

# Impact of Law on the Commercialization of Biotechnology in Asia

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# Key Legal Forces Affecting Commercialization

- Regulations affecting research
- Commercial law influencing financing and product/service development
- Public safety & product efficacy regulation
- Intellectual property rights

# Regulation of Research

- Rules constraining or promoting specific fields of research
- Regulations can bar or impede research on certain topics (e.g., human cloning)
- Legal action can promote research (e.g., by providing funding)

# Commercial Law

- Includes law of contracts, commercial transactions, financing/investment
- Law provides enforcement mechanism to support financing of research and commercialization
- Financing is essential to support successful research and commercial applications

# Safety & Efficacy Regulation

- Regulations require review of biotech products to ensure they are safe for human use
- Regulations also review to ensure the products are effective
- Process directed toward protection of the public
- Process adds significant time to the transition from lab to marketplace

# Intellectual Property Rights

- Consist of patents, copyrights, trademarks, trade secrets
- Legal mechanism to control access and rights of use to inventions and innovative work
- Provide incentives for research and sharing of information
- Can also restrict access to research and information

# Impact of Law on Biotech Commercialization

- Direct impact facilitating or restricting research
- Creates financial environment necessary to support research and commercial applications
- Controls public access to biotech products
- Establishes & enforces rights of ownership, access, use of biotech intellectual property

# Law as a Major Force in Biotech Commercialization

- Direct impact by influencing research & controlling access to consumer markets
- Indirect impact by affecting intellectual property rights and commercial transactions/financing necessary for research & commercial development
- Net effect: Law plays a critical role in biotech research and commercialization