



WHITE PAPER



Elevating Invention to Innovation

The three keys to ensuring success in a
competitive marketplace

In today's medical world where FDA approval is uncertain and investors shy away from risky ventures, a clever invention with incremental advantages over the competition is not enough. Successful innovation must go further than invention to turn good ideas into promising ventures that attract investors, gain regulatory approval, and meet the higher expectations in tough economic times.

Here's our take on what pharmaceutical and medical device companies need to do to lay the groundwork for commercially successful product innovations:

Know your market

We've always emphasized that conducting a Commercial Opportunity Assessment is the first step to make in developing a new product, a new indication, or a new market or delivery method for an existing product. It's a critical step. Assessments for new medical devices should be done before getting a patent, determining regulatory strategy, conducting clinical trials or developing a marketing plan. Assessments for new drugs or new indications should start even earlier and begin with determination of medical need well before the big ticket investments in biological manufacturing and clinical trials become necessary. Delaying patenting for new molecules is not so easy outside the big pharmaceutical companies but a patent strategy to extend scope and duration of protection should be in place, especially for new indications. A well-executed Commercial Opportunity Assessment will give you a complete understanding of:

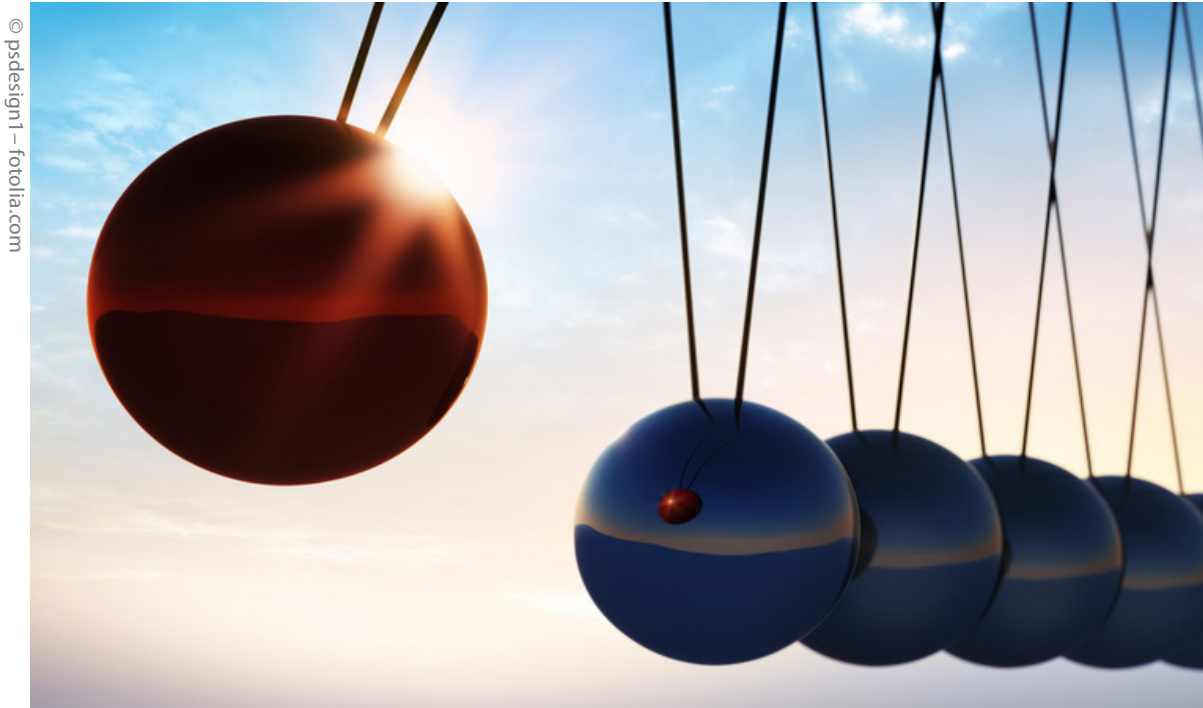
- ▶ **Market profile:** What is the prevalence of the condition your product targets in the country where you want to launch, and how does that affect the market opportunity?
- ▶ **Definition of the customer:** This includes not only who will use the product, but also who will pay for the product.

- ▶ **How the product will be used by medical professionals, and how it will be viewed by payors:** How will the product change the treatment paradigm? Will it motivate physicians to change behavior and switch from the current product they have been using for years?
- ▶ **Competition:** How is your product different or unique, and are these factors meaningful enough to result in a clear differentiation and marketing strategy? How will competitors respond to your product? How might the market have changed by the time your product is ready for launch?

Employ an iterative process

If we want to build a product that fulfills an unmet need to the degree that a customer, prescriber or user will actually change their behavior enough to buy it, we need to consider the matter carefully. Truly successful innovation occurs when you take a thoughtful and iterative approach to the entire process. First, start with the basic idea, what you believe is the "medical need" or the "unique selling proposition" of your proposed product. Talk to customers and use their feedback to modify the product concept. Then, before you invest more of your company's resources or time, go back and do it again. Be sure to talk to all categories of potential customers, including the economic buyers, and not just who you believe the users and prescribers of the product will be.

Done well, this approach, while requiring discipline and a willingness to let go of unfounded assumptions, will give you a chance to learn specifically what you need to do to improve on your idea. Market feedback almost always indicates the need to adjust your thinking, however minor, away from the original preconceived idea for the product. Sometimes, this feedback dictates a need for a more



A lesson to learn from Newton's cradle: Employ the feedback power of real customers to improve the positioning of your new product.

radical approach – requiring that you pivot or turn the product concept towards a completely new direction.

The important thing is to listen to the customer and be willing to make the necessary changes in the product or product idea. Following this iterative process ensures all opportunities and obstacles to market acceptance are rooted out before you go to the expense of completing and launching the product.

In addition to needing experience and a well-balanced and fully resourced team, success requires a commitment to objectivity and openness. Sometimes the cold hard facts of truth can be painful to accept. Team members have to be focused yet open-minded enough to recognize the signs indicating it's time to rethink product design or the customer offering. You can't wear blinders and ignore signals in the market. If you do, this behavior will ultimately come back to bite you.

There are more than enough examples – and not just in the medical field – of what happens when a management team, even one balanced with commercial and scientific expertise, proceeds too far on their own internal assumptions without adequately listening to the marketplace. Here's one well-known example: Pfizer's development of inhalable insulin. The company assumed diabetics would rather inhale their insulin than stick themselves with needles. A lot of money was spent developing a device that patients would carry on their belt. It wasn't until the product was sitting on the shelves and sales were poor that the company learned patients found the device cumbersome and too expensive and doctors wouldn't prescribe it. On the other hand, Adrenex Pharmaceutical is an excellent example of a company that took an iterative and market-driven approach to assessing the market opportunity. Their single-minded goal in product development

was to pursue the fastest pathway to commercialization of their product. They started off thinking an ADHD indication would be fastest. Conversations with potential customers and partners told them the fastest and least expensive route would be via a hypertension indication. They made pivotal decisions based on the objectivity of the market.

Team up with specialists

While focus on a single objective is important, companies should take care not to commit substantial resources to any one pathway until there is solid market validation for the product. Until then, don't commit precious resources that will have been wasted if you find, too far down the path, that your original assumptions were faulty due to incomplete or inaccurate data.

Even when you have an experienced management team, sometimes the addition of an outside specialist can help. Teaming up with a firm that has substantial expertise in conducting commercial assessments and bringing medical products to market can provide these advantages:

- ▶ **Objectivity:** Enhancing your team's perspective with a member from outside the company often leads to more accurate insights due to their unbiased and

objective perspective. Internal team members, for a variety of reasons, have a tendency to plow ahead ignoring signals from the market.

- ▶ **Faster to market:** Specialists with a toolkit of lessons learned can help you avoid the common mistakes and accelerate time to market.
- ▶ **Flexible expense:** Much as you might outsource part of the engineering design for your new product, teaming up with market assessment and commercialization specialists boosts your capability when you need it, with the ability to dial the cost back down later, when you don't. Strengthening your team with a commercialization expert can result in faster time to market along with greater cost savings in the long run.

Remember this

Inventing is about creating ideas. Innovation is about turning those ideas into profitable business ventures. The key to successful innovation begins with employing an iterative, market-driven approach to assessing your product's commercial viability, along with sharp ears and eyes to see the signs when you need to pivot and a willingness to do so!

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