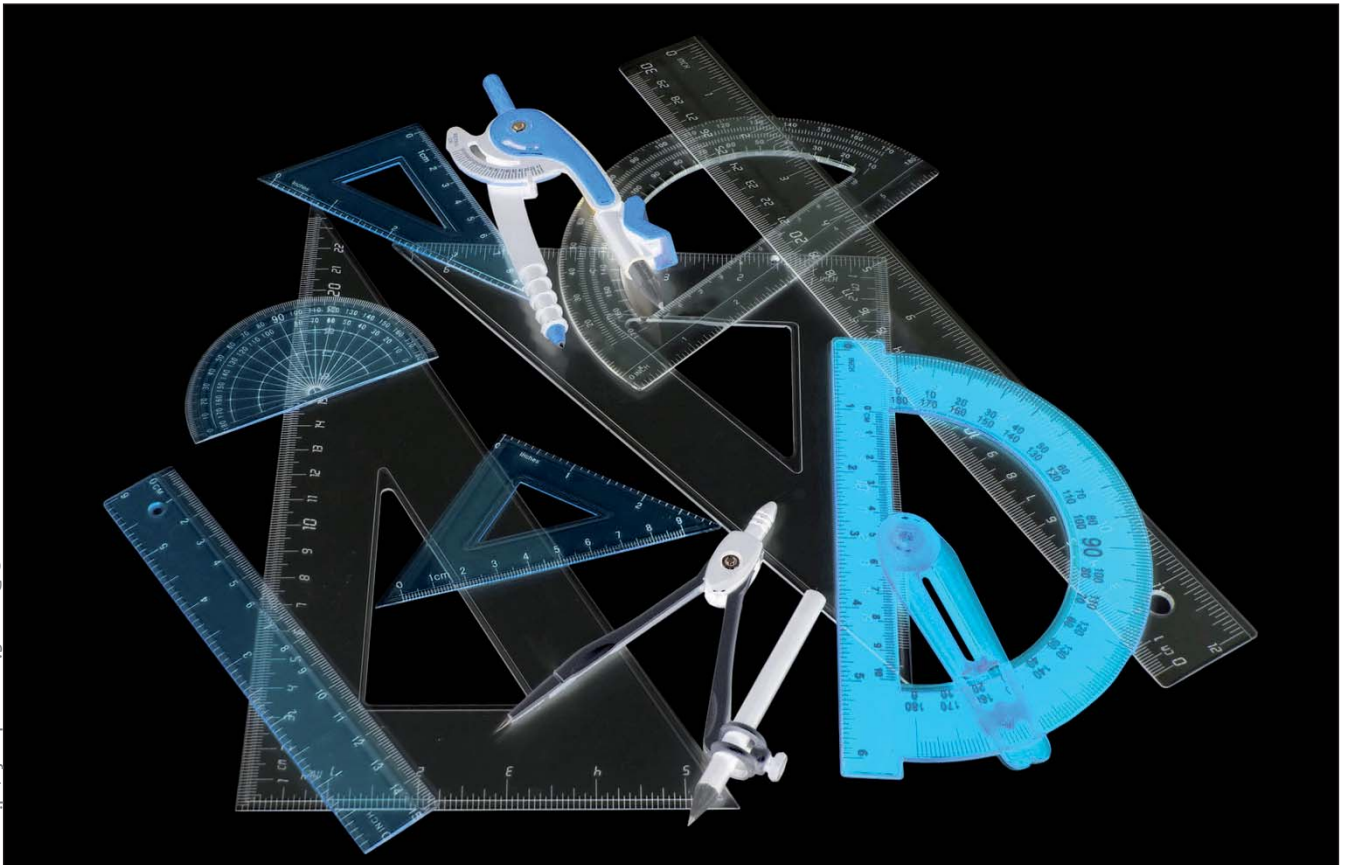




# WHITE PAPER



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## Pivot to Succeed

Success is often about letting go of preconceived ideas not supported in the marketplace

By Dr. Robert C. Keefer and Ray W. Swanson

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 is required to turn good ideas into promising ventures that attract investors, gain regulatory approval, and meet the higher expectations that are common to tough economic times.

True innovation, however, appears to be an elusive goal for many companies, if the results of a recent global survey are any indication. While 84 percent of executives surveyed said innovation is extremely or very important to their company's growth strategy, only 55 percent claimed their company is better than their peers' at innovating. These results haven't changed since 2008.\* Clearly, many companies are struggling with how to be innovative.

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

In previous Pulse newsletters and when working with clients, 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 should be done before getting a patent, determining regulatory strategy, conducting clinical trials or developing a marketing plan. Don't proceed without it.

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.

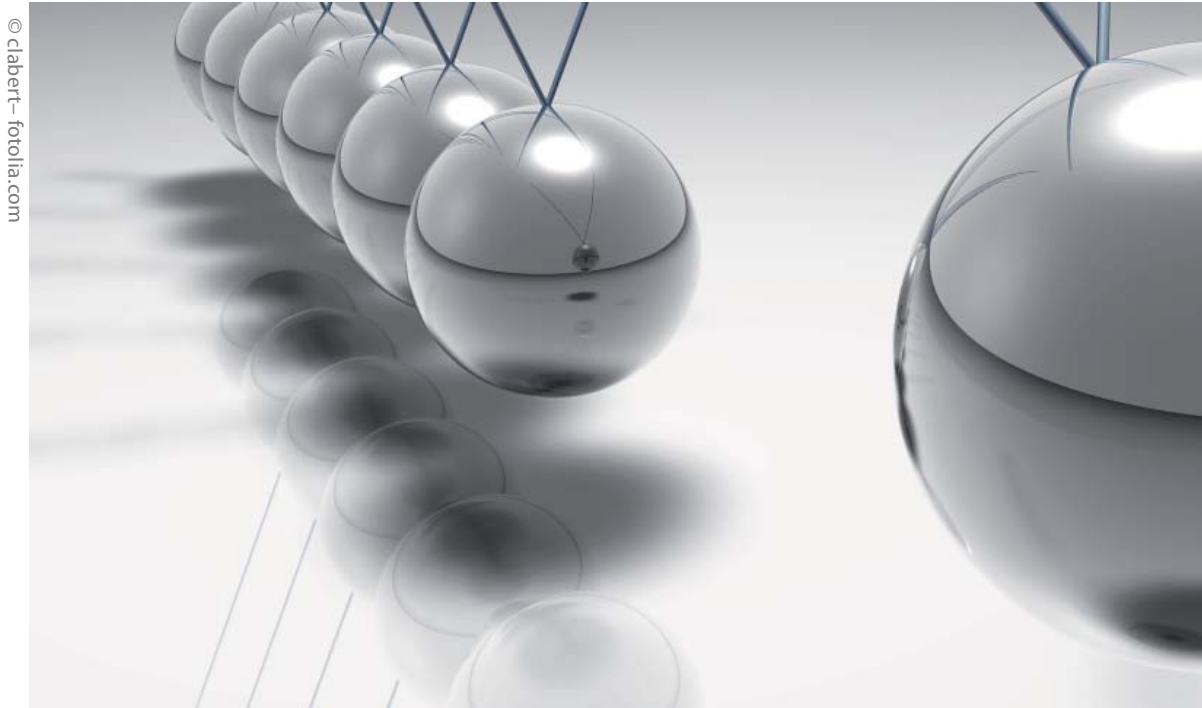
→ **How the product will be used by medical professionals, and how it will be viewed by payors:** How will the product change the treatment paradigm? Will it motivate physicians to change behavior and switch from the current product they have been using for years?

→ **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?

### Employ an iterative process

If we want to build a product that fulfills an unmet need to the degree that a customer will actually change their behavior enough to buy our new product, our view is that the process to gather the information on what to build is as important as the questions we ask. 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 "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 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 pre-



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

conceived idea for the product. Sometimes, this feedback dictates a need for a more 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 then 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 sig-

nals 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, Addrenex 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 in the form of a hypertension indication. They made pivotal decisions based on the objectivity of the market.

### Team up with specialists

While focus is important, companies should take care to not 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 accu-

rate 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

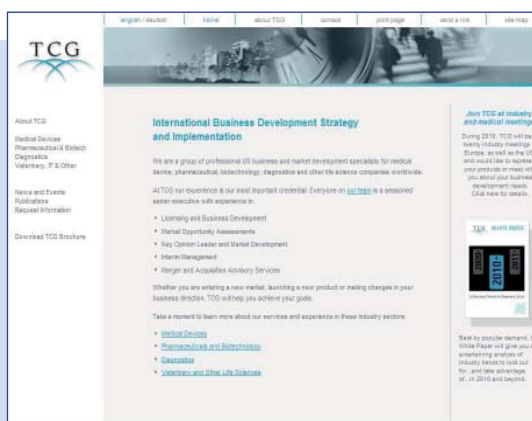
Inventing is about creating ideas. Innovation is about turning those ideas into profitable business ventures.\*\* The key to successful innovation begins with employing an iterative, market-driven approach to assessing your product's commercial viability, along with sharp ears and eyes to see the signs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

➔ Read about the authors: [http://www.tcgmedtech.com/website\\_Sections/about\\_TCG/team.html](http://www.tcgmedtech.com/website_Sections/about_TCG/team.html)

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