

International Summit of Human Gene Editing December 2, 2015

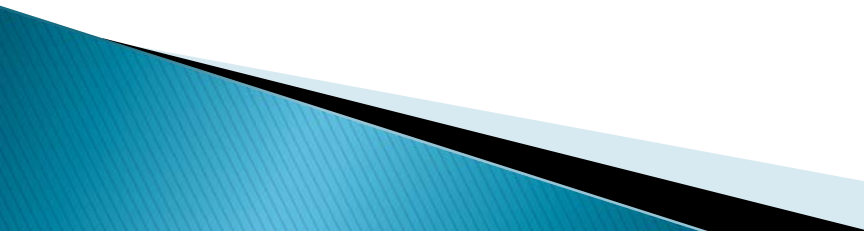
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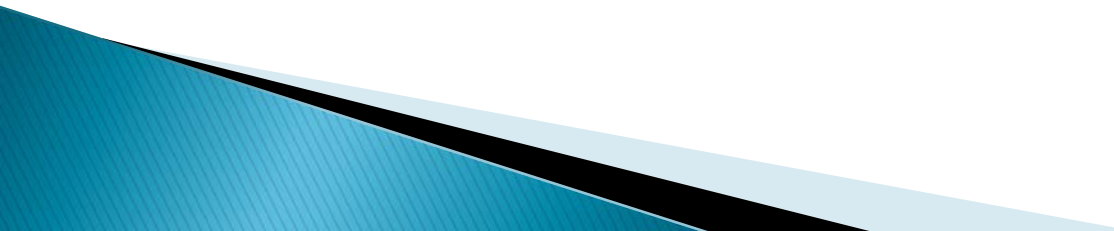
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Innovating law, policy and ethics for science & technology

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
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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
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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)

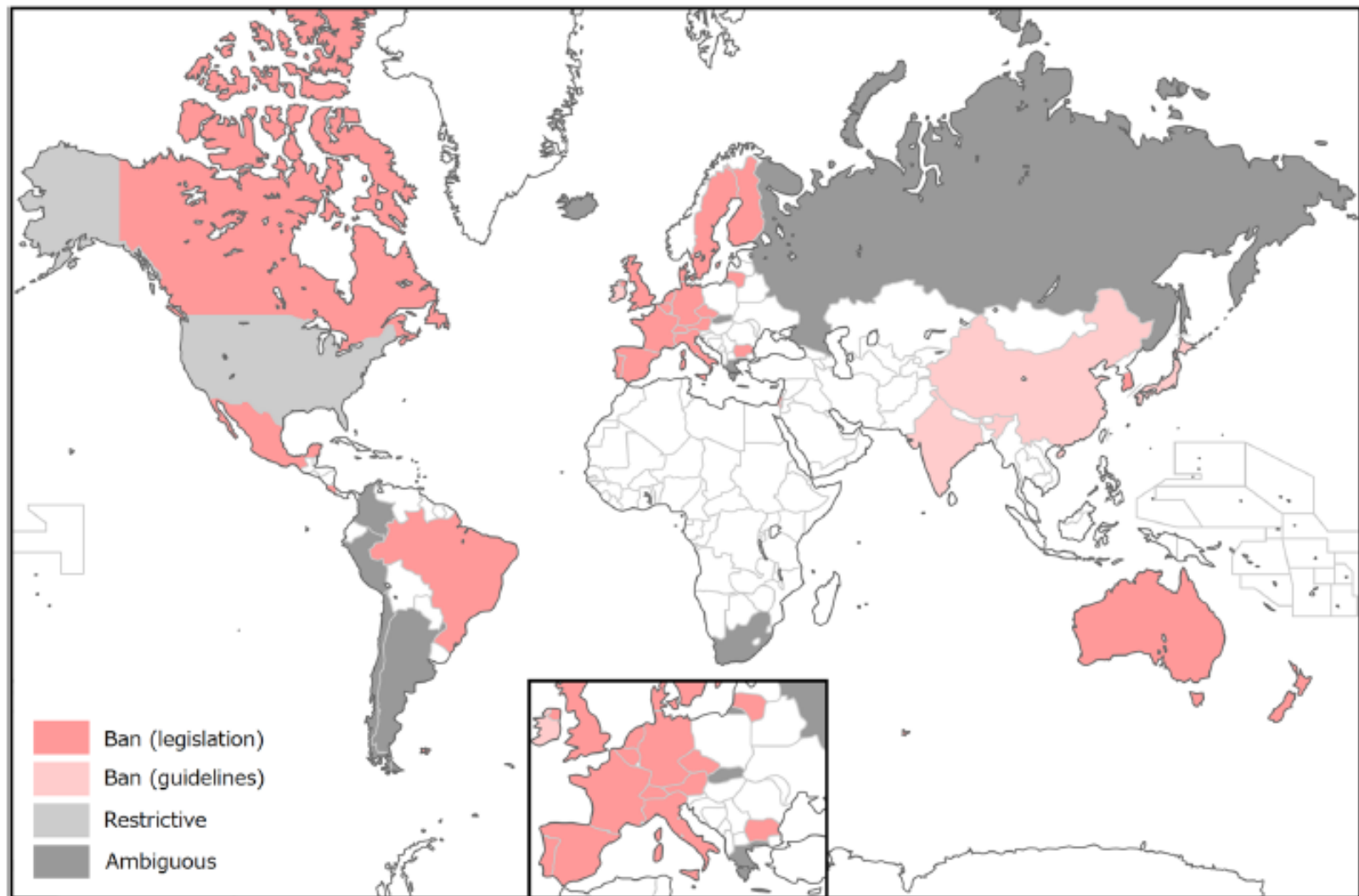


Figure 3 An international regulatory landscape regarding human germline gene modification. Thirty nine countries were surveyed and categorized as "Ban based on legislation" (25, pink), "Ban based on guidelines" (4, faint pink), "Ambiguous" (9, gray), and "Restrictive" (1, light gray). Non-colored countries were excluded in this survey. See also Additional file 1: Table S1.

Mechanisms of International Convergence

Table 1: Convergence: mechanisms and processes

Convergence processes	Definition	Examples
Policy diffusion	Informal process of communication and policy learning between regulators.	Bilateral links between regulatory agencies (e.g. between US EPA and European Commission on REACH).
International coordination and cooperation	Formal or informal international process of developing congruent approaches without large-scale adjustment of domestic laws and regulation.	OECD-based guidelines (e.g. OECD Test Guidelines and Principles of Good Laboratory Practice).
Treaty-based harmonization	Formal negotiation of an international agreement on common rules and standards for domestic regulation.	WTO trade agreements (e.g. Trade-related aspects of intellectual property rights (TRIPS) agreement).

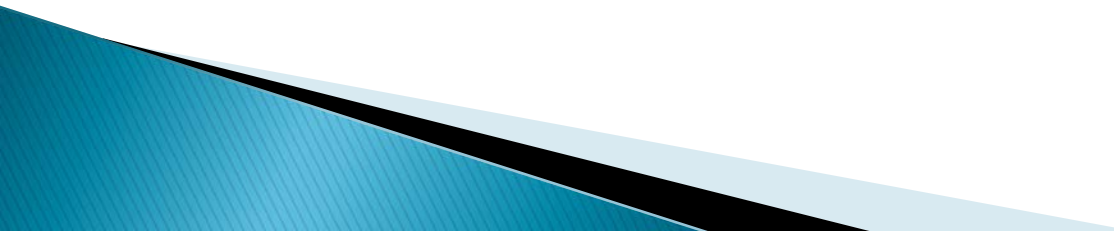
Traditional “Hard Law”: Treaties and Other Formal Agreements

- ▶ 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

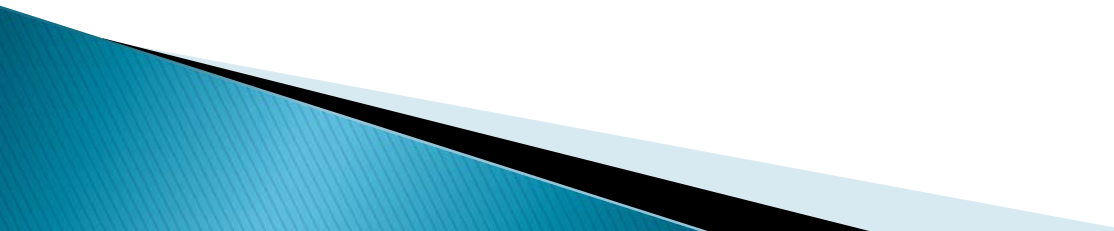
Treaty Precedent: UN International Cloning Convention

- ▶ 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

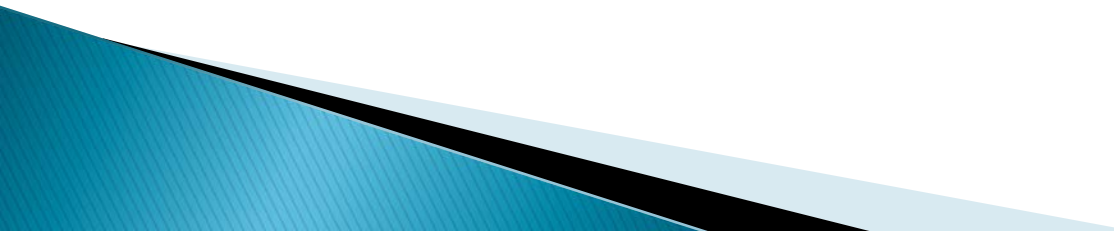
“Transnational New Governance”

- ▶ 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
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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
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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
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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