, the Global Sullivan Principles for Social Responsibility, to which many businesses are signatory, list corporate and business codes of conduct that are compatible with the Draft. [2] These include commitments to:

- Provide a safe and healthy workplace; protect human health and the environment; and promote sustainable development.

[1] Medicines Guidelines, p. 3.
[2] http://www.globalsullivanprinciples.org/principles.htm

- Promote fair competition including respect for intellectual and other property rights, and not offer, pay or accept bribes.
- Work with governments and communities in which we do business to improve the quality of life in those communities-- their educational, cultural, economic and social well being--and seek to provide training and opportunities for workers from disadvantaged backgrounds.
- Promote the application of these Principles by those with whom we do business.

The Medicines Guidelines may adapt some of the Sullivan Principles wording. Perhaps equally useful is to recognize that the Principles call for harmonized application of all commitments so that they do not act at odds with each other. Competition is deemed "fair" to the extent it supports other values to improve quality of life and is protective of human health.

**Disparities for Different Populations**

Health disparities caused by underrepresentation in research and access to medicine have been documented for a number of populations based on race, ethnicity, advanced age, sexual identity or orientation or socio-economic status.[3] In the United States for example a disproportionate number of African Americans and Hispanics affected by HIV typically learn of their infections only after serious immune system compromises have occurred which could have been treated more effectively had they been discovered earlier. Affordability and lack of trust in health care may cause these delays. These concerns are universal even if the makeup of a particular underrepresented group varies in different countries. Discrimination based on sexual orientation or identity in many countries results in denial of care. Members of the UN and the Special Rapporteur's office have recognized ways to reverse this disparity in adoption of "PRINCIPLE 17. The Right to the Highest Attainable Standard of Health" within the Yogyakarta Principles.[4] For these reasons, the list of patient populations needing particular attention identified in Guideline 6 may be expanded.

**Access at the End of Research for Participants and Other Post Research Commitment**

The case for access to beneficial interventions, procedures or products or other care at the end of research is well established.[5] Continued affordable access for the persons who

[3] See for example, Institute of Medicine. Unequal Treatment. Confronting Racial and Ethnic Disparities in Health Care (2002) http://www.nap.edu/catalog.php?record_id=10260 and David Easa, MD, Keith Norris, MD, Zoë Hammatt, Esq, MPhil, Kari Kim, BA, CIP, Esther Hernandez, RN, BSN, Kambrie Kato, Venkataraman Balaraman, MD, Tammy Ho, MBA, and Samuel Shomaker, MD, The Research Subject Advocate at Minority Clinical Research Centers: An Added Resource for Protection of Human Subjects JD Ethn Dis. 2005; 15(4 Suppl 5): S5–107-10. ; Vivek H. Murthy, MD, MBA; Harlan M. Krumholz, MD, SM; Cary P. Gross, MD Participation in Cancer Clinical Trials Race-, Sex-, and Age-Based Disparities JAMA. 2004;291:2720-2726.

[4] http://www.yogyakartaprinciples.org/principles_en.pdf

[5] See for example Shapiro HT and Meslin EM. Ethical Issues in the Design and Conduct of Clinical Trials in Developing Countries. New England Journal of Medicine 2001; 345: 139-141

actually took part in the study or sequence of studies is especially necessary to confirm the principles of justice in undertaking research that exposes them to medical risks. Ethical research must be conducted so that those who participate are not subjected to an imbalance of risks and benefits. In the event that a particular research study or sequence of studies is unable to prove the safety and effectiveness of an intervention or product, justice may be served by attention to principles of reasonable ancillary care that avoids characteristics of undue influence to participate.[6]

Research often ends after successfully proving safety and efficacy in a relatively short time period and in a sizeable but still select group. When medicines are used chronically in large populations, continued attention and response to safety and efficacy contributes to protection of human health.

## Special Considerations in Pharmaceutical Company Collection and Use of Genetic Data

The Medicines Guidelines, in elements 19-28, address some but not all relevant intellectual property rights. Intellectual property consists of patents, manufacturing know how, ownership of trade secret or other data and materials as well as other property rights.

Increasingly, pharmaceutical companies, academic researchers and clinicians collect biological specimens and other data to characterize genetic determinants of disease or to develop products. The potential public health value of this data deserves enthusiastic support. At the same time misuse of genetic information could affect family or groups related to the research participant or patient.[7] Added security and confidentiality for the data and preventing nonmedical use of data are appropriate.[8] A duty of care in these circumstances includes actions in addition to providing cautions expressed during the research informed consent process, and that duty applies to individuals related to the specimen or sample donor.[9] Actions that are within their control to protect privacy, prevent sharing of data for any nonmedical purpose or a purpose that could result in discrimination, stigma, denial of insurance or care are values companies may adopt.

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[6] Potter D, Goldenberg RL, Chao A, Sinkala M, Degroot A, Stringer JS, Bulterys M, Vermund SH.Do targeted HIV programs improve overall care for pregnant women?: Antenatal syphilis management in Zambia before and after implementation of prevention of mother-to-child HIV transmission programs .J Acquir Immune Defic Syndr. 2008 Jan 1;47(1):79-85. and also http://philosophy.georgetown.edu/ancillarycare/

[7] UNESCO. International Declaration on Human Genetic Data (October, 2003) http://portal.unesco.org/shs/en/ev.php-URL_ID=1882&URL_DO=DO_TOPIC&URL_SECTION=201.html ; Council for International Organizations of Medical Sciences current draft "International Ethical Guidelines for Epidemiological Studies." http://www.cioms.ch/070516april_epi_revisions.pdf , accessed February 23, 2008. The draft explains impacts on the individual, families and groups on pp. 65-66.

[8] NIH has conducted helpful public comment procedure on these issues available at http://www.nhlbi.nih.gov/funding/policies/rfi-genome.htm

[9] Reinhard R. Consent for Genomic Epidemiology in Developing Countries: Added human subject protection also needed."(2007) PLoS Med 4(6): e214. doi:10.1371/journal.pmed.0040214

Pharmaceutical companies also should take special care when data are shared or transferred to others during acquisitions, mergers or combinations that successors who come to own the data maintain the protections that individuals require. These protections can be implemented consistent with the great value expected from genome study.

Another aspect of pharmaceutical company practice in the use of genetic data is to consider ways to return value to individuals in exchange for the use and ownership of their biological samples. It is often not practical or possible to recognize a distinct personal ownership interest in products or research tools that emerge years later from long term use of biological samples or data without deterring the very product development that should be encouraged. However, other means are available to recognize the contribution of individual donors. Please consider incorporating the recommendations of the international Human Genome Organisation Ethics Committee, STATEMENT ON BENEFIT-SHARING.[10]

**Pricing Practices of Pharmaceutical Companies**

The Medicines Guidelines appreciate the difficulty of proscribing mandatory or command and control requirements over pricing. Pharmaceutical companies often assert that high costs of some medicines are necessary because of extraordinary costs to bring new products to market and the need to fund further research into new products, many of which are not ultimately successful and cannot enter the market.

Those industry rationales make sense but may not respond clearly to full human rights issues in relation to access to medicines. First, all industries, not just pharmaceutical businesses, reinvest profits for growth and experience high costs for product development. In the case of most standard commodities, human rights elements are not as central as they are as when human life is at stake. For those standard products, "whatever the market will bear" is a rational pricing mechanism. A more sensitive and transparent operational implementation of reinvestment is required when medicine is the product.

Pharmaceutical companies may be asked to provide transparent reporting about the ways in which research for new products emerges from revenues for expensive essential drugs. A research agenda that is robust and emphatic in the development of truly new molecular entities or significant advances in therapy directed at serious illness respects the burden patients bear in paying for essential pharmaceutical products. Many discussions refer to patients as health care "consumers," seemingly free to exercise wide personal choice. Patient use of medicine is not often similar to consumer behavior for nonessential goods. By investing in new products that may offer marked improvements in global public health, the direct connections between high costs and advances in health care become more intelligible.

[10] Human Genome Organisation Ethics Committee, STATEMENT ON BENEFIT-SHARING; April 9 2000 http://www.hugo-international.org/Statement_on_Benefit_Sharing.htm

Second, the selection of broad differential pricing schemes based on low, middle or high income national measures may not capture a sufficient range of the inequities for access to medicine. Even in high income countries, large segments of the population may be excluded from enjoying the benefits others have access to, and great disparities in health care result. Pharmaceutical companies may be asked to take into account the ability to pay of affected populations regardless of nationality in setting pricing and discount schemes. These pricing practices should exhibit leadership and cooperation with government programs and not rely solely on government programs to remove the pressures on individuals to pay for medicines.

A high price for a product may result, inadvertently, in a competition among patients with different illnesses, a regressive transfer of burden. Should a cancer patient's payments be a source of revenue relied upon to fund HIV research or vice versa? Should either fund research by their payments into drugs for illnesses that are not life threatening? A one to one correspondence of revenues and costs for illnesses would not be practical and could cause overall harm. Patients benefit mutually over the course of their lifetimes. The Medicines Guidelines attention to neglected diseases is a primary step companies may take to address a global inequity. But, to mitigate the way in which individual, perhaps unconnected, patients are relied upon as the ultimate source of revenue for those efforts, companies may also take actions to moderate prices and to secure access to medicine for serious life threatening illness or which treat serious impairment or disability.

Pharmaceutical companies may legitimately ask why they should practice each or all of the Guidelines. A partial answer is that these practices, collectively, build necessary long term and significant public trust in the research and pharmaceutical enterprise which companies require to maintain the whole life cycle of their development and marketing programs.

Thank you for consideration of these comments. The Medicines Guidelines effort, which has already evolved to a level of great worth, is much appreciated. Please contact me at tel: 01-415/268-7469 or email at RJReinhard@gmail.com if you have any questions.

Sincerely,

Robert Reinhard
Community Advisory Board Member