



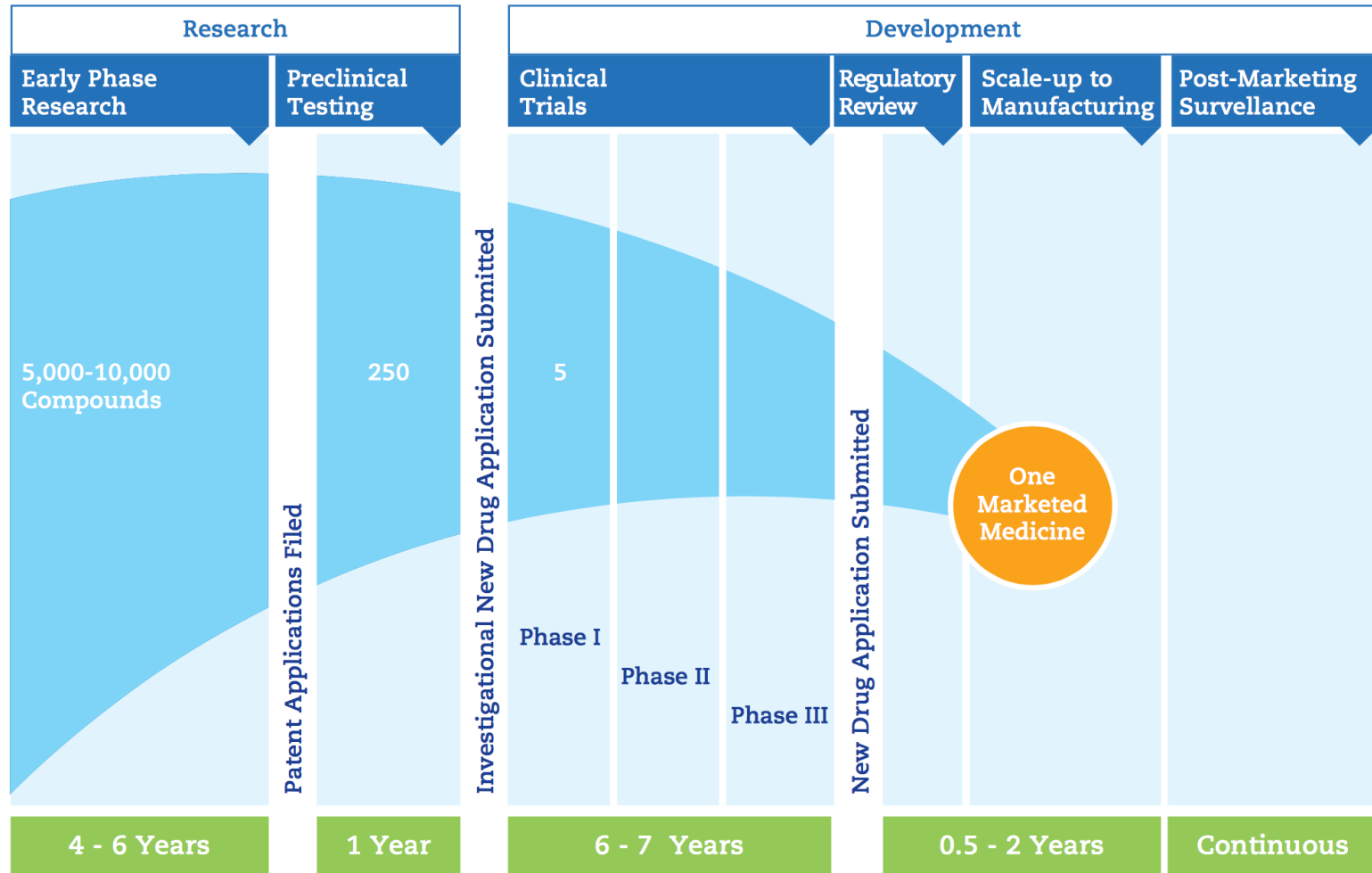
IP and Genetic Resources: Policy Objectives in Practice

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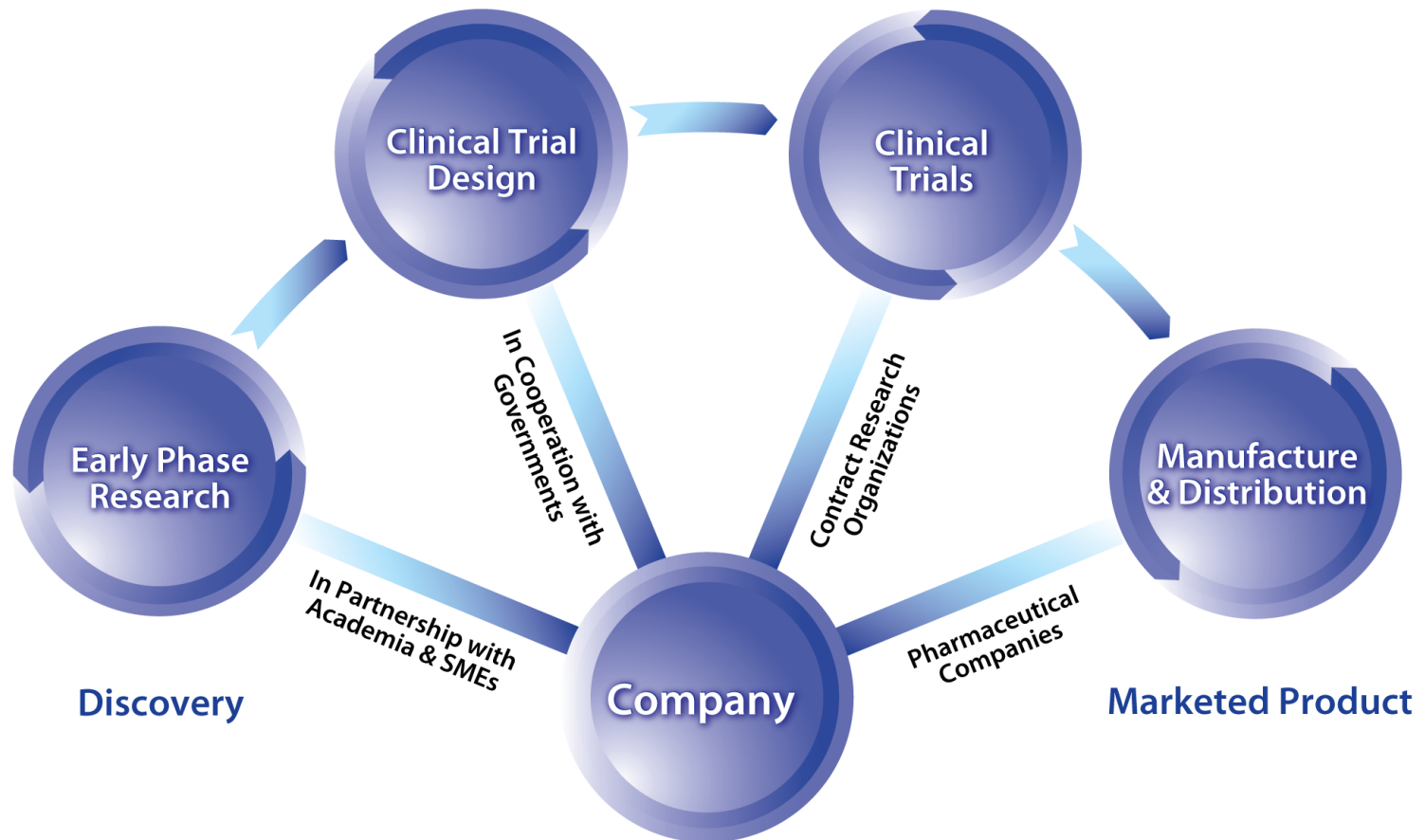
Contents

- The Research & Development (R&D) process for pharmaceuticals
- The increased complexity of natural product R&D
- Real-world examples and experiences gained from working with partners on natural product R&D

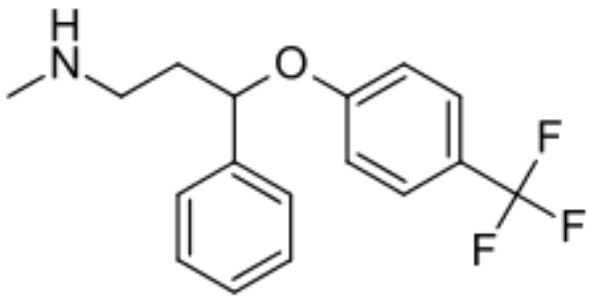
The R&D Process: Long, Complex, and Costly



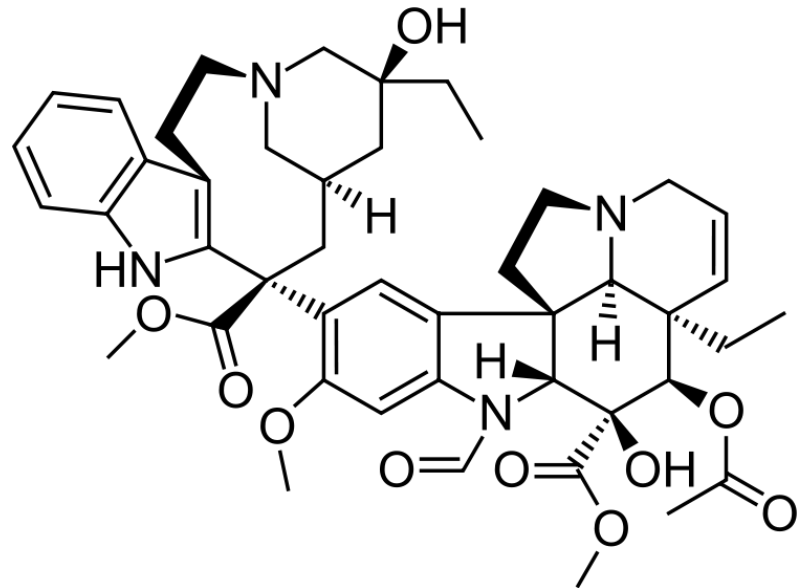
The Innovation Ecology



Chemical vs. Natural Product



Fluoxetine

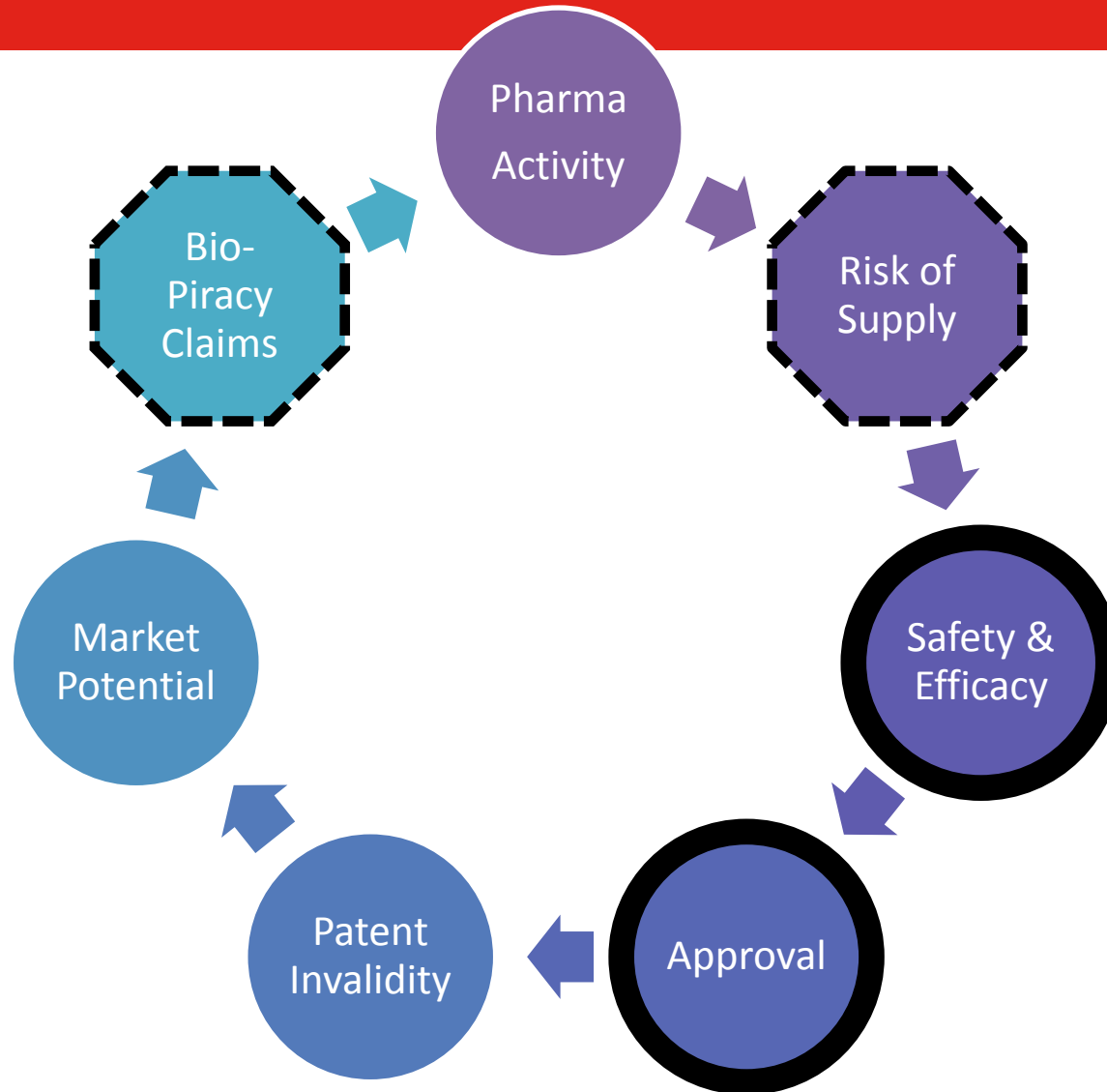


Vincristine

Risk Factors: Chemical Product



Risk Factors: Natural Product



Chemical vs. Natural Product R&D: Assessing Risk Factors

STANDARD PRODUCT RESEARCH

- ❖ Pharmacological Activity
- ❖ Safety & Efficacy
- ❖ Challenges of R&D process
- ❖ Patent Invalidity
- ❖ Market Potential



NATURAL PRODUCT RESEARCH

- ❖ Pharmacological Activity
- ❖ **Reliability of Supply**
- ❖ **Safety & Efficacy: Longer, more complex R&D**
- ❖ **Stricter Regulatory Approval Process**
- ❖ Patent Invalidity
- ❖ **Claims of Bio-piracy & Misappropriation**
- ❖ Market Potential

Example 1

Would Patent Disclosure Facilitate
Access and Benefit Sharing?



National Laws Facilitate ABS even in the Absence of Patents

- Lilly – INBio Research Collaboration, 1999-2000
- INBio collected and transferred plant extracts
- Lilly tested the extracts within the fields of human and animal health and agriculture
- Payments to INBio for each sample transferred, including possible milestones and royalties
- Technology Transfer
 - Visiting scientist program between INBio and Lilly
 - INBio obtained perpetual rights to use Lilly proprietary plant extraction procedures
- Scientific collaboration benefited both parties, despite the lack of a patentable invention

Well-Established, Transparent National Laws Are Essential

- Potential research collaboration between Lilly and a scientific institution in Cameroon
- Lilly informed the scientist that transfer of GR without proper authorization may be a violation of national law
- Research scientist unable to obtain proper authorization
 - Authorization forms supplied by the wrong ministry
 - Lilly letter to Cameroon Focal Point to resolve deficiencies
 - Scientist reply thanking Lilly for good-faith efforts
- Risk of violation of national law and uncertainty regarding future obligations led Lilly to abandon the potential project
 - No collaboration = No benefit sharing
 - No inventions = No patents = No disclosure obligation
 - No new medicines = We all lose

IFPMA ABS Guidelines

- IFPMA first launched guidelines for all members companies in **2007**
- Updated in **2011** after the CBD Nagoya Protocol (Oct 2010)
- Industry agrees:
 1. To obtain **prior informed consent** (PIC) to the acquisition and use of GR controlled by a **country/indigenous people** and provided to the company in accordance with **local law**.
 2. In obtaining PIC, **to disclose the intended nature and field** of use of the GRs.
 3. To gain necessary approval to remove materials found in situ, and to enter into formal **contractual benefit-sharing agreements** reflecting the **mutually agreed terms** (MAT) on the use of the GRs obtained through that removal. These agreements may contain conditions on permissible uses of the GRs, transfer of the GRs to third parties, and appropriate technical assistance and technology transfers.
 4. To **avoid taking actions**, in the course of use or commercialization of GRs obtained as specified under these commitments, **that impede traditional use** of such GRs.
 5. To agree that any disputes as to compliance with the clauses contained in formal contractual benefit-sharing agreements are dealt with through arbitration under international procedures or as otherwise agreeable between the parties.

See: <https://www.cbd.int/abs/submissions/icnp-3/EU-IFPMA-EFIA-Guidelines.pdf>

Example 2

Does disclosure of Source and/or Origin
Prevent the Grant of Erroneous Patents?

US Patent No. 5,401,504

- “Use of Turmeric In Wound Healing”
 - Inventors: Suman K. Das and Hari Har P. Kohly
 - Non-resident Indians, based in United States
 - Disclosure of Source: Raja Foods, Lincolnwood, Illinois (US) (Column 5, lines 3-4)
 - Disclosure of an Origin: “turmeric has long been used in India as a traditional medicine” (Col. 1, ll. 36-37)
 - Improved databases would have done more to ensure patent offices had access to appropriate information

Has Disclosure Ensured Access to Appropriate Information?

Source or Origin is disclosed in applications listed in “A Sample List of Bad Patents” from IP/C/W/459:

- US 5,304,718 (quinoa)
- US 5,894,079 (enola bean)
- US 5,401,504 (turmeric)
- US 5,536,506 (pepper extracts)
- US 5,484,889 (Momordica charantia)
- US 5,900,240 (dried vegetables/seeds)
- US 6,410,596 (pigeon peas)
- EP 0973534 (hoodia)

Example 3

Despite Full Transparency,
Retroactive Claims of “Biopiracy” Persist...
Sometimes For Decades

Vinca Extracts for Treatment of Cancer: Key Facts



- Research was conducted in 1950's
- Two research groups working simultaneously in the late 50's
 - U. Western Ontario (Canada) scientists investigating anti-diabetic properties
 - Lilly scientists screening more widely for endocrine, oncology, neuroscience, antimicrobial, antiviral, or insecticidal properties
 - All extracts subject to the same screens, “regardless of medical claims found in the literature.”
- Sources of vinca plant material
 - Evidence suggests Western Ontario team received first sample from Jamaica.
 - Lilly received first sample from commercial biological supplier, and plant material for commercialized product was sourced worldwide from any available supplier.
 - To ensure constant supply, plants eventually sourced from commercial growers in Texas, United States.

- **Velban®**
(vinblastine sulfate)
 - Approved 1961
 - Hodgkin's disease and treatment-resistant choriocarcinoma

- **Oncovin®**
(vincristine sulfate)
 - Approved 1963
 - Acute childhood leukemia

Housewife Writes Thanks For New Anticancer Item

Have you ever wondered how the product you researched, developed, manufactured, packaged, or shipped served a patient. A housewife in Menomonee Falls, Wisconsin, whose husband has been treated with some of the company's new anticancer products describes the results they had for her husband.

"Three years ago my husband had extensive surgery for a neoplasm in the bronchus, left lung, and extending slightly onto the lower lobe of the right lung. We were and are thoroughly familiar with the high mortality rate for this type of cancer, and we experienced all the sorrow, dread and terror usually associated with this disease. At that time, my husband had the usual physical therapy, drug therapy, etc. I will admit that this therapy is very expensive; however, I have not begrudged too much the expense.

"When I stopped in our drug

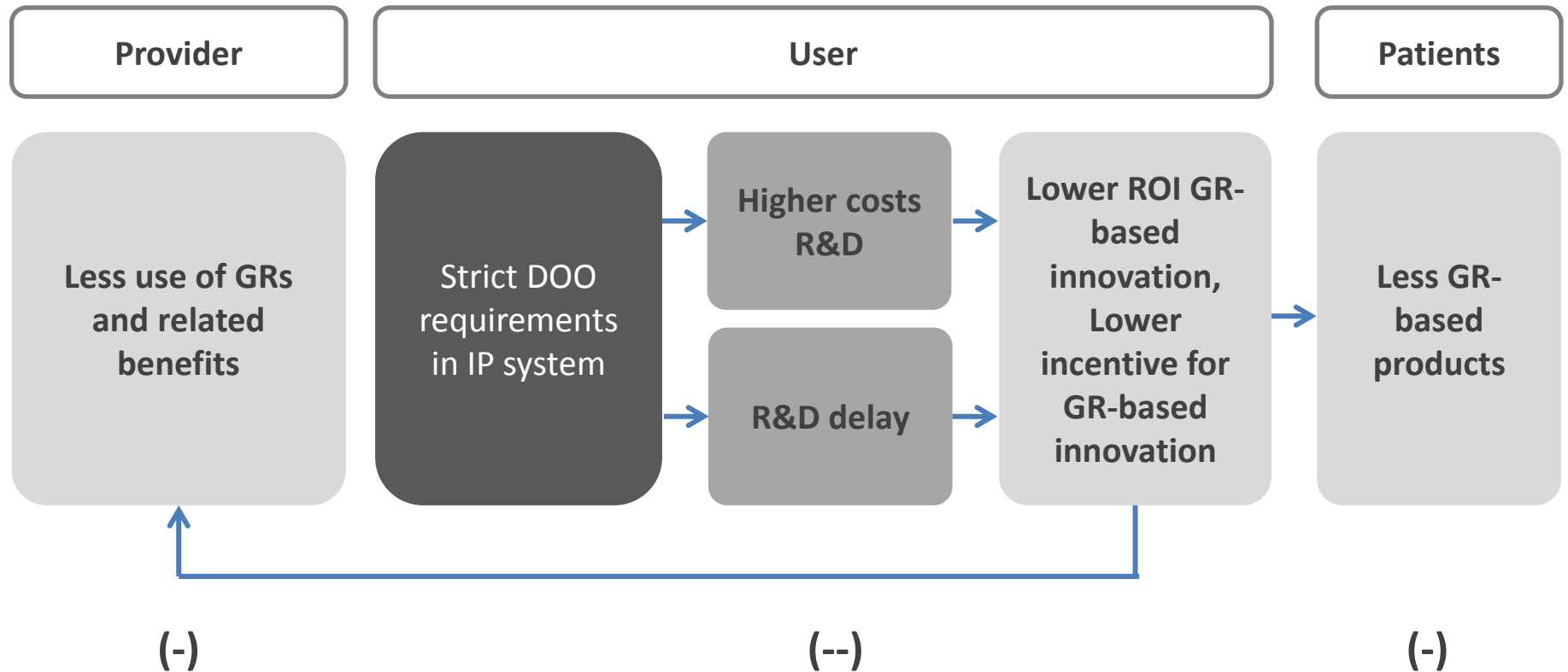
store yesterday, the druggist asked how Bill was getting along, and I told him the truth—that Bill looks, acts, and feels better than he has for 15 years. That's when the druggist made the startling statement. He said, 'You can thank Eli Lilly for that.'

"So I do. I thank you from the bottom of my heart.

"You see, Bill's just an ordinary man, doing an ordinary job. But he means everything to me and to our children. I thank you for the three years we have had, and for the years that we will have in the future. The children thank you for letting them have a father during their teen years. We are all aware that this might not be permanent, but the years you have given us are sincerely appreciated.

"I thank you, Eli Lilly. And I ask that you extend our appreciation to everyone in your organization who has made this possible."

The Result of Disclosure Requirements on R&D



Conclusion

- Industry has shown commitment to obligations under the CBD and abides by strict ethics in our collaborations
- Legal certainty is a vital component for the R&D of natural products
- Disclosure requirements cannot achieve the stated policy objectives *And* risk unacceptable levels of legal uncertainty
- Industry has commissioned research into national disclosure requirements to see how they operate in practice

THANK YOU

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