The Limits of Scale

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The difference in profitability between the top five pharmaceutical companies and the smaller pharma companies has been reducing over the last decade. The operating margins of the top five pharma companies rose by mere 1%. This was in spite of huge increase in the drug sales of the top five pharma companies. These companies need to restructure their organizations if they have to increase their operating margins and increase their profitability compared to the smaller companies. This article explains the existing organizational structures of the top pharma companies, the industry trends and challenges faced by them—and how Big Pharma, the top five pharma companies, should restructure themselves in order to face the challenges and increase their profits.

Keywords: Genomics, OTC (Over-the-Counter)

Over the past decade, drugs sales by Big Pharma, the pharmaceutical sector's five largest companies, have grown fivefold to $16.8 bn. Yet their operating margins rose by a mere 1%. At the same time, Big Pharma quadrupled its R&D spending while producing the same number of drugs. And the gap in profitability between the top five pharmaceutical companies and the smaller ones actually shrank. Have the big drug companies reached the limits of scale?

Big Pharma's organizational model—based on strict functional boundaries around R&D, sales and marketing —appears to be limiting rapid decision-making and causing business performance to plateau. Something has to change. Pharmaceutical companies need to restructure around a few Therapeutic Franchises (TF) to better leverage their R&D spending, bring drugs more effectively and efficiently to market, and reach profitable new customers. (see Figure 1)

Each of the five largest firms now spends at least $2.2 bn on R&D annually. This is more than the combined discovery spending of the 20 largest "new-age" pharmaceutical companies, like Millennium and Vertex. Such "new-age" companies use technology to overcome traditional R&D bottlenecks. Yet despite Big Pharma's increased spending, the largest pharmaceutical companies have not increased the number of New Chemical Entities (NCEs) they launch each year. (See Figure 2).

Each of the ten largest pharmaceutical companies by revenue still launches, on average, 1.6 new chemical compounds per year. In other words, Big Pharma is spending more on research for the same number of drugs. This not only misallocates scarce resources, but also is unsustainable in the long run, even for an industry with earnings and investor confidence as strong as in pharmaceuticals.

By the drug industry's own estimate, each big pharmaceutical company needs to launch 3.1 drugs per year to achieve a 10% growth in sales. That means the top ten pharmaceutical companies need to double the number of new drugs they launch each year to meet a typical sales-growth target.

Narrow Your Focus

Historically, the big pharmaceutical companies have all pursued an undifferentiated strategy—the quest for blockbusters—driven by a strong belief in the role of serendipity in drug discovery. This strategy has led them to pursue blockbusters in unrelated disease and therapeutic categories. Mergers have also increased both the depth and breadth of R&D and the reach of sales and marketing. But Bain's analysis suggests this thinking rests on faulty assumptions. Our findings indicate that in the past, a narrower focus, not serendipity, led to blockbusters. That truth will hold.

Bain research shows that players that focused on and built strong positions in a few therapeutic franchises (those focused on customers or disease) vastly outperformed players that followed a more broad-based approach. We looked at the performance of pharmaceutical firms such as GlaxoSmithKline (GSK), AstraZeneca, Pfizer, Merck and Lilly—which get 80% of their revenues from their top three therapeutic franchises. And we compared their performance with that of broad-based companies like Roche and Novartis, which reap fewer sales, just 58%, from their top three therapeutic franchises. Since 1990, the more narrowly focused companies have reported 1.7 times more revenue growth and market capitalization than the broader-based ones. (See Figure 3).

And contrary to industry belief, blockbusters do not happen by chance. About 70% of blockbusters created from 1970-2000 were generated in therapeutic franchises in which the companies had already established a presence that was either moderate (over $500 mn in sales from one or more drugs) or strong (over $1 bn in sales from multiple drugs).

Face Down Four Threats

Several industry trends threaten the prevailing, traditional business model of the fully integrated, large-scale pharmaceutical firm:

- In the first place, new competitors, particularly biotech firms, are using new technologies and discovery techniques to make the discovery process far more productive and less reliant on serendipity. Vertex, for instance, which spent about $150 mn in 2001 on R&D, has more promising compounds in clinical trials than do many major pharmaceutical companies. At the beginning of 2002, Vertex had more than ten compounds in late stage trials, on par with some of the largest companies in the industry. New

ways of discovering and testing drugs—such as high-throughput screening and **genomics**—are reducing the barriers to entry, making it easier for smaller companies to compete against the Big Pharmas.

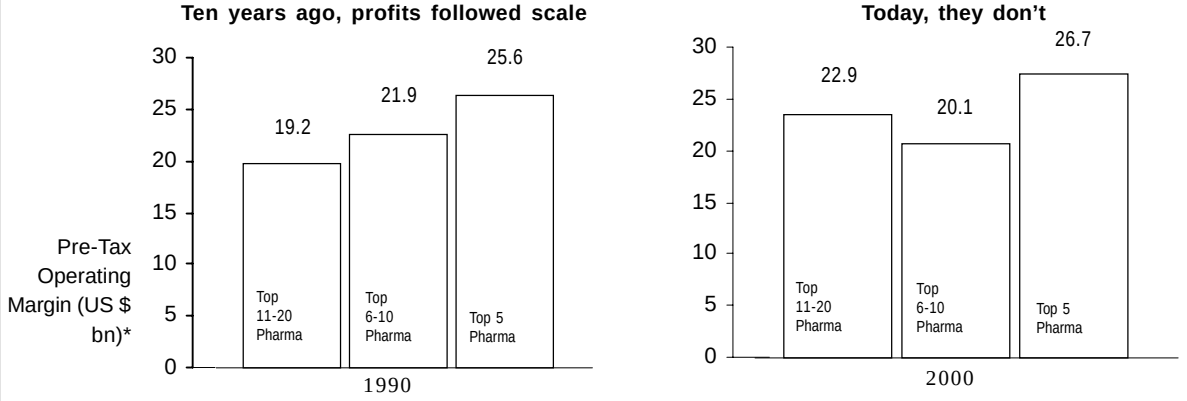
- Some of the new technologies are also challenging Big Pharma's one-size-fits-all approach to drug sales. Historically, the large companies have used their broad-reaching distribution networks to sell the same brand of drug to every consumer with the same condition. But many think the emergence of pharmacogenetics (and related technologies like pharmacogenomics and pharmacoproteomics) holds out the promise of custom drugs for specific genetic profiles. One example is Genentech's new drug Herceptin, used to treat aggressive breast cancer. It targets HER2, a growth-factor receptor protein overproduced in 25%-30% of patients with breast cancer. The new drug is credited with increasing, by 25%, the chances of surviving aggressive breast cancer, although it has also caused a handful of fatal hypersensitivity reactions.
- Traditionally, Big Pharma viewed pharmacogenomics with suspicion. Executives believed that genotyped drugs would increase costs while decreasing revenues, because each drug would serve a narrower market. But we believe the new drugs will actually increase the industry's long-range profitability. There will be a short-term negative impact on the cash flows generated by an average drug as a result of higher attrition rates in early trials driven by greater yields in the pre-clinical phase. However, long-term profits should be higher: These new, more targeted compounds will benefit R&D by decreasing attrition rates in ongoing trials and providing second chances for drugs that caused adverse reactions in limited populations during clinical trials. Sales will benefit too. Better drugs will mean happier, more loyal customers, and loyal customers are more likely to refill their prescriptions.
- Another challenge to the distribution network comes from more knowledgeable consumers. Although doctors remain the primary targets of gigantic drug-company sales forces, rising drug costs and fixed levels of managed care reimbursement are turning once-passive patients into price-sensitive consumers. Today, consumers often choose generic over brand-name drugs. Some of the most educated consumers even ask for formulary products if the generic is unavailable. Today's consumers are also less likely to simply take their doctor's word about their health: According to one survey, 45% of Internet users read on health issues. The growing number of narrowly targeted drugs and the increasing role of consumers in choosing their drugs will inevitably change Big Pharma. Licensing deals, co-promotions, partnerships, bundling—many of the development and marketing tools common in other industries, but still relatively new to Big Pharma—are likely to become standard practice. At the same time, growing market complexity will lead corporate strategists to take a portfolio approach to their products. They'll begin viewing their business as satisfying a number of closely watched market segments, not creating individual blockbuster drugs.

Given these issues, it's time for Big Pharma companies to re-evaluate their common business model—the fully integrated, research-led, functional organizational structure—and find a new basis for competition. Many ways exist to create organizational focus and accountability. One way of Big Pharma's most viable options is to create business units around selected therapeutic franchises, focused on customers or disease, where the company has historical or emerging strength.

Redraw the Organizational Chart

Transforming a fully integrated, research-driven firm into a more narrowly focused organization requires fundamental structural change. Big Pharma companies typically are organized around traditional business functions, such as R&D, sales and global marketing. Apart from the chief executive and the chief operating officer, no one is responsible for the profit and loss of any individual therapeutic franchises. If the company

Figure 1: The Importance of Scale



*Note: 1990 Top 11-20 Avg. sales is for top 11-15 players only; Operating margins include non-pharma businesses in some cases.

Sources: IMS; HSBC: Global Pharmaceutical Review (3/00); Lit Searches; Bain analysis

invests hundreds of millions of dollars in an immunology drug that fails in the marketplace, no one—apart from the top officers—is held accountable. Little wonder that pharmaceutical companies, historically unsuccessful in grooming strong general managers, have had their entrepreneurial management talent eroded in R&D, sales and marketing. New-age pharmas like Vertex Pharmaceuticals and bio-pharmas like Amgen and Genentech lure away top performers.

The organizational structure of medical device companies provides a sharp contrast to Big Pharma's approach. Medical device companies operate in highly segmented markets with relatively short-lived products that must be quickly replaced with new models. Such companies tend to be organized around fully integrated business units focused on customers or technology. For example, Medtronic's 25,000 employees are organized in four primary product line groups—cardiac rhythm management, vascular, cardiac surgery and spinal—each with its own global, product-line Profit and Loss (P&L) statements.

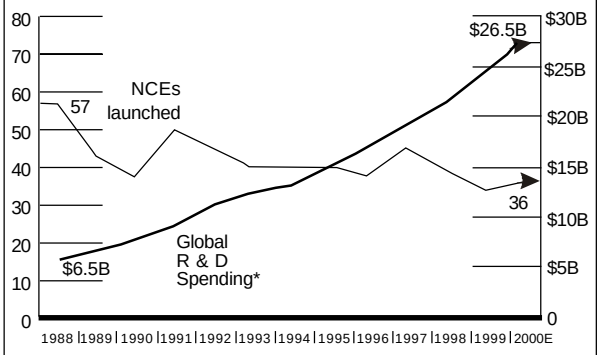
Of course, there are many ways to create a differentiated strategy. The key is first to understand which core competencies set a firm apart from its competitors, then to build a unique offering from such strength, wherever on the value chain it resides. Many drug companies' strengths lie in specific therapeutic franchises. Big Pharma companies have the opportunity to reconstruct their organizations. A company can start by turning its discovery arm into an independent agency and converting its development, marketing and sales functions into business units based on the firm's therapeutic franchises. This reorganization would effectively decouple the traditional pharma value chain, with profound implications for both the science and the commercial organizations. Big Pharma should consider three key steps in reorganizing. (See Figure 4)

First, companies can set up business units based on therapeutic franchises. Today, Big Pharma ascribes the lion's share of value creation to its commercial or customer-related functions, and it discounts the value of discovered compounds based on the probability of their success. Yet commercial functions are inefficient when dealing with the complexity inherent in drug development, customers and global business management. One way to better allocate value creation is to integrate the commercial with the development functions into business units based on therapeutic franchises.

Each Therapeutic Franchise (TF) would be responsible for its own clinical development, sales and marketing. Each would control global profit and loss and own a dedicated sales force. Each TF also would be free to obtain promising compounds from outside firms or from the company's own research division. A general manager would run each therapeutic franchise and would be entirely accountable for its financial results.

Second, companies need to separate R from D. Companies should carve out Research (scientific, through early drug discovery) into autonomous organizations that deal at arm's length with the company's

Figure 2: Pharmaceutical Industry Spends More on R&D but Produces Fewer NCEs



*Note: Annual Global R&D Spending by Research-based Ethical Pharmaceutical Companies

Sources: Datamonitor 1999; Annual PhRMA Survey 2000; Parexel's 2000 R&D Statistical Sourcebook; Analyst Reports; Tufts University Attrition Rate Study; Juergen Drews "Innovation Gap" Study.

business units and are run by a general manager with a blended profit and loss. An independent research division such as this would give the pharmaceutical parent several advantages. It would bring together critical technologies scattered around the organization, such as high-throughput screening, combinatorial/computational chemistry, or genomics. This would allow the company to fully realize the true benefits of scale—not size—and grow bigger in specific strategic areas. It would also increase accountability and entrepreneurship. Current scientific trends, such as genomics and high-throughput discovery, would probably facilitate the shift to an independent discovery organization, although it will likely be some time before any parent company sees a payback. Still, this independent research unit could increase its "option" value in the event the parent decides to spin it off, or at least partially float it in a public offering.

And third, Big Pharma companies should start rigorously managing their portfolios of drugs. At present, most do not have formal portfolio management systems, with Merck and Eli Lilly the rare exceptions. Rather, project teams come together ad hoc and disband after a product launch, which means no team remains accountable for results. More often than not, compounds reviewed meet threshold criteria for commercial launch because reviewers have self-interest in pushing their products forward. There's no countervailing body with the knowledge to challenge a team's assertions, and no team stays in place long enough to remain accountable if its recommendation fails its promise. At the typical Big Pharma, decisions to invest in drugs are passed from decision point to decision point without much strategic rigor. Alternatively, a senior cross-functional team overseeing all TFs should decide on key trade-offs—what to do with new compounds, which TF to focus on, and which TF to exit.

The Portfolio Management Team's role should be threefold:

- to push the TFs to defend their compound decisions;
- to make cross-TF resource allocation decisions; and
- to decide which TFs to initiate investment in, increase investment in, disinvest or exit.

Reap Fivefold Returns

Organizational change bears a high cost in employee time, concentration, asset utilization and cash resources, but the payoff should more than repay the investment. We calculated the full potential of reorganizing the business around a few carefully chosen therapeutic franchises. The net present value, or the incremental cash a company could have today from the lifelong proceeds of a successful drug, could be nearly five times higher for a company with therapeutic franchise business units than for the typical broadly focused Big Pharma company. That could translate into between $2 bn and $3.5 bn of incremental cash over the life of a blockbuster drug. The extra value emerges at several stages.

First of all, value comes from an increase in R&D productivity. A pharmaceutical company with an independent research division and highly focused therapeutic franchises for drug development, marketing and sales can expect to launch 2.8 new compounds per year, compared with 1.6 new compounds for the conventional company. The former launches will cost less because focused trials will lead to faster discovery and have a higher probability of success.

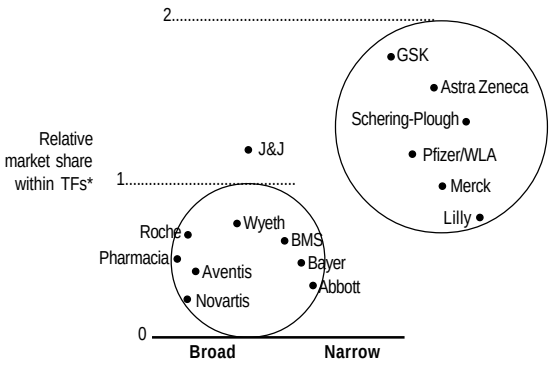
In addition, if the therapeutic franchises are truly entrepreneurial, they will license new compounds from outsiders. This, too, will increase the number of compounds, hasten development, and increase the chances of success. For example, Merck successfully licensed its anti-hypertensive cardiovascular offerings—Cozaar and Hyzaar—from DuPont Pharma. Because Merck has such a strong cardiovascular franchise, it became the logical partner for DuPont, a relatively small player in the pharma business. Moreover, a company organized around therapeutic franchises will be able to more quickly reach full-potential market penetration and hence enjoy a higher market share and a longer peak sales period.

Third, business units organized around therapeutic franchises will also be better positioned to effectively manage a drug's lifecycle. For example, before a drug's patent expires, such units can plan what to do with it—whether, for instance, to build the brand as an **over-the-counter** drug or launch a strong generic strategy.

Finally, therapy-based business units can more easily target new products that address medical problems related to their therapeutic franchises. For instance, the manager of a business unit devoted to diabetes could also target heart disease, a common killer of diabetic patients. A TF general manager could likewise look for new profit streams—for example, diagnostics and devices needed for his therapeutic franchise, such as new insulin delivery systems for diabetics.

Leading pharmaceutical companies continue to pursue blockbuster-type strategies. However, several players have started to experiment with alternative models such as limited therapeutic franchises, multiple product focus within the franchise, and global brand management. These are good first steps, but they fall short of an integrated solution. For instance, GlaxoSmithKline is promoting entrepreneurship and a narrower focus. It has announced a radical restructuring of its R&D to take advantage of scale. Glaxo is setting up six "centers of excellence for drug discovery" that will be responsible for early discovery and early clinical development of new drugs. Each center, the company says, will be autonomous, accountable and entrepreneurial along the lines of a biotech company. By this standard, Glaxo needs to migrate its quest for focus to the development half of R&D, and then on to its commercial functions.

Figure 3: Pharmas with a Narrow Focus have Higher Relative Market Share in the Same Therapeutic Franchise...



... and they grow revenues and market cap faster

	Broad	Narrow
Percent of revenues from top three TFs	58%	80%
Average annual growth rates	9%	15%
Market-cap multiplier**	4.4x	7.6x

Source: Bain & Company

Notes: * For the market leader, relative market share is defined as the ratio of units or revenues compared to those of the #2 player. For market followers, it is the ratio of their output compared to that of the leader.
** The number of times that market capitalization rose between 1990 and 2000.

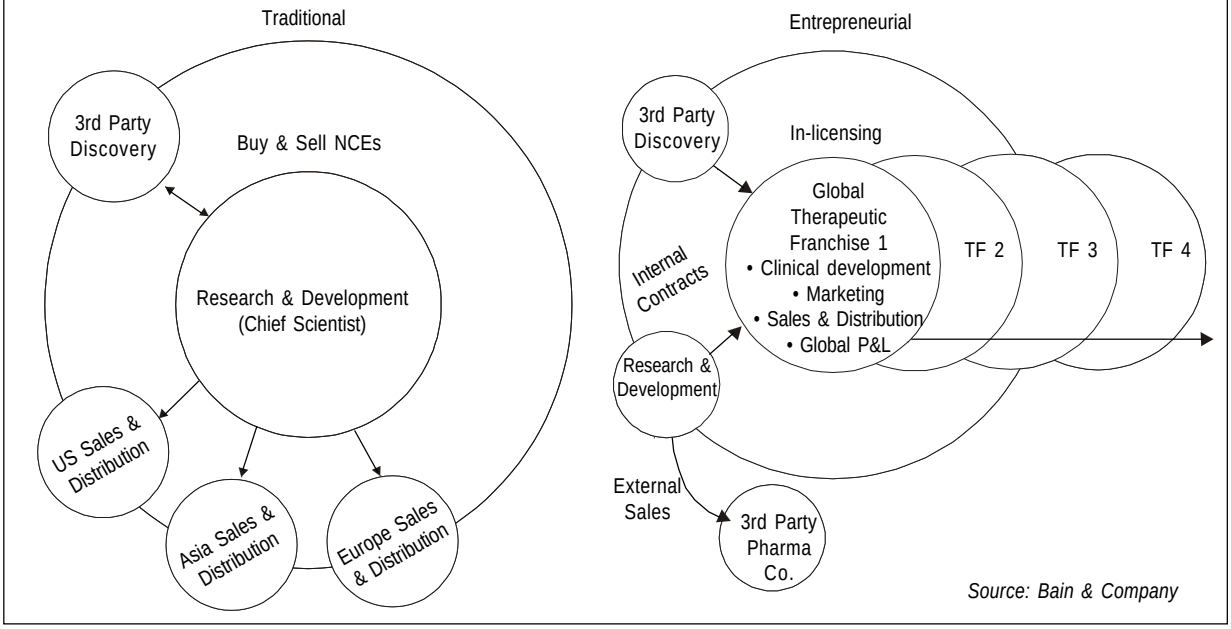
AstraZeneca also has tried a new approach by creating a centralized sales and marketing infrastructure in hopes of turning the merger of two, mid-size, European companies into a global power. The new structure revolves around a product strategy and licensing unit, which will form the bridge between R&D, and sales and marketing. Comprising three divisions, the new unit will manage the company's product portfolio and prepare the company and the market for the launch of new products. Next, AstraZeneca should apply this approach to its R&D operations.

Companies have plenty of options, of course, and the best options will depend on the company itself—its strategic position and its organizational and technical capabilities.

Manage Down Risks

Some executives say that a focus on therapeutic franchises is like putting all their eggs in one basket. What if one company chooses to specialize in immunology and another company's drug comes along and takes that market? While this concern is

Figure 4: Rebuilding the Business Around Therapeutic Franchises



understandable, concentration on a few therapeutic franchises may well be the less risky option. That's because potential competitors are less likely to be attracted to an area in which another company has demonstrated leadership. And it's because the best response to another company introducing a better drug is licensing, co-promotions and joint ventures—not spreading corporate resources too thinly.

Another key concern is the failure to spot attractive opportunities in new TFs, which fall outside a tight focus on existing TFs.

Our answer? Internal management processes have to change, or be created, to minimize any concentration of risk or potential for missed opportunities. Establishing processes like rigorous portfolio management and regular reviews across therapeutic franchises and research investment portfolios should help. This will facilitate directing, or redirecting, investments to attractive area's, including establishing new TFs and exiting from less attractive ones.

In truth, maintaining Big Pharma's current, undifferentiated approach may prove to be at least as risky as the path we suggest. The strategy of growing scale to better pursue blockbusters has topped out. It doesn't work in the current business environment. Big Pharma will have to adopt a business strategy that does work, a differentiated, focused strategy.

What Can You Do Monday Morning, 8 o'clock?

- Assess how to turn your discovery business into an independent operation, either within the company or spun off as a separate entity. Consider establishing a research organization, run by a general manager, which would own its own P&L and serve all therapeutic franchises.
- Begin identifying your select franchises that could be reorganized as independent, integrated units. Start looking for a general manager who could direct each one and be accountable for the TFs' own P&L from development to global sales and distribution.
- Start setting up a cross-functional, senior committee to manage the company-wide portfolio of all the therapeutic franchises plus research, evaluating which compounds to promote, which franchises to promote, and where to phase out or start anew. ■

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Genomics: Genomics is the study of genes, their role in diseases and our ability to manipulate them.

OTC (Over-the-Counter): Over-the-counter drugs do not require a physician's prescription. Some examples include aspirin, sunscreens, nasal sprays.

Question for discussion

1. What strategies should Indian drug companies adopt, the focus strategy or the strategies followed by the top five pharma companies of the world?

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