Assessing Commercial Opportunities for New Products

Characterization of the business opportunity associated with the introduction of a new product to a biomedical market is one of the most strategically important tasks required of a supplier's senior management. The assessment of each opportunity sets the expectations of employees, investors and alliance partners. Most importantly, its findings often determine whether or not a new product gets introduced or developed in the first place (providing the assessment is carried out soon enough).

This discussion is focused upon the most important issues requiring consideration when an assessment of new-product commercial opportunity is carried out. It is derived from the real-world experiences of Trilogy Associates supporting dozens of clients in their new-product commercialization endeavors. These are not the only issues to consider, but they are certainly the ones yielding the greatest potential for missteps if not properly addressed.

What's the Product?

Exactly what product or service is being introduced to the market's users? This rather obvious question is of primary importance in accurately projecting a business opportunity. The product's definition must be very specific and very precise because its definition is a prerequisite to understanding the nature of its available market. How is it like competitive products? How is it unlike them? Who is the user, and under what specific circumstances is the product used? What benefits accrue to use of the product and to adoption of the procedure associated with it? Is it used once, then discarded, or is it subject to multiple uses? What happens between uses? Will the product or service be sold, leased, or donated for some consideration? Generally, how does the proposed product compare in form, fit and function to existing solutions? These (and others) are all important questions because the precise definition of a product and its use environment can dramatically affect its commercial potential. And, a product that has not been precisely defined cannot be successfully developed!

Existing or New Market?

Different approaches are taken to assessments of commercial potential in an existing market and a new one, and the results associated with an existing market will usually be more accurate. The issues are well known. In an existing market, unless one offers unique benefits not already available from competitive products, the offering will not by its presence cause the market to expand so one must divert revenues from a competitive firm to one's own; market revenues can be estimated with reasonable accuracy, and one can determine which users are buying and which are not; and the product can be rather easily described to prospective customers because it probably bears a close relationship to existing products serving that market. On the other hand, if the target market does not already exist, a new product must *create* it; one then has the advantage of defining the new market by virtue of the product brought to it, often with little or no immediate competition; the supplier will face the rigors of the adoption process and the associated difficulty of predicting its pace; one will be plowing fertile ground and anticipating an unlimited harvest, but in the early stages of commercialization one must explain in detail to each prospect what the product does (better) and what benefits will accrue to its use; the supplier will probably face greater regulatory scrutiny owing to the newness of the product; and one

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must endure the inherent conservatism of most clinicians and the healthcare system overall.

As the analyst moves through the assessment process, it is important to be reminded at each step whether one is dealing with an existing market or a new one, and to proceed accordingly.

U.S. Healthcare

The largest geographical healthcare market in the world, the United States of America, is beset by problems. Converting these problems into opportunities is the burden of medical products suppliers. One must pay proper attention to these socioeconomic and political matters when conducting market assessments.

While arguably the best healthcare in the world is accessible in the U.S., it is not accessible to all. That nation includes about 47 million persons who are uninsured, a remarkable 18% of the population. The old system based upon reimbursing fees for services rendered has been discredited owing to its built-in incentives for raising costs uncontrollably. A newer system based upon managed care—some would say managed cost—has also been discredited because it includes incentives for denying allegedly needed care. The per-capita need for medical care grows larger as the aged population grows in proportion to the total. At the same time the number of available genuinely helpful interventions grows at an increasing rate and generally at high costs. Hospitals all over the country are operating in the red because, they claim, payer reimbursements are inadequate. While there is no consensus for a new direction of the U.S. healthcare system, primarily because our elected officials consider healthcare to be the "third rail" of politics, it is clear that the U.S. is now experiencing a genuine backlash against managed care. This will almost certainly portend further increasing costs. Many analysts anticipate annual insurance premium increases at double-digit rates over the next few years.

What does this all mean for suppliers of medical products, and more particularly for predictors of new-product commercial success? We believe the implications are:

- Genuine, dramatic improvements in patient well-being will continue to be warmly embraced and paid for, despite their costs; however, these improvements will not be available to all patients, so available markets will be smaller than otherwise predicted.
- Products that dramatically reduce the cost of healthcare will be quickly and widely accepted; direct replacement of an expensive procedure by an inexpensive, equally effective one will be especially well received.
- Products offering a favorable and wide differential between actual cost of ownership and Medicare or commercial insurance reimbursement will be strongly favored.
- Products and services that somehow enhance clinician productivity or preserve their income in the face of threats of reduction will be preferred.
- New products offering no differentiation or modest differences in both patient healthcare outcome and provider expenditure will be ignored.
- Commodity products will endure vigorous, ever-increasing pricing pressure.

Customers: Users, Purchasers and Payers

Medical products are unusual because they have three customers, all of which must be satisfied in order for repeated sales transactions to be accomplished: (1) the user (clinician) must choose and decide to use the product routinely; (2) the purchaser (a hospital, physician practice or other healthcare facility) must approve the product for purchase and consent to the terms of sale; (3) the payer (government or commercial insurer) must consent to reimburse the healthcare facility and clinician for use of the

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product in a specified procedure at a pre-approved rate.

Consequently, a medical products supplier must serve three masters. Users must be convinced to use the product regularly; purchasers must be given satisfactory pricing and deal terms; payers must agree to an established procedural reimbursement. A deficiency in the relationship with any of these customers will reduce the market potential of a new product.

The most common failing in determining customer acceptance of a new product is to focus primarily on *user* acceptance, ignoring or inappropriately de-emphasizing the influences of purchasers and payers.

Regulatory Approvals

The need for regulatory approvals in various countries of the world is well recognized and generally well understood. Appropriate experts must be consulted to deal with these matters, and such experts are plentiful. Regulatory requirements affect opportunity assessment, sometimes in dramatic fashion, in two ways. First, a predicted failure to gain approval for a non-exempt device essentially dooms the product; it cannot be commercialized in the affected country. Second, the predicted category of approval, e.g. PMA versus 510(k) in the U.S., can greatly influence the timing of commercialization.

It is necessary to make informed assumptions about the required regulatory approval track in each country of interest as part of the assessment process. Expert guidance is often appropriate.

Costs and Reimbursement

The importance of customer cost cannot be overemphasized in today's healthcare market. And, of course, the customer's net cost is directly affected by the amount of payer reimbursement received for the affected procedure. New medical products used in unreimbursed procedures face extraordinary barriers to widespread adoption because the product's net cost then becomes excessive from the customer's perspective. New products and corresponding new procedures offering clear clinical benefits beyond the status quo will be accepted, but a generous reimbursement will make acceptance much easier and quicker.

Clearly, an accurate assessment of commercial potential requires an accurate estimate of product pricing *at the customer level* along with a best guess of the associated procedural reimbursements available from Medicare and private payers. And, these two quantities must be projected over the product's life. Most inexperienced analysts tend to overestimate both the price that customers will be willing to pay and the reimbursement available from payers. To maintain credibility, one should try to use actual values applicable to comparable products whenever possible. Projecting reimbursement levels is especially tricky. The analyst really has two choices: (1) use a conservative estimate corresponding to the actual value for an existing procedure, or (2) engage the services of a reimbursement specialist to examine the arena of interest in detail, possibly starting a dialog with payers to gain initial estimates of reimbursement levels.

Assessment Methods

There are as many different approaches to opportunity assessment as there are analysts, and there is no single, proper approach. The most appropriate approach depends on circumstances. All known methods boil down to just a few principal techniques:

1. Start with published information from public and/or proprietary sources, and extrapolate those data in a manner appropriate to the defined new product.
2. Ask some number of prospective customers whether, and under what circumstances, they would buy.
3. Using actual, proprietary purchasing data from a reliable source, estimate the supplier's expanding market share over time based upon a careful comparison of the

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prospective product with offerings from all significant competitors.

4. Conduct an exhaustive, detailed survey of prospective customers, distribution channels and competitors—using several sophisticated and complementary survey instruments—to project the new product's market penetration in each applicable segment.

Method 1 is sufficient to determine whether a particular opportunity should even be considered, e.g. is this a $2 million or $20 million opportunity? Method 2 is a "sanity check", i.e. does this new-product idea have any merit at all? It is used routinely by professional investors for first-cut analysis and due diligence examinations. Method 3 is commonly used on an ongoing basis to assess new or existing products serving existing markets for purposes of setting budgets and commission targets. Method 4 is the technique of choice for real strategic business planning, setting organizational goals and expectations, and justifying capital investment.

Our advice is to let the method fit the need. Don't expend resources unnecessarily on excessive analysis, but don't under-analyze and thereby endure the consequences of a mismatch between realities and expectations.

Market Research: Promise and Problems

In the minds of many, opportunity assessment means market research. Not quite true. Market research is a term most appropriately applied to characterization of an existing market—its products, its customers, its suppliers, and their sales revenues. A proper opportunity assessment requires that one focus first on the proposed product, then identify and characterize its available market. It is a very common mistake to make overarching assumptions about the market served by a proposed new product (usually a large, existing market), then collect data on that market—the wrong one.

Despite this important distinction, the techniques of market research are often the same techniques used to conduct opportunity assessments. These techniques are well known, and they don't require elaboration here. We will, however, cite a few of the more egregious errors made by suppliers of prospective new products in their attempts to conduct opportunity assessments:

- Not being objective in their interactions with prospective customers or in their analytical approach
- Failure to adequately define (or understand) the product and its intended uses in discussions with prospective users
- Not talking to prospective users at all
- Taking published market research data at face value without appreciating its methods of collection and its implicit uncertainty
- Conducting focus groups of users without clear communication of product attributes, design details and applications
- Failing to recognize the value added by respondents for their participation in interviews and surveys, therefore not offering appropriate compensation when it's called for
- Fudging market potential to match arbitrary revenue growth targets

Market research should be carried out thoughtfully by an experienced practitioner using methods appropriate to the circumstances. Poorly executed market research can, in fact, be worse than none at all.

Accuracy of Market Estimates

U.S. industry is obsessed with the accuracy of market-size estimates, sometimes to ridiculous degrees. Is the market for post-surgical respiratory widgets $102 million or $112 million? Does it really matter to anyone? There is a widespread failure to appreciate the inaccuracy of most estimates; variabilities among analysts of *existing markets* of ±20% are

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not uncommon. And, when the subject turns to *new markets* created by breakthrough products that are not yet available, errors can be much greater. Is the potential market for clinical genotyping microarrays $800 million or $2.2 billion? Well, nobody knows. And here's a secret: it doesn't matter! Would any of these choices of market numbers stimulate a change in product-introduction plans? Probably not.

What really matters is what's behind the estimates. Are the analyst and analysis credible? What insights are developed that will help *you* to make a decision? Are the published data applicable at all to the product being considered? Was the analysis carried out by an objective source? Perhaps *you* should gather some opinions and analyze the resulting data on your own.

One should not worry about quantitative accuracy unnecessarily. However, one should obsess about the qualitative insights gained in market research.

Customer Attitudes and Biases

Prospective customers will routinely mislead a market researcher! They don't intend to mislead, but researchers routinely force them to do so by not asking the right questions, or not setting up questions expertly enough to uncover the truth. And, of course customers have biases—they're human.

Physicians usually provide the most reliable information regarding the potential success of a new medical product because they are often the key decision-makers and users. However, extracting their real views can be challenging. As a whole, physicians are notoriously conservative and very reluctant to adopt new, unproven methods—and that's probably for the best. However, a small number of physicians in every specialty will be willing to try anything once, but it does not follow that they will champion the product or use it routinely. The market researcher must deal effectively with both types of respondents and predict their actual usage behaviors after product commercialization.

There is no magic formula for success. The challenge is to engage prospective customers in a structured dialog of sufficient duration to touch all the bases: (1) fully describe the new method and new product in sufficient detail; (2) address both apparent benefits and limitations, especially in comparison to existing procedures; (3) listen carefully to their reactions and to the questions raised; then (4) summarize what was heard to be sure it was heard right. It is also important to distinguish between physicians in private practice and those in academic settings; the former group will be much more sensitized to issues of cost and reimbursement.

Every attempt must be made to work through respondent attitudes and biases to answer the essential question: What will it take for this prospective customer to choose, champion and routinely use the new product? In the process of teasing out the answer to this question, certain product improvements will often emerge that make all the difference in its commercial success.

Adoption Dynamics

The concept of "crossing the chasm" from early adopting customers to the mainstream market is now widely recognized (Geoffrey A. Moore, *Crossing the Chasm*, HarperCollins, 1991). This concept is perfectly represented in the biomedical arena. One can usually make quick sales to thought-leading early adopters, but these sales cannot sustain a business. The supplier must "cross the chasm" over time by convincing the much larger body of users to adopt the new product and new method, and this process takes much longer and requires much more effort than initial sales to early adopters. Crossing the chasm is the heavy lifting of marketing and promotion.

By the same token, one must take this phenomenon into account when projecting the adoption of a new product, i.e. one must allow for sufficient resources to be deployed and time

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to pass. Routine use requires that early adopters publish their findings and otherwise spread the word to their colleagues, who will eventually become convinced to try a new product when they determine that their risks are manageable and the economics are at least neutral if not favorable. The opinions and rationale one hears from both categories of users—early adopters and mainstream users—in the course of an assessment will reveal how much marketing must be done and how long the adoption process is likely to play out.

We recognize four levels of consideration by users and purchasers of new medical products when confronting a decision to adopt, all of which need to be accounted for in understanding the adoption process:

- *Technical*. Does the product perform its intended function adequately and reliably?
- *Clinical*. Does the product provide the anticipated medical advantage, i.e. does it improve the patient's state of health or quality of life?
- *Practical*. Is the product easy to use, and does it fit current patterns of medical practice—whether for screening, diagnosis, therapy or monitoring?
- *Socioeconomic*. Does the product offer societal and/or economic benefit?

High Tech versus Low Tech

New products can be loosely categorized as high-technology or low-technology products. If a product falls into the high-tech category, we suggest that this attribute be de-emphasized when talking about it and marketing it. The great majority of potential customers equate high tech with expensive, hard to learn, and hard to use—perceptions that will not help. We recommend avoiding this characterization altogether; just describe what the product does, its similarities and differences compared to existing products and methods, and why its use is clinically and economically advantageous. Potential users with an affinity for high-tech products (probably early adopters) will appreciate this attribute without it being advertised.

Estimating Latent Demand: The Available Market

In projecting sales revenues for a new product, we usually start by estimating its latent demand, which is the maximum number of units that would be purchased annually in the region of interest after the market has been fully saturated. This is equivalent to the product's *available market*, a value which can then be discounted, and sales projected over time, in accordance with the many factors that influence new-product revenues. Depending upon circumstances, one might need to estimate placements of capital equipment, supplies, or both.

Estimating placements of capital equipment requires knowledge of the number of available sites of use, e.g. hospitals, critical care units, operating rooms, physician offices, nursing homes, rehabilitation centers, or whatever. In each case the total number is relatively easy to determine from published data. Once this number is known, one must then determine which, and how many, facilities would actually deploy the product and how many units would be deployed per facility. The result is latent demand for capital equipment.

Similarly, an estimate of demand for supplies requires an estimate of the total number of procedures employing the subject product per year. Procedure counts are also known, or can be estimated with reasonable accuracy, in most countries of the developed world. Then, one must determine how many units would be consumed per procedure and what fraction of the total procedure count would actually involve use of the subject product. The latent demand for supplies can then be calculated.

Market Access

There is a prevailing tendency to overestimate a supplier's ability to access the targeted

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customers of a new product. The frequent result is an overestimation of commercial opportunity. Market access has become increasingly difficult for small medical products firms in the U.S. over the last decade because hospital purchasing organizations have been reducing the numbers of their suppliers in an attempt to increase purchase volumes, thereby presumably striking better deals with the remaining suppliers and decreasing administrative costs. Likewise, physician practices are restricting access by salespersons for similar reasons. Consequently, higher volume distribution channels are becoming the norm, which tilts the balance in favor of large producers and established stocking distributors at the expense of direct channels of distribution by small producers.

Of course, many new products must survive a "concept selling" phase that requires direct interactions with clinicians before adoption can occur. It is now more difficult to engage in these direct interactions than it was just a few years ago, so one must allow for more time and more resources to complete the concept-selling phase. And, every supplier must now rely more on innovative marketing techniques—notably thought leader referrals and peer publications—and less on direct sales activity.

The higher barriers to market access confronted by small suppliers encourage their consideration of marketing and sales alliances with large, established companies. While such arrangements always have a negative impact on per-unit revenue, they can maximize total product revenue over time if the alliance is carefully crafted and mutually beneficial. The approach planned for product distribution must be taken into account when the opportunity assessment is conducted. If all the details are not known at that time, alternative scenarios should be developed corresponding to each distribution approach.

The Process

While the process of assessing commercial opportunities for new products cannot be reduced to a formula, we present below an outline of the steps that are always required in the examination of the potential offered by a *new* market. Shortcuts for existing markets are possible.

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Opportunity Assessment Process

Define the new product:
- Details and frequency of use
- Comparison to existing products
- Unique benefits

Define the market by identifying and characterizing *likely* customers among:
- Users
- Purchasers
- Payers

Characterize the economics:
- User costs
- Reimbursement
- Product pricing

Estimate the available market:
- Number of sites
- Number of procedures per annum
- Annual revenue at saturation

Project market introduction and product adoption over time by considering:
- Regulatory approval track
- Customer accessibility
- Clinician referrals
- Marketing alliances

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