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# Lilly Recent History in Natural Products Research

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**Answers That Matter.**

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# Today's Discussion

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- Lilly history with natural product research
- Recent experiences
- Use of contracts to manage Access Benefit Sharing (ABS), technology transfer, and conservation/sustainable use of GR/TK
- Requirements for Successful ABS Contracts

# Natural Products Research at Lilly

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- Natural Products research at Lilly dates back to founding of the company, in 1876 and ended in the early 1990s
- New techniques, such as combinatorial chemistry, led to use of synthetic organic chemistry in research and development of new compounds
- Passage of the CBD and lack of national laws implementing the objectives of the CBD, including mechanisms for ABS, created challenges/ambiguities

# Historic Breakthroughs Lead to Inaccurate Charges of “Biopiracy”

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Decades of research on rosy periwinkle plant, by Lilly and others, led to historic discovery of vinca alkaloids for treatment of cancer, in 1961



## FACTS:

- Rosy periwinkle is found throughout the world, and plants used by Lilly were commercially grown in Texas, United States
- Original research efforts were for treatment of diabetes, not cancer
- Scientific research, not TK, led to development for cancer indication
- Products launched 30 years before CBD
- Risk-intensive research, combined with inappropriate claims of biopiracy, discourage natural products research

# A Successful ABS Agreement: Lilly-INBio Collaboration Agreement

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- Research Collaboration from 1999-2000
- Collection of extracts from plant samples by INBio
- Testing for human and animal health and agriculture
- Payment for each individual extract received, with possibility of milestones and royalties
- Technology transfer
  - Visiting scientists from INBio to Lilly
  - Perpetual rights to use Lilly proprietary plant extraction procedure
- Dispute resolution mechanism

# National ABS Strategy: Recent Lilly Experience in Cameroon

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- A research scientist in Cameroon contacted Lilly to engage in a natural products collaboration
- Lilly informed the scientist that transfer of GR without authorization is a violation of Cameroon national law
- Research scientist is unable to obtain authorization from relevant ministries
  - Authorization forms were later found to be from the wrong ministry
  - Lilly letter to CBD Focal Point in Cameroon to resolve the deficiencies
  - After over one year, Lilly closed its files on this potential collaboration
- No collaboration = no access, no benefit-sharing, no technology transfer, no new medicines

# Contracts: A Practical Solution

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- Legal mechanism for access and prior informed consent
  - Contracts provide legal certainty to the user and to the provider
    - Document access when it occurs
    - Establish benefit-sharing up front, at the time of access
  - May result in benefit sharing even if the research is unsuccessful
    - License Fees
    - Milestones/Royalties
    - Technology transfer

# The Basis for Contracts: The Convention on Biological Diversity

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- Article 15(4): Access [to genetic resources], where granted, shall be on mutually agreed terms.
- Article 15(7): Parties shall implement measures to ensure fair and equitable sharing of benefits arising from use of genetic resources. Benefit-sharing shall be upon mutually agreed terms.
- Article 16(3): Parties shall take measures to provide access to and transfer of technology, on mutually agreed terms.
- Article 19(2): Access to results and benefits arising from biotechnologies based on genetic resources shall be on mutually agreed terms.



# The Basis for Contracts: The Bonn Guidelines

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- Para. 13: National Focal Point – “to inform applicants for access to genetic resources on procedures for acquiring prior informed consent and mutually agreed terms.”
- Para. 14: Competent National Authority – responsible for advising on entering into mutually agreed terms; monitoring and evaluation of ABS agreements; implementation and enforcement of ABS agreements.
- Para. 42-45: Lists basic requirements for mutually agreed terms and typical mutually agreed terms to be included in agreements.
- Appendix I: Suggested Elements for Material Transfer Agreements

# Conclusions

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- Management of ABS via contracts can be effective, with the appropriate national policies in place.
- Implementation of these national policies is less burdensome than other proposals, such as patent disclosure or certificates.
- Use of patent disclosure is an unsuccessful attempt to shift the burden of implementing ABS policies
  - Increases uncertainties for patent applicants and patent examiners
  - Fails to achieve the intended compliance goals

# THANK YOU

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