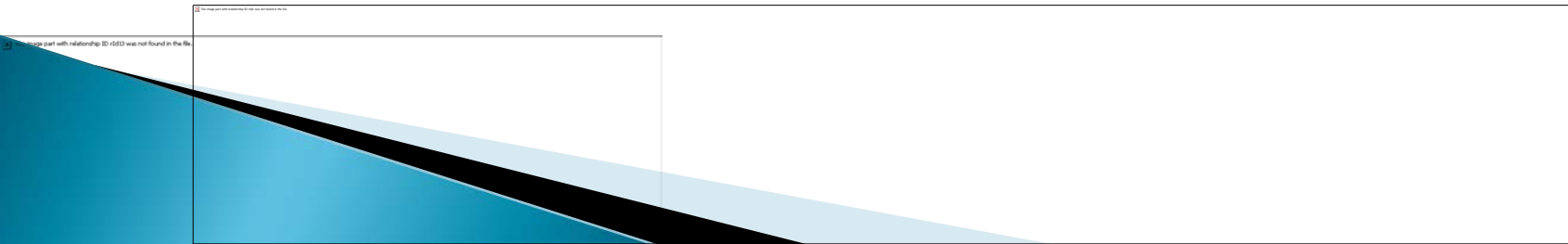


Human Gene Editing: International Governance

International Summit of Human Gene Editing
December 2, 2015

Gary E. Marchant, Ph.D., J.D.
gary.marchant@asu.edu



Arguments for International Governance

- ▶ International standards assure equal protection for citizens of all nations
- ▶ Uniform national requirements discourage medical tourism
- ▶ International standards provide consistent requirements for companies and scientists in the field
- ▶ Harmonized national standards prevent trade disputes (eg GMOs)
- ▶ Prevent “race to the bottom” or “risk havens”
- ▶ Regulators benefit from economies of scale and sharing resources and workload

Arguments Against International Governance

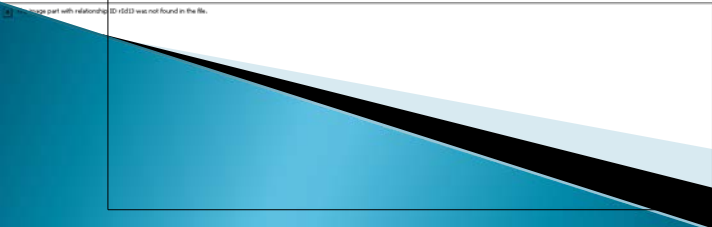
- ▶ Different social, political, and ethical norms in different countries
- ▶ Different national approaches allows for experimentation on different governance approaches
- ▶ Large resources, time and effort needed to create international standards might be better utilized in developing national oversight
- ▶ Complete agreement and compliance by all nations highly unlikely

Timing of International vs. National Standards

- ▶ Francis Fukuyama:
 - “[R]egulation cannot work in a globalized world unless it is global in scope. Nonetheless, national-level regulation must come first. Effective regulation almost never starts at an international level” *Foreign Policy*, Mar/Apr 2002.
- ▶ But developing national regulations first may:
 - unduly delay international regime
 - be more difficult in the face of entrenched and inconsistent national regulations (e.g., GMOs)



Image part with relationship ID:5513 was not found in the file.



Mechanisms of International Convergence

Traditional “Hard Law”: Treaties and Other Formal Agreements

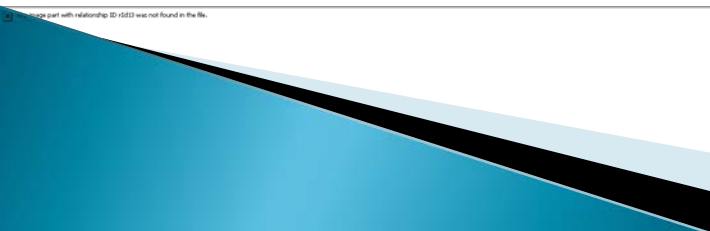
- ▶ Negotiation of international treaty requires enormous commitment of resources, time and political capital
 - e.g., climate change
- ▶ Irresoluble compliance and enforcement challenges
 - e.g., Biological Weapons Convention

Treaty Precedent: UN International Cloning Convention

- ▶ In 2001, the U.N. General Assembly established an Ad Hoc Committee to draft an international convention to prohibit human reproductive cloning
- ▶ The Human Cloning ban deadlocked in the U.N. in December 2003 due to disagreement
- ▶ U.N. Legal Committee discussed ban again in Oct. 2004; again failed to reach agreement
- ▶ Key points of disagreement:
 - Scope
 - Duration
 - Enforcement

“Transnational New Governance”

- ▶ Originates from “soft law” concept in international law
- ▶ Substantive obligations and requirements created by instruments that are not directly legally enforceable
- ▶ International scope/focus/participation
- ▶ Broadening oversight from top-down government requirements to include a much broader range of decision-makers
 - e.g., companies, researchers, NGOs, public-private partnerships, other third parties



Advantages of Transnational New Governance

- ▶ Voluntary; cooperative
- ▶ Reflexive
- ▶ Can be adopted or revised relatively quickly
- ▶ Many different approaches can be tried simultaneously
- ▶ Can be gradually “hardened” into more formal regulatory oversight

Limitations of Transactional New Governance

- ▶ Norms / standards not directly enforceable
- ▶ Risk of “whitewashing” or “greenwashing”
- ▶ Participation limitations
- ▶ Not always as flexible and adaptable as hoped
- ▶ Potential for confusion / overlap
- ▶ Less legitimacy

Examples of Transnational New Governance Tools & Examples

- ▶ Transnational regulatory dialogue and networks
 - OECD working Groups
- ▶ International regulatory harmonization committees
 - International Conference on Harmonization
- ▶ United Nations Declarations
 - UNESCO International Declaration on Human Genetic Data
- ▶ International principles
 - World Medical Association/Helsinki Principles
- ▶ International Scientific Assessment bodies
 - Intergovernmental Panel on Climate Change (IPCC)
- ▶ Professional society guidelines
 - ISSCR Guidelines for Embryonic Stem Cell Research
- ▶ International statements of policy
 - HUGO statements
- ▶ Private/industry standards
 - IGSC Harmonized Screening Protocol
- ▶ Framework conventions
 - Framework Convention on Tobacco Control