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A ProAssurance Company

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Products Liability Insurance for Clinical Trials: Research with Pregnant & Lactating Persons

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Insurance Market Fundamentals

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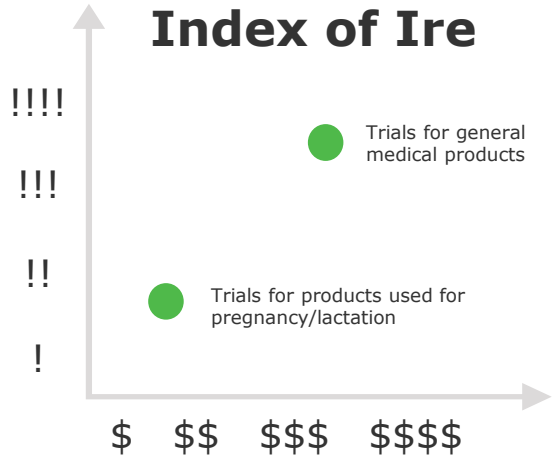
- Products liability insurance for life sciences companies is **inexpensive right now**.
  - Insurance markets undergo cycles of expansion and contraction.
  - We are in a prolonged period of expansion—in insurance terms this would be described as a "**soft market**"—and there are approximately **20 carriers** offering products liability insurance for life sciences companies.
- Not all carriers are the same as respects their **appetite**.
  - **Carriers specialize** in areas, preferring devices over pharmaceuticals, preferring cardiovascular over orthopedics, preferring start-up companies to multi-national manufacturers, etc.
  - Some carriers specialize in hard-to-place risks (versus "standard" risks).
- Life sciences companies purchase insurance through **insurance brokers**.
  - Buyers rely on the expertise of brokers to steer buyers to carriers with an appetite for certain risks, such as clinical trials that include pregnant/lactating persons.

The insurance landscape is **comparatively easy** for life sciences companies, given the soft market. This is not to say that this particular population is easy to insure—but the conditions are optimal from a market standpoint.

The Perceived Risk

- Juries tend to view **corporate defendants** negatively, particularly life sciences companies.
- Clinical trials that include vulnerable populations, including pregnant/lactating persons, have not fared well in litigation, historically speaking.
  - Juries can be **punishing to life sciences** companies and generous to sympathetic plaintiffs.
  - "Why would you include pregnant/lactating women in the trial, if you didn't know the risk?"
- Juries believe that the FDA is a poor **gatekeeper**.
  - Jurors believe FDA regulations are the "minimum requirement."
- Companies (and carriers) typically prefer to **settle** these cases.
  - Settlement agreements usually include **non-disclosure clauses**, making it difficult to develop historical information on outcomes to cases and data on settlement amounts.



Is the product treating a condition related to pregnancy or lactation, or is it for an unrelated medical condition?

The Underwriting Process

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What does the underwriter look at when underwriting this type of risk?

- The product and its risk profile
  - General riskiness of the product – low v. high hazard
  - The product's application – for pregnant/lactating persons or general medical
  - Device v. pharmaceutical risks – immediate impact v. latent risk
- Informed consent – both the content and process
  - This is the "warning label" for the clinical trial
- The IRB's findings and feedback
- Risk mitigation measures implemented by the sponsor
- The clinical trial phase and body of research
  - The intent is to ascertain what is already known about the use of the product in pregnant or lactating women

Products liability policies do not include standard exclusions that deny coverage to pregnant or lactating women. However, underwriters can add such an exclusion to a policy or, more commonly, they can use the underwriting process to decline coverage altogether.

Supplemental Information

Who is Covered?

- Most policyholders are **manufacturer-sponsors** of clinical trials.
  - The policyholder can also be a nonmanufacturer-sponsor, such as a university or nonprofit, that is seeking to bring a use "on-label."
- Most policies extend coverage to other entities related to the trial, assuming the damages do not arise from their sole negligence.
  - Any **Clinical Research Organization** (CRO) conducting clinical testing on your behalf of products manufactured or distributed by you but only if testing protocols are followed.
  - Any **Institutional Review Board** or **Medical Ethics Committee** but only with respect to clinical testing performed on your behalf.
  - Any **person or organization** conducting clinical testing on your behalf but only if the clinical testing follows testing protocols approved by an Institutional Review Board.

What is Covered?

Coverage and policy terms vary by carrier. However, certain provisions are considered "standard" in the marketplace.

- Damages for **bodily injury** or **property damage** that arise from your work, including your medical product and clinical trial protocol.
  - Only when the protocol is being followed
  - Other policy terms and conditions must be met, such as reporting requirements
- We will pay any **medical expenses** (up to a sublimit) for any subject who is treated in a medical facility for bodily injury arising out of the clinical testing of your product.
  - Called, "med pay"
  - Usually a "no fault" coverage feature
- We will <u>not</u> pay medical expenses related to the **deterioration of the subject's health** that would have occurred without participation in the trial.

Alternative Risk Transfer Solutions

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What happens when a risk becomes "un-insurable" (such as vaccines and opioids)?

- **Vaccine court:** As a result of liability, pharmaceutical companies stopped making vaccines, which led to shortages. The National Vaccine Injury Compensation Program (VICP) enables plaintiffs to seek compensation through the U.S. Court of Federal Claims. Compensation, when approved, is provided by the U.S. Department of Health and Human Services (HHS).
- **Alternative markets:** Many hard-to-place risks end up in the London market, which is a "subscription" form of insurance in which many carriers share in coverage. This means that companies can find insurance for risks that are too large or complex for one insurer alone.
- **Fair Access to Insurance Requirements (FAIR):** State-run insurance plans that make property insurance available to those who cannot obtain it in the voluntary market.

CRACKED

The 6 Strangest Tales of Celebrity Body Part Insurance

By: Adam Tod Brown
February 10, 2008

https://www.cracked.com/article_15887_the-6-strangest-tales-celebrity-body-part-insurance.html

CBS COLORADO

Colorado considers creating state insurance pool amid growing risks

March 22, 2023

https://www.cbsnews.com/colorado/news/colorado-state-insurance-pool-wildfires-claims/

Mitigating Liability Through Public Policy

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Do preemption and liability shields help? Yes!

- These protections give underwriters confidence and can positively influence a carrier's appetite for the risk.
- Typically, life sciences companies still buy (and use) insurance for products that are subject to preemption and liability shields.
  - The treatment of these products in court may not line up with theories of law.
  - These protections can be eroded over time as applied by courts to unique circumstances.
  - Insurance policies assist with defense costs.
- See *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013), *Wyeth v. Levine*, 555 U.S. 555 (2009), *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).
- See the liability shield associated with products approved through Emergency Use Authorizations (EUAs) and the Public Readiness and Emergency Preparedness (PREP) Act.

Risk Management Advice: Improve Your Risk Profile

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- Demonstrate a **concern for potential risks** to pregnant/lactating persons.
  - Conduct significant bench and animal trials to develop data related to this risk.
  - Ensure that risks to pregnant/lactating women have been theorized.
  - Develop warnings and mitigation plans specific to this risk.
- Conduct **informed consent** on video.
  - Create evidence of the subject's acknowledgment of risks and interaction with the investigator.
- Ensure **compensation** is "reasonable."
  - Compensate this population in line with what other studies are providing and with what subjects who are not pregnant/lactating are receiving.
  - Associate compensation with reimbursement for expenses, time, etc.
- Consult with a **reputable IRB**.
  - Select an IRB that has experience with this population.
  - Conduct multiple ethics evaluations (i.e., beyond what is normal in trials).
- Select **trial sites** that have substantial expertise in high-risk pregnancy.

Thank you.

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