Abstract

# The Business of Drug Development: Highway to Heaven or Road to Ruin

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It has been said that only 1% of biotech development programs win through to regulatory approval, and less than 30% of those approved drugs ever recover their R and D costs and persevere to profitability.

Successful development and marketing of inhaled drugs requires a "trifecta" of indication, formulation and device. These elements are critical to give your product development a fighting chance.

It also helps if company leadership is rational (or at least properly medicated) in establishing realistic empirically based expectations for both the potential market for the product, and does not drive the development process to take draconian shortcuts to meet arbitrary expectations of the investors or the street. "Sane" companies that provide sufficient time for multiple iterations in various stages of device development, and sufficient time and resources to start clinical trials only when the device and formulation are ready, have a greater chance for success. Meeting short term milestones may make the CEO look good in the short term, but failed products don't look good to anyone in the long run.

Add to this mix the marketing partner who needs to have the vision, resources and patience to effectively promote an effective campaign to appropriate stakeholders to not only connect the new drug or drug device combination to the appropriate prescribing physician population, but to do the ground work necessary to assure reimbursement from governments and third party payors.

In the course of this presentation we will discuss that rational basis for the development "trifecta", and provide some examples of some great successes which met that criteria and some stunning failures that did not.