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HOW THE "SMALL MOLECULE PENALTY" DETERS Rx INVESTMENT

NEW MEDICINES ARE COSTLY, TIME-INTENSIVE AND RISKY TO DEVELOP

Research and development of a single drug can take

10-15 years and cost **~$2.6 billion**

9 out of 10

products that enter clinical trials never get approved by the FDA.

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VENTURE CAPITALISTS FUND EARLY-STAGE R&D

A significant share of early-stage research – the riskiest phase – is conducted by small companies.

Investors have a responsibility to generate returns on their investments. Pension funds, endowments and foundations rely on these returns.

Funding for these companies falls primarily on venture capital.

One way that investors generate returns is by selling or licensing medicines in development to larger biopharmaceutical companies.

VCs NEED TIME TO RECOUP INVESTMENT

VCs' investments get recouped based on a number of factors, including the valuation of the timeframe over which the medicine will be protected from competition.

Patents and exclusivities are fundamental to intellectual property protections and VCs' investment decision-making.

Patents

A crucial part of the Intellectual Property system enshrined in the Constitution and widely recognized for fueling American economic success.

Offer the inventor **20** years of protection from the day of discovery.

Exclusivities

Provided by the FDA to make up for gaps in patent protections and encourage investment, including:

- **Orphan Drug Exclusivity (ODE) –** 7 years
- **New Chemical Entity Exclusivity (NCE) –** 5 years
- **Generating Antibiotic Incentives Now (GAIN) Exclusivity –** 5 years added to certain exclusivities
- **New Clinical Investigation Exclusivity –** 3 years
- **Pediatric Exclusivity (PED) –** 6 months added to existing Patents/Exclusivity
- **Patent Challenge (PC) –** 180 days (this exclusivity is for ANDAs only)
- **Competitive Generic Therapy (CGT) –** 180 days (this exclusivity is for ANDAs only)

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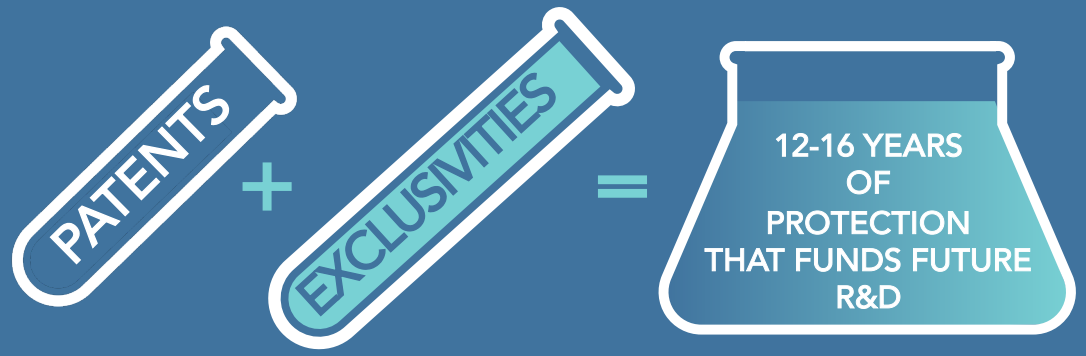
THE COMBINATION OF PATENTS AND EXCLUSIVITIES CREATES A SYSTEM THAT WORKS

A mix of patents and exclusivities ensures that successful medicines receive **12-16 years** of profitability after the medicines are approved for future R&D.



This timeframe is well-recognized by Congress and key stakeholders as necessary for recouping the significant investments needed to bring medicines to patients

Thanks to this system, the U.S. leads the world in life sciences innovation.

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SO, WHAT'S THE PROBLEM?

The Inflation Reduction Act changes this by creating a price control on certain small molecule drugs after 9 years, while biologics are given 13 years before price controls set in.

50% of investment returns come in years 9-13 after a drug is approved.

Small molecule medicines are generally pills, tablets, or capsules that provide important treatment options for cancer, neurological conditions, and more.

Small molecules also become low-cost generics after IP protections expire.

Biologics are generally infused or injected treatments for serious health conditions. They may require administration in a doctor's office, hospital or clinic.

WHAT ARE THE CONSEQUENCES?

Nine years is not enough to recoup the necessary investments, meaning investors will be deterred from investing for such a short return horizon.

Small molecule drugs – no matter how effective they may seem – could go unfunded and undeveloped – **this is the small molecule penalty**.

WHAT ARE THE CONSEQUENCES?

Companies have already announced that they will be re-evaluating – and in some cases ending – the development of certain small molecule medicines due to this penalty in IRA.

ENDPOINTS NEWS

In spinning out cancer pipeline, Alkermes cites Inflation Reduction Act's hypothetical incentives for biologics R&D

ENDPOINTS NEWS

IRA impact: AstraZeneca and Merck CEOs warn of oncology drug development shifts

FT FINANCIAL TIMES

Bristol Myers Squibb warns US price reforms will dent drug development

MEDWATCH

Novo Nordisk faces potential impact of new US legislation

REUTERS

Novartis warns U.S. plan to curb drug prices could hit key research

FORTUNATELY, THERE IS A SOLUTION

This problem can be easily fixed without undoing the IRA.

Bringing **13-year parity** to small molecule medicines will ensure science of all types can advance and continue to improve health outcomes for patients.

ABOUT INCUBATE

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Incubate is a coalition of early-stage life science organizations from the investment, corporate, and philanthropic communities.

We're a vessel for the voice of our members, committed to educating policymakers on venture capital's role in bringing promising ideas to patients.

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