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Defending the dream; perils beyond science and finance

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Statement of the Problem: Scientists, medical researchers and their financial backers, particularly in the field of rare diseases and particularly with orphan drug development are entirely focused on the efficacy of the science and the impact of their work on the mitigation and cure of disease. Successful development however can come to grief because of alienation of affiliate groups, difficult or misunderstood clinical trials, public and legislator perception, unexpected lawsuits.

Methodology & Theoretical Orientation: A discussion of the cultural pitfalls surrounding drug development from 15 years of insuring life sciences companies. A discussion of growing distrust of clinical trials (from Constant Gardiner to distrust of results), perceptions on pricing and availability of product and alienation of orphan drug affinity groups, a tidal wave of public antipathy towards the drug industry and the critical role of a well-constructed informed consent, insurance and risk-management tactics and a look at what has put potentially successful companies out of business and ended promising research.

Conclusion & Significance: Attention must be paid to the cultural, social and legislative environment of drug development. Informed consents and monitoring in clinical trials, open and extensive communication with disease sufferers and their families, sensitivity to public perception and the use of insurance and risk management can assure that the focus can remain on the science.

Biography

Laura K Sunderlin has 30 years of experience in the Insurance Industry; the last 15 of them insuring life sciences. She has insured biotech start-ups and some of the largest biotechs in the country, for clinical trials and products liability. She brings the experience of a decade and a half of defending against claims, analyzing risk, discussing exposures with risk managers and scientists.

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