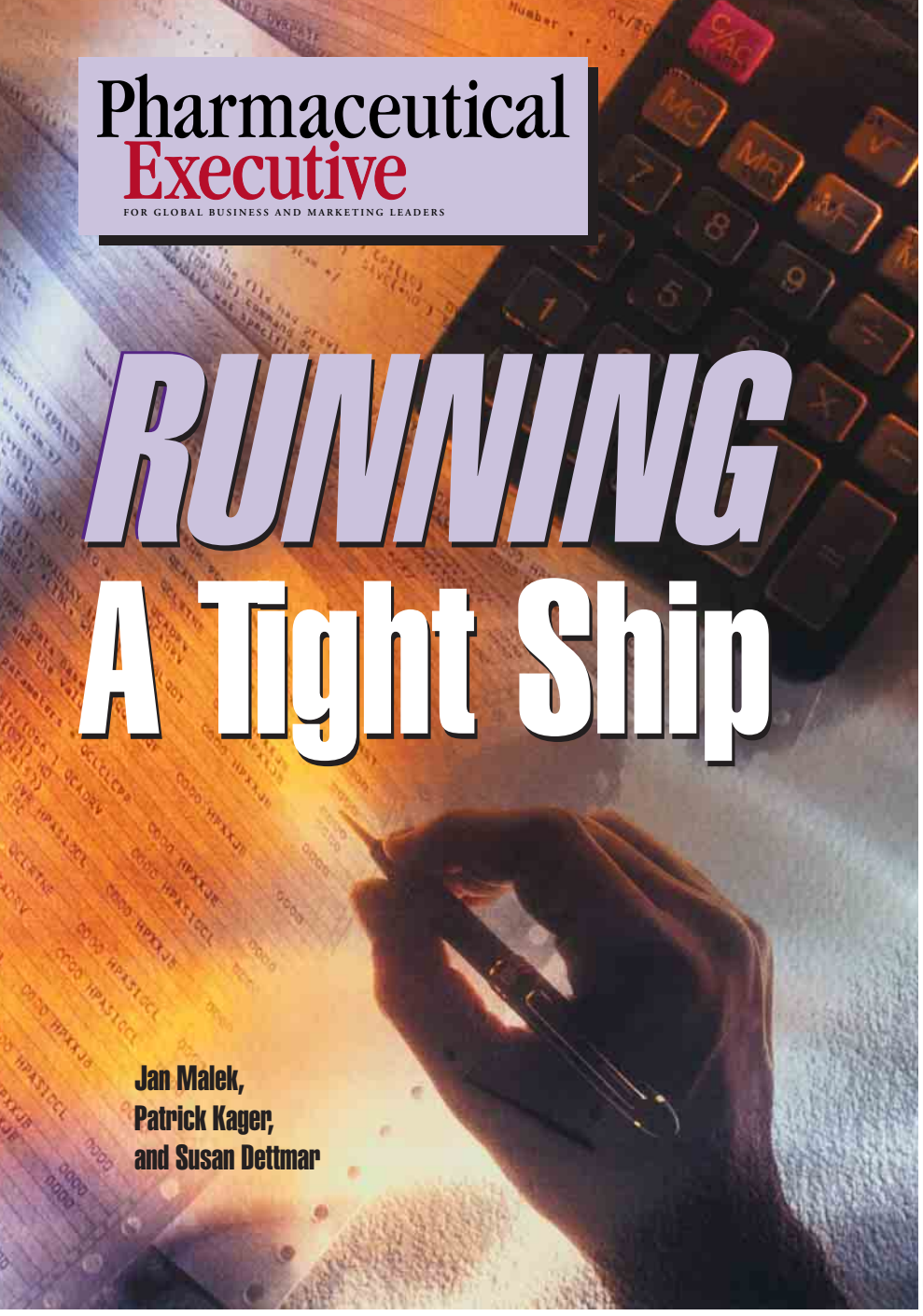
Pharmaceutical Executive
FOR GLOBAL BUSINESS AND MARKETING LEADERS



RUNNING A Tight Ship

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ARTVILLE

TO BE COMPETITIVE, PHARMA COMPANIES MUST LEARN TO MANAGE RESOURCES MORE EFFECTIVELY.

In a tight market, pharma companies are asking themselves: "How can we get more from scarce resources?" As a result, R&D and sales/marketing expenditures are under increased scrutiny—and they should be. Both areas consume significant resources (about 25 percent of revenues combined) have experienced rapid growth, and their results have been difficult to quantify. But to make the most of both human and non-human assets, management must first understand how those assets are currently allocated, how to make them more productive, and if there are better ways to deploy them. That substantial task will be further exacerbated as the industry begins tailoring medicines to smaller sub-populations, resulting in a greater number of marketed products competing for resources.

Executives struggle with resource management issues on two levels: determining the aggregate level of resources that will enable the company to achieve its goals and allocating resources for competing initiatives such as specific programs (compound A versus compound B) and functions (DTC versus detailing). Research shows that successful portfolio and resource management decisions must be

- grounded in market-based strategies by therapeutic area
- explicit and internally consistent
- based on empirical relationships between resource consumption and results
- tied to the company's goals and objectives
- based on a probabilistic view of the pipeline and future resource requirements
- transparent and readily available to other decision makers.

All of that is easier said than done. This article identifies the processes and infrastructure that pharma companies need to manage portfolios and allocate resources more effectively.

Who, Where, and Why

The industry is a victim of its own success. The rapid growth of the last few decades catapulted it to a point where traditional management methods have become obsolete. Those predominantly intuitive tactics worked well when the body of scientific knowledge was much smaller and most senior executives were not only well versed in it but also involved with most of the company's research and sales

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efforts. But with a proliferation of scientific breakthroughs in addition to an escalating volume of activity, pharma R&D labs and product teams have grown in size, scope, and complexity far beyond any executive's ability to maintain first-hand knowledge and involvement.

To effectively manage today's R&D organizations—comprising hundreds or thousands of researchers, working on hundreds of projects, in multiple locations across several continents—requires highly sophisticated processes and systems. Likewise, product team management, responsible for hundreds of millions or billions of dollars in revenues from a single product across multiple country-specific markets, requires a similarly high level of sophistication. Another complication is that many of today's Big Pharma companies are amalgamations of previously independent companies, and the executives who lead them come from one of the merged companies or from outside the industry. Thus they lack the hands-on knowledge of at least some of the compounds and marketed products about which they must make decisions. With more merger and acquisition activity on the horizon (see "Get Ready to Merge or Diverge," *PE*, August 2001) pharma companies that expect to participate in the M&A game need to enact processes that will enable them to effectively manage expanded portfolios and increased resource bases.

Portfolio and resource management issues in R&D on one hand, and sales and marketing on the other, share common characteristics but also differ in some important respects. (See "Resource Management Issues Vary by Group.") Managers need to take into account the differences when designing potential solutions, but both areas can benefit from a cross-fertilized approach. Portfolio and resource management decisions are intimately linked and must be dealt with in tandem. The activities take place at three interrelated levels in the company. (See "The Management Pyramid," page 60.)

Strategic. At this level, the focus is on direction-setting portfolio decisions and high-level directives about the types and level of resources that the company requires to achieve its goals.

Tactical. This management level deals with scheduling activities and resources, based on the strategic decisions made. It also involves program/project managers as well as department heads who control physical resources such as facilities, equipment, and personnel.

Operational. Decisions at this level concern the execution of plans and the collection and reporting of basic data, including the systems and coding schemas that make data capture and reporting possible.

Top-Level Strategy

Effective management at the strategic level requires a three-pronged framework:

- market-based therapeutic area (TA) strategies and a standardized methodology for evaluating compounds and marketed products
- a "gating" process that prioritizes decisions according to projects, products, and resource allocation
- a resource forecasting and balancing process that highlights potential bottlenecks and ensures that functional areas have resources commensurate with the projected pipeline.

Therapeutic area. These strategies must be grounded in fact-based, dynamic perspectives of TA markets and must provide direction and focus for R&D and sales/marketing organizations. TA leaders and senior managers formulate such strategies based on a data-driven approach that takes into account key market inputs, including:

- key medical attributes such as met and unmet clinical needs, and product performance as identified by prescribing physicians and opinion leaders
- epidemiological data and forecasts of expected future market size for the ther-

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Resource Management Issues Vary by Group

Characteristics	R&D	Sales & Marketing
Dependencies	**High**: The activities in each area are highly dependent on the outcomes of "upstream" activities.	**Low**: Groups are relatively self-contained but must be aware of pipelines to plan accordingly.
Degree of predictability	**Low** for the success of specific compounds; **Higher** by phase, or the compound portfolio in aggregate.	**High** for revenues for the next 6–12 months but high uncertainty about which activities contribute most to revenue.
Degree of management discretion in allocating resources	**Medium**: Management sets resources at the portfolio level but has limited discretion once scientific requirements of a project take over.	**High**: The level marketing required is largely a judgment call.
Attitude toward management's measurement of productivity	Highly anti-cultural; considers productivity measurement appropriate for "widget makers," not scientists.	Business-focused, but the effectiveness of campaign activities is rarely rigorously qualified.

apeutic area and specific product categories
- the competitive landscape based on analysis of patent applications, product announcements, expected launch dates, and key product attributes
- fact-based analysis of the competitiveness of the company's products, taking into account expected launch dates of competitors' products and their attributes
- assessment of emerging technologies that may affect the competitive landscape, probabilities of success, key impact, and risks.

Companies also need a standard methodology for assigning an expected monetary value to pipeline and marketed products. Research shows that an options pricing framework adapted from financial options instruments is particularly useful because it can capture the multidimensionality and the inherent uncertainty of the variables and summarize them in a way that makes possible apples-to-apples comparison between compounds—at different points in the life cycle and in different therapeutic categories.

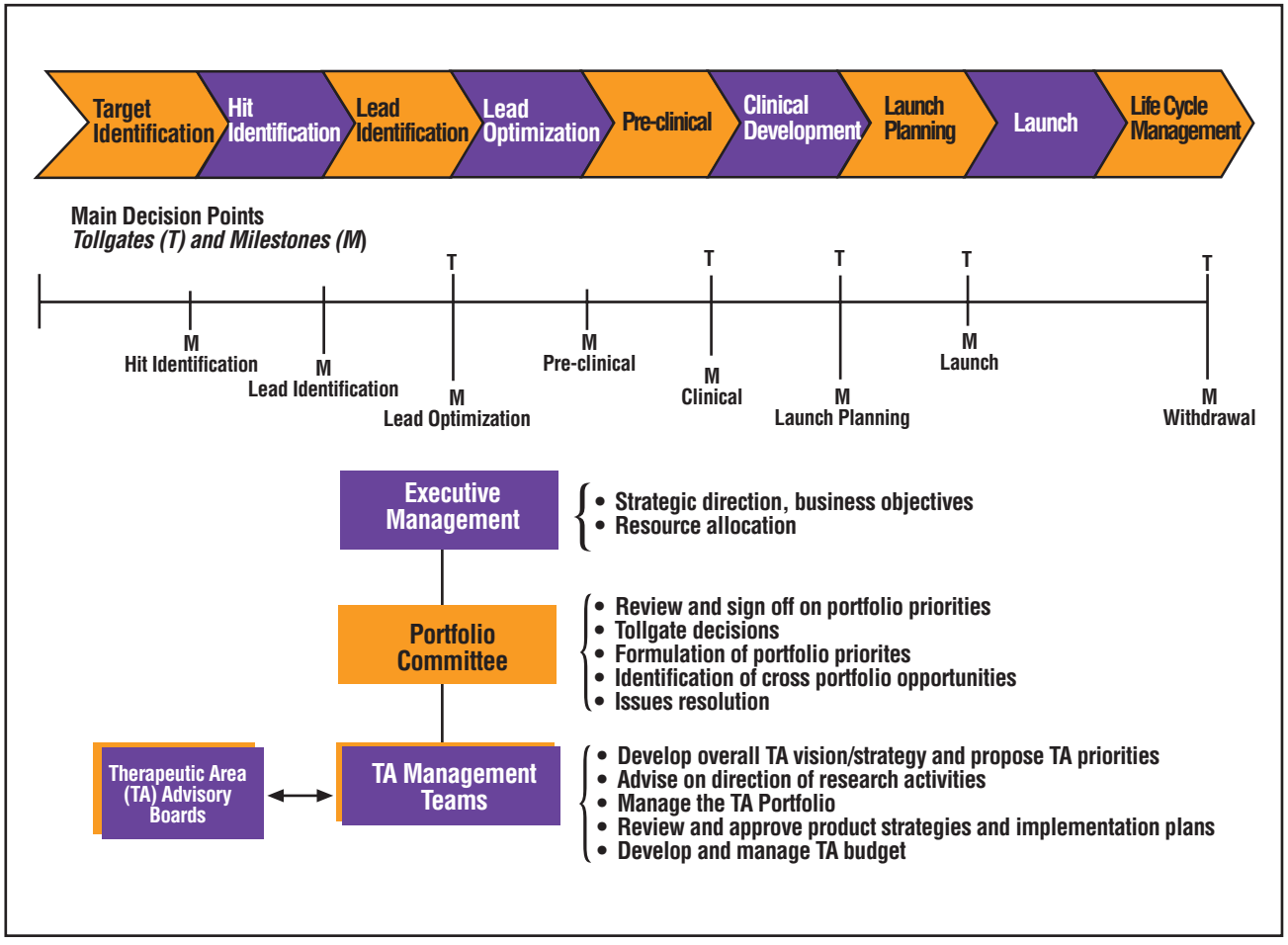
Gating. A well designed gating process provides managers with a predefined set of "toll gates" and "milestones" for reviewing compounds/products on a regular basis and determining if they meet the scientific and commercial criteria necessary to move forward. (See "Critical Path.")

The gating process begins with compound and therapeutic area teams making recommendations and ends with senior management decisions. The TA teams typically champion their own projects, and senior managers must temper that enthusiasm and ensure that there are solid scientific and commercial reasons to continue investing resources in the compound.

To avoid letting mediocre compounds slide through to the next phase or funding declining products, management must establish in advance, then adhere to, clear scientific and commercial hurdles that projects must meet to continue receiving funding. Without such well-defined and publicized criteria, companies run the risk of wasting significant resources by continuing to support products with limited future prospects. Gating reviews must be coordinated with, and operate within the parameters established by, the annual budgeting and long-range planning cycles or

CRITICAL PATH

Reviewing projects at tollgate and milestone points can help companies make critical decisions about resource allocation.



support the needs of a more flexible rolling forecast approach. Although that gating process should be familiar to most pharma and biotech companies, research reveals that few organizations have processes and support systems that are sufficiently tight to manage resources effectively. Many organizations also lack a rigorous methodology for evaluating projects, thus they sometimes fail to stop some projects while starving more promising internal or in-licenses candidates of needed resources.

With a view of the portfolio in hand, senior managers can evaluate the interplay between project goals, the portfolio composition, and the company's resources.

Balance. The third component of the strategic level is a process that examines the portfolio to ensure that all functions are sized proportionately to the pipeline, thus preventing bottlenecks caused by resource shortages. Bottlenecks can take the form of a pilot plan lacking the capacity to support all compounds in a timely manner or a sales organization lacking the capacity to support multiple product launches. To prevent such situations from occurring, companies must actively manage internal resources and secure qualified outsourcing partners in a timely manner. (See "R&D Outsourcing That Works," *PE*, March 2000). The ability to make those decisions is dependent on the company's ability to

- link a realistic pipeline model with empirical resource consumption coefficients such as the level of resources required to conduct high throughput screening, to write a clinical protocol, or to conduct a biostatistical analysis
- to forecast, by type, the expected resource usage required to complete the development of pipeline compounds
- to support sales and marketing activities across the portfolio.

Decisive Levels

With a comprehensive view of the portfolio in hand, senior managers can evaluate the interplay between project goals, the portfolio composition, and the company's resources. Specifically, they can start asking and answering key questions such as:

- Given the resources available, which projects should we continue to support and which should we shut down or delay?
- Will we increase the value of the portfolio if we reallocate resources to accelerate development of a promising compound to beat competition to market? Will we need to outsource some aspects of R&D for other important compounds to keep them on schedule?
- To accomplish our strategic objectives, what skill sets do we need to bring on board—computational chemists, molecular biologists? Which platform technologies should we invest in?
- Our flagship product X is losing patent protection. Should we continue to support it to keep the shelf warm for our next-generation product that will reach the market in three years? If so, what level of resources is appropriate?
- What is the best way to organize our R&D and sales and marketing activities to achieve our objectives? By therapeutic area, by function, or by location? Should some resources be allocated to therapeutic areas and others be shared, and if so, which ones?

Those are complex decisions that must be made in the context of the entire portfolio. To make the best decisions, management needs access to extensive information, which the tactical and operational layers of the infrastructure must be able to provide.

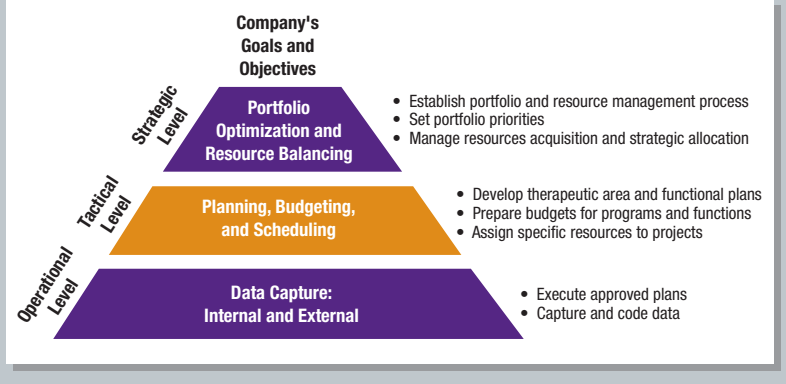
Tactical. This level of decision making corresponds with program/project and functional/departmental management, which develops project plans and assigns resources to specific tasks. It is probably the area most familiar to managers because all pharma companies have some budgeting, planning, and staff assignment processes in place. What many organizations lack, however, is a comprehensive tool set that allows them to consolidate and compare across projects as well as the ability to simulate alternative scenarios.

Operational. This is the front line, where data are generated and captured. Data capture takes many forms, including

- time-and-expense (T&E) capture
- accounts payable for the capture of external service providers—labs, investigators, advertising agencies, contract sales organizations, and joint ventures
- service centers within the organization but outside the R&D and sales and marketing organizations

THE MANAGEMENT PYRAMID

Effective resource management requires a structured and well defined approach.



Source: Deloitte Consulting

PE Graphic

Scientists, as well as sales and marketing people, may protest the idea, but in a complex and resource-limited world, companies must create a much greater level of transparency.

- the gating process that updates information about projects in the R&D pipeline.

To be useful to decision makers, the data must be captured at source, in a timely manner, in sufficient granularity, and must be coded appropriately. Unfortunately, many pharma companies are handicapped by incompatible coding schemas and multiple T&E, project management, or financial systems in different regions, many of which are the result of past mergers and acquisitions.

As companies conclude that they need more accurate and timely resource data, it is likely that they will install global enterprise resource planning (ERP), project and portfolio management systems and uniform coding systems. Such global systems will give companies the much needed transparency regarding budgets, expenditures, staff and asset usage, and other data. That, in turn, will enable decision makers to review and analyze data in a way that supports their decisions by location (across multiple functions), by function (at multiple locations), by project (across multiple functions and locations), and by program and therapeutic franchise. Portal technology is well suited to be the ubiquitous access point for such information.

With such an operational infrastructure in place, companies can move to the next phase: linking resource consumption (inputs) with deliverables (outputs) to ascertain the productivity of resources, to track the extent to which their strategic goals and objectives are being met, and to clearly define and make visible bottlenecks and obstacles that prevent them from attaining their goals.

Although no pharma company has yet achieved it, the goal is to establish empirical relationships between inputs and outputs for all functions and activities and to base future resource management decisions and productivity improvement efforts on those productivity relationships. Capturing input–output relationships is difficult, but it is certainly feasible.

Changing Culture

Many scientists—as well as sales and marketing people—may protest the idea, but in a highly complex and resource-limited world, organizations must create a much greater level of transparency and must manage resources much more actively and purposefully than they have in the past.

At the core of the transition ahead lies the need for the industry—and the people who work in it—to come to terms with the fact that both R&D and sales and marketing have, with the exception of some discovery research activities, become highly "industrialized." It is important to recognize that, although they require intelligent and educated people to complete them, most processes are well defined, highly standardized, and software enabled.

Industry professionals must come to terms with the reality that, like lawyers, consultants, physicians, journalists, and other professionals, they, too, will be held accountable for their productivity.

To facilitate the transition and to harness their employees' energy, pharma companies must involve employees at all levels and actively manage the culture—including expected, acceptable, and unacceptable behaviors. To stand a chance of succeeding, senior executives must engage the hearts and minds of their employees. They must communicate the underlying reasons for their actions, share productivity information, and communicate specific imminent changes and how those changes fit into the overall effort. That requires a well orchestrated effort engaging all internal and external constituencies.

Pharma companies face increasing pressures from regulators, patients, and shareholders. Many observers question whether the industry will succeed in bringing to market a sufficient number of new compounds to offset the forthcoming patent expirations of blockbuster products. In that new environment, the industry can ill afford to waste efforts, misallocate resources, or invest in projects with limited prospects.

With the advent of targeted medicines for better defined patient populations, the industry faces the prospect of a proliferation of small-market products and a potential portfolio-management and resource-allocation nightmare. The time has come for pharmaceutical companies to replace their outdated, intuitive approaches to resource management with an institutionalized, quantitative, fact-driven approach that will provide managers—as well as scientists and marketers—with more detailed, accurate, and timely information.

The process and infrastructure challenges associated with the transition are significant, but the major challenge will be to change mindsets and to accept that R&D and sales and marketing organizations can no longer be managed like loosely affiliated groups of artisans. Ironically, the best chance of retaining some of the independence so valued by industry employees may come as a result of the increased transparency that lets management know what they are doing. If that is a Faustian bargain, it is one worth striking. ▮

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