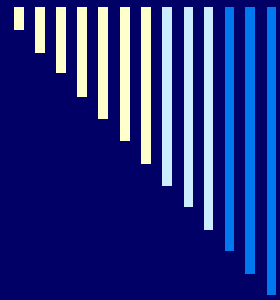


The WHO and the IGWG: Unspoken Concerns about Intellectual Property and Access to Drugs Around the World

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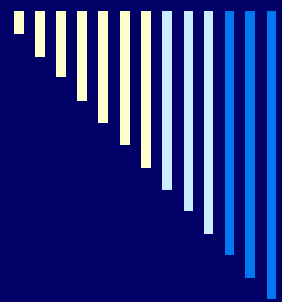
My interests/biases

- Started my health career in public health in the late 1970's
- Since 1986 have been at McMaster university where "innovation" is our way of life
- Being a mid-career academic I respect role of IP in research incentivization



My concerns *cont'd*:

- In preparing for this presentation, 9/10 points in IGWG's Draft have been re-numbered and shuffled about by the two drafting teams
 - Why?
 - What are they trying to hide?
 - Very hard to track changes, subtleties, intentions etc.
-



My concerns:

□ Implementation

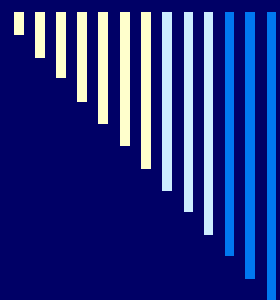
- Realization of intended outcomes will be dependent upon its implementation
- Regulation changes behaviours not policy
- Research shows that policies without regulations or with improper regulations exacerbate problems meant to be fixed
- Government schemes usually exacerbate and institutionalize problems



My concerns *cont'd*:

□ Disease types

- IGWG focusing on *all* 3 types whereas the public health crisis in mid- and lower-income countries is in Type II and Type III diseases
 - Whole world benefits now when a new product for a Type I disease comes to market
 - Focus on private-public partnerships re Type II and Type III



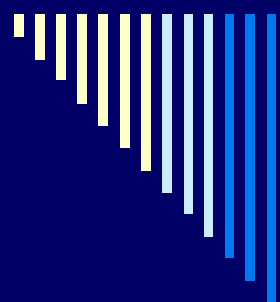
My concerns *cont'd*:

- International R&D Treaty
 - Aim: cost-effectiveness
 - WTO purview
 - Ignores legal rights re protection of intellectual property (WIPO)



My concerns *cont'd*:

- Flexibilities under the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS)
 - in the name of “public health” governments and commercial pirates have circumvented laws re IP
 - E.g. compulsory licensing produces product for export and not for a pandemic at home as intended



My concerns *cont'd*:

- Compulsory Licensing
 - A “flexibility” under TRIPS
 - Established for humanitarian reasons
 - Patent owners already producing at lowest marginal cost
 - Has allowed privateering by mid-income countries
 - Thailand et.al. - out-right patent theft for economic gain; economic privateering not public health



My concerns *cont'd*:

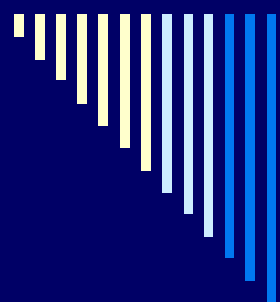
- Compound libraries open to all
 - 700,000 substances → 1,000 compounds → 1 effective, commercial drug (10-12 years/ \$1.3billion)
 - This is not simple
 - Safety an issue
 - Bioterrorism a real threat
 - Voluntary partnerships exist and should be promoted, supported and expanded
-



My concerns *cont'd*:

□ Open Source Research

- IP is the only incentive to devote one's life to the pursuit of the improbable
 - Open source works where costs are low
 - Difficult to attract research scientists, reagents, capital and equipment where costs are high (pharma)
 - Voluntary arrangements exist and should continue
-



My concerns *cont'd*:

□ Open Access Databases

- Data is key to scientific advancement; innovation of tomorrow builds upon yesterday's research
- Data protection is as important as patent protection as an incentive to invest in R&D
- Safety and security again



My concerns *cont'd*:

□ Patent pools

- Ideal where commodities are being manufactured and little innovation required
 - New innovative drugs (whether small or large molecule) are not commodities
 - Voluntary collaborations between and among firms exist and growing
-



My concerns *cont'd*:

□ Safety

- Toy recalls!
- Good manufacturing procedures tough to meet even in developed countries
- Need global harmonization and enforcement of health, safety and environmental mfg standards
- 20% of drugs manufactured in mid and low-income countries are NOT safe
 - 50% are counterfeit



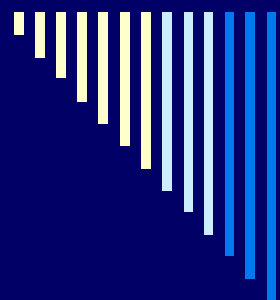
My concerns *cont'd*:

- Whither the patient's voice?
 - Consultation timelines were too short
 - Patient groups were not consulted
 - Paternalistic, top-down social engineering does not work
 - Potentially pits patients in developed countries against patients in developing countries
-



My concerns *cont'd*:

- Discovery is serendipitous
 - Governments don't innovate
 - US\$56B in 2003 or 45% of global R&D \$
 - Big business doesn't innovate
 - US\$61B in 2003 or 48% of global R&D \$
 - Individual researchers discover innovations
 - IGWG Proposal: governments fund drug R&D and let the generics make them
 - Climate for innovation in all jurisdictions
-



My concerns *cont'd*:

- Intellectual property as a barrier
 - Nonsense; IP breeds innovation & its dissemination (WIPO – sister to WHO); IP improves access
 - 90% of WHO's essential medicines are off-patent
 - Reality is money, power, politics and ideologies are the real barriers



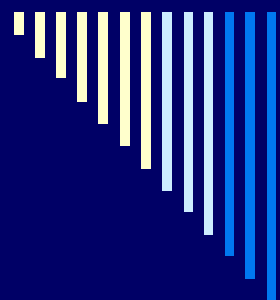
My concerns *cont'd*:

- The poorest of countries can get the drugs they need
 - Already negotiated, preferential, no-profit pricing as well as “giveaways”
 - Need to shift domestic government spending from bullets and caviar to drugs
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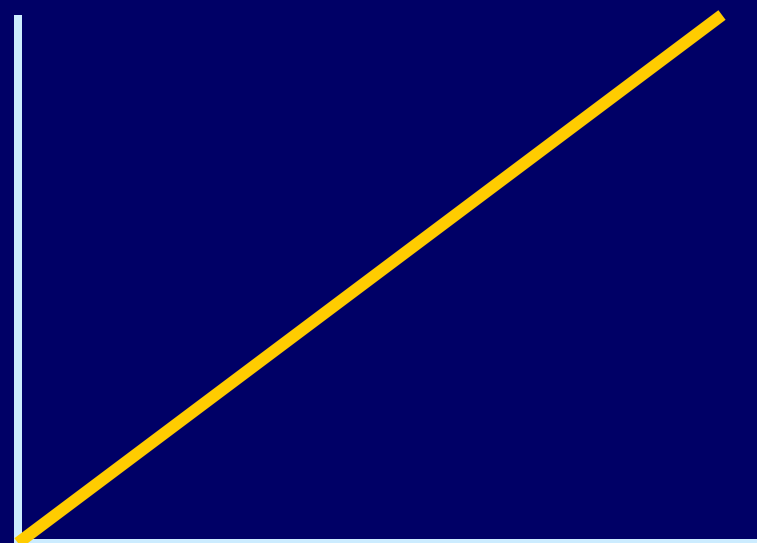
Real Issues in Mid- and Lower-Income Countries

- ❑ Market failure
- ❑ Corruption
- ❑ Roads/transport
- ❑ Potable water
- ❑ Basic education
- ❑ Rule of law
- ❑ Sexual behaviours
- ❑ Health budgets
- ❑ Communication
- ❑ Health Human Resources
- ❑ Taxation/tariffs
- ❑ Security
- ❑ Lack of political will

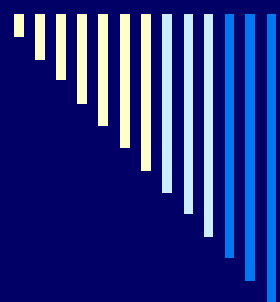


Real Issues in Mid- and Lower-Income Countries *cont'd*

Democracy,
Freedom,
Wealth distribution



Innovation



The Democratic Deficit @ IGWG

- Unelected elites succeed, trample IP rights and stifle innovation, whither health in low- and mid-income countries then?
 - Yes, there *is* a public health crisis
 - Yes, *we all* need to help
 - Caused by the ruling regimes and needs to be *solved by those same* ruling regimes
 - *Not* at the expense of healthcare innovation

