Tufts Center for the Study of Drug Development

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NEWS RELEASE

Tufts Center for the Study of Drug Development Pegs Cost of a New Prescription Medicine at $802 Million

11/30/2001

PHILADELPHIA – (Nov. 30, 2001) – The Tufts Center for the Study of Drug Development today announced that the average cost to develop a new prescription drug is $802 million.

That figure is the major conclusion of a recently completed in-depth study conducted by the Tufts Center based on information obtained directly from research based drug companies.

Today's announcement updates a similar study done by the Tufts Center a decade ago, when the average cost to develop a new drug was estimated to be $231 million, in 1987 dollars.

"Bringing new drugs to market has always been an expensive, high-risk proposition, and our latest analysis indicates that costs have continued to skyrocket," said Tufts Center Director Dr. Kenneth I. Kaitin.

He added, "The single largest challenge facing drug developers — both pharmaceutical and biotechnology companies — is to contain R&D costs and reduce development times without compromising clinical test design. It's a tall order."

Over the past two decades, the Tufts Center's comprehensive studies on the cost to develop a new drug have been consistently cited worldwide as providing the most reliable estimate of the total cost of new drug development.

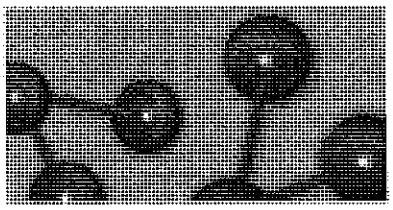
Related Tufts Center research has found that it takes between 10 and 15 years to develop a new prescription medicine and win approval to market it in the United States.

Reasons Behind the Rising Cost of Drug Development

Had costs increased at the pace of inflation, the average cost of new drug development would have risen from $231 million in 1987 dollars to $318 million in 2000 dollars, according to Dr. Joseph A. DiMasi, director of economic analysis at the Tufts Center and the principal investigator for the latest study. Instead, the new study found that the average cost of new drug development had increased to $802 million in 2000 dollars.

DiMasi attributes much of the increase in the total cost of new drug development beyond inflation to rising clinical trial costs.

"The difficulty in recruiting patients into clinical trials in an era when drug development programs are expanding, and the increased focus on developing drugs to treat chronic and degenerative diseases, has added significantly to clinical costs," said DiMasi.



Included in the drug cost analysis are expenses of project failures and the impact that long development times have on investment costs. The estimate also accounts for out-of-pocket clinical costs, out-of-pocket discovery and pre-clinical development costs, clinical success and phase attrition rates, as well as the cost of capital.

Among the study's key findings were the following:

- The full capitalized resource cost of new drug development was estimated to be $802 million (2000 dollars). This estimate accounts for the cost of failures, including research on compounds abandoned during development, as well as opportunity costs of incurring R&D expenditures before earning any returns.

- When compared to the results for previous similar studies, the R&D cost per approved new drug increased 2.5 times in inflation-adjusted terms.

- After adjusting for inflation, the out-of-pocket cost per approved new drug increased at a rate of 7.6% per year between the 1991 study and the current study. The annual rate of growth in capitalized cost between the two studies was 7.4% in inflation-adjusted terms.

- While costs have increased in inflation-adjusted terms for all R&D phases, the increases were particularly acute for the clinical period. The inflation-adjusted annual growth rate for capitalized clinical costs (11.8%) was more than five times greater than that for pre-clinical R&D.

About the Tufts Center for the Study of Drug Development

Based in Boston, Mass. and affiliated with Tufts University, the Tufts Center for the Study of Drug Development (http://csdd.tufts.edu) provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. The Tufts Center conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums on related topics throughout the year.

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Rebuilding Big Pharma's Business Model

The blockbuster business model that underpinned Big Pharma's success is now irreparably broken. The industry needs a new approach.

By Jim Gilbert, Preston Henske and Ashish Singh

- While the business climate for pharma companies has changed dramatically in the past five years, the pharma business model has not kept pace.
- Declining R&D productivity, rising costs of commercialization, increasing payor influence and shorter exclusivity periods have driven up the average cost per successful launch to $1.7 billion and reduced average expected returns on new investment to the unsustainable level of 5%.
- Mergers conceived to build scale will not improve returns. Pharmaceutical companies need new business models to restore healthy financial results.
- Four inter-related building blocks can provide the new foundation: focusing R&D efforts and commercial capabilities; making use of product and capability partnerships; providing customer solutions (not just "therapeutics"), and creating a business unit based organization model instead of a functional one. Companies need to find a combination of these building blocks that makes best use of their strengths, improves returns and manages risk.
- Breaking out of the blockbuster mentality — the quest for larger and larger opportunities in whatever disease areas they may occur—will require planned experimentation, aggressive use of partnerships, and eventually a far-reaching transformation in the way most pharma companies organize to compete.

The pharmaceutical industry is a prisoner of its past successes. While the business environment for pharma companies has changed dramatically in the past five years, the pharma business model that served the industry well over the past decades has not kept pace.

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REBUILDING BIG PHARMA'S BUSINESS MODEL

This is hardly news to many pharma executives, a surprising number of whom doubt the viability of the blockbuster model. But they can't force their companies free from the massive investments in science, selling capability, plants, and organization that used to yield the rare lottery-winner drug. Nor can they dissuade drug industry leaders who believe that incremental changes to the blockbuster approach (alone or with an acquisition) will rekindle the old sparks and restore historic returns, at least for a while.

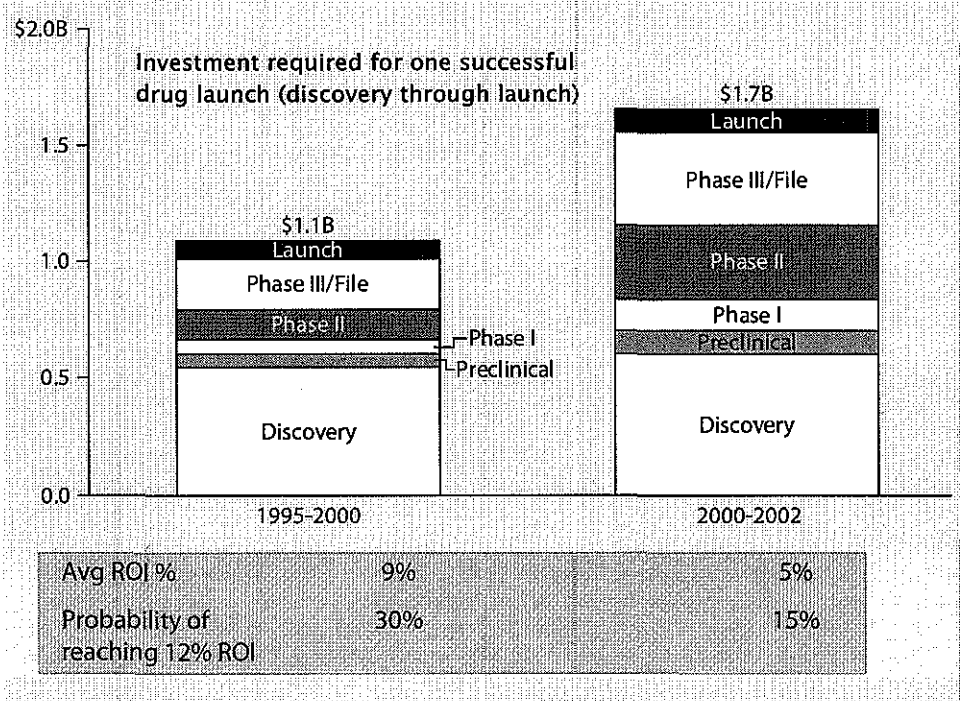
But these strategies will at best only delay the inevitable. Based on recent investment levels, success rates, and forecasts of commercial performance, we expect the blockbuster drug model to deliver just 5% return on investment — significantly lower than the industry's risk-adjusted cost of capital. Only one out of six new drug prospects will likely deliver returns above their cost of capital, an unattractive prospect for investors.

For all but the three largest firms—**Pfizer Inc.**, **GlaxoSmithKline PLC** and **Merck & Co. Inc.**—the choice is relatively stark: with fewer resources to drive primary care products and to invest in the "arms race" in R&D and sales & marketing, they will likely be driven sooner to replace their blockbuster-based strategies. Market value is shifting already to some smaller players that have adopted new models, as companies like **Novo Nordisk AS**, **Genentech Inc.** and **Forest Laboratories Inc.** have demonstrated.

In some respects, the three industry heavyweights face an even more perilous situation. Highly profitable legacy product portfolios, coupled with inflated expectations about pipelines and future business development, have held back executives from developing new business models. With scale where it matters—in the development and commercialization of new drugs—they can afford to draw out the transition. As second-tier players restructure away from having large primary care sales forces, for instance, each of the largest pharma companies may position themselves as the primary care commercialization partner of choice, providing reach and frequency to smaller companies.

INVESTMENT ESCALATION PER SUCCESSFUL COMPOUND

Exhibit 1



	1995-2000	2000-2002
Avg ROI %	9%	5%
Probability of reaching 12% ROI	30%	15%

SOURCE: Bain drug economics model, 2003

But it can't last. The prevailing model—a fully integrated pharma company that participates everywhere it gets a chance—won't deliver sustainable growth. And because the long cycles of science tend to hide costs and divorce accountability from action, many pharma executives have been slow to respond. With time to plan, they need to begin revamping their business models now.

We believe that four inter-related building blocks will define the next stage. First, companies must shift drug development strategies and commercial capabilities from being *opportunistic*—pushing a broad array of compounds on the premise that every chance is worth exploring—to being *focused* on the most promising areas of science and most attractive target customers. Second, they will transition from *fully integrated* pharma companies to greater reliance on *partnerships* to manage risk and return, across both product pipelines and functions. Third, they will gradually change their emphasis from science-driven *therapeutics* to *customer solutions* with the drug at the center. And fourth, they will replace *functional* organization models with *business units* that encourage more integrated decision-making, coupled with direct accountability for the consequences of those decisions.

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companies are living on borrowed time until their blockbuster patents run out. In-licensed drugs can buy time, but with the costs of in-licensing rising quickly and the returns from such compounds falling, this approach is unlikely to create much shareholder value.

Finally, experience with PBMs and disease management in the 1990s creates a natural reluctance to lead the creation of a fundamentally new business model. Although these service approaches did not provide the expected benefits, they contain some useful lessons. The investments were more productive, for instance, when companies either took a more focused approach, such as **Schering-Plough Corp.** did with disease management, or made early aggressive moves as Merck did with **Medco Health Solutions**. While **Eli Lilly & Co.** and SmithKline Beecham (since merged into GlaxoSmithKline) experienced large PBM investment losses, Merck preserved the value of Medco, and gained at least some market share for its pharmaceutical business.

Story Continued on Page 6

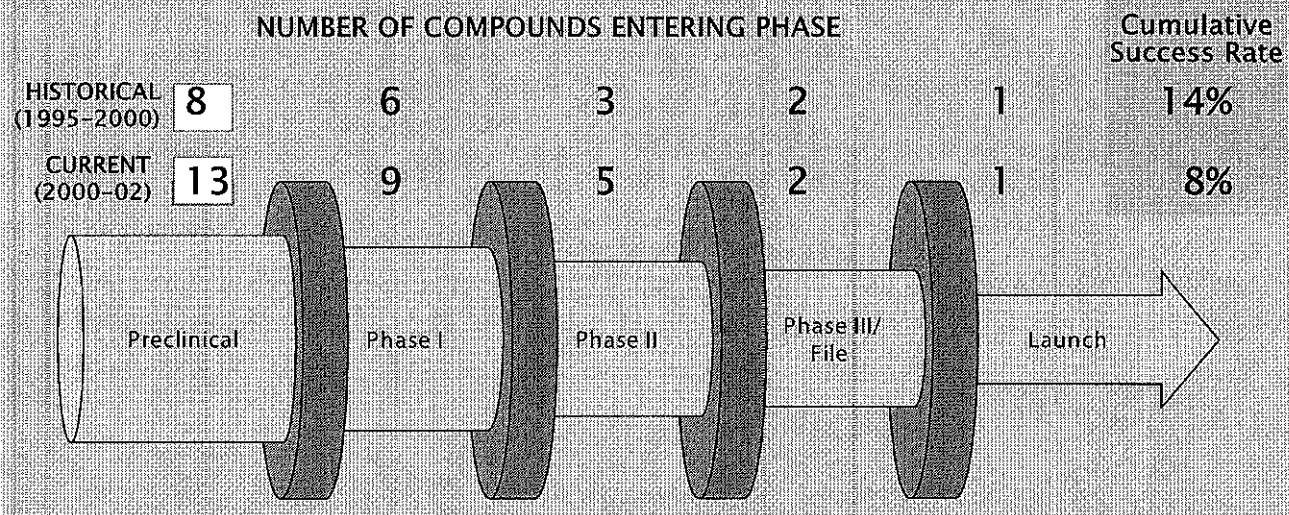
The Rising Cost of New Drugs

Industry estimates peg the cost of bringing a chemical entity to market at about $900 million, including post-launch studies. Based on recent performance data, however, the true cost is nearly twice as high—closer to $1.7 billion per successful launch, when you also include average launch costs of $250 million. The former estimate derives from data from the period 1983 to 2000. Analysis of more recent data from 1997 to 2001, taking into account both direct and indirect costs, indicates that performance has declined substantially.

This higher total cost, combined with lower average margins and shorter exclusivity periods, translates into single digit average returns on investment: about 5% for an average compound. Statistical simulations suggest that there is only a one in six chance of a new compound achieving a return on investment of 12% or more.

DECLINING R&D SUCCESS RATES

Exhibit 2



SOURCE: Bain drug economics model, 2003

One major reason for increased costs and lower ROI is a dramatic decline in productivity. Only one compound now reaches the market for every thirteen discovered and placed in preclinical trials, compared to one for every eight between 1995 and 2000. *(See Exhibit 2.)* Attrition has been particularly severe in Phase III development. Average development costs per compound have increased from $131 million to $200 million, while the chances of

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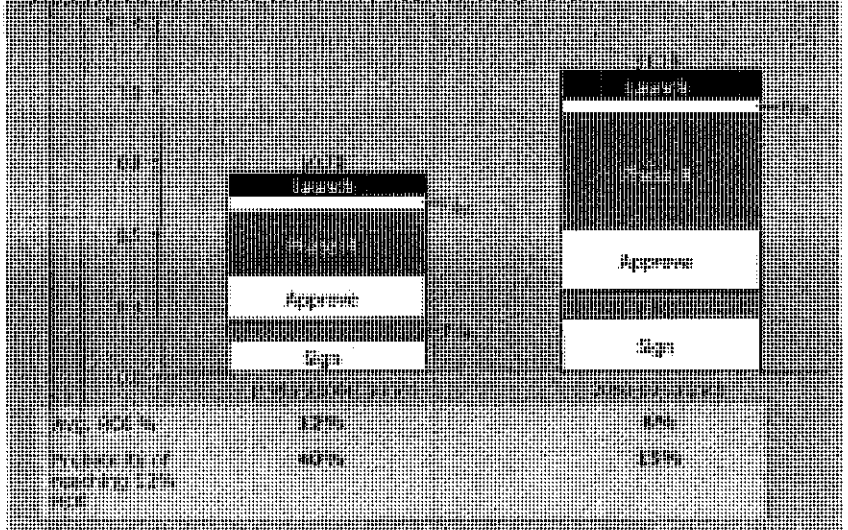
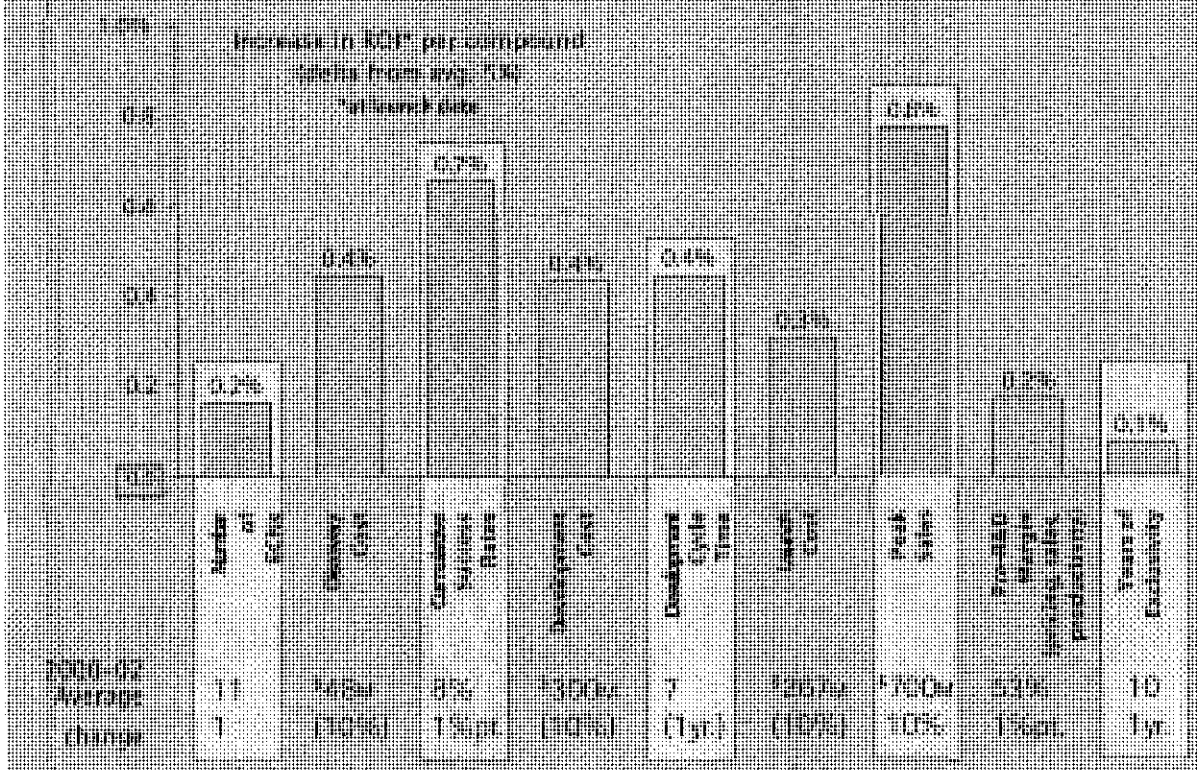
DECLINING IN-LICENSING PRODUCTIVITY



SOURCE: Windhover's Strategic Transactions Database; Pharmaprojects; Corporate reporter; Morgan Stanley; Bain drug economics model 2002

BLOCKBUSTER ROI IMPROVEMENT OPPORTUNITIES



SOURCE: Bain drug economics model 2002

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each compound receiving approval has fallen from 73% to 59%.

Further downstream, the commercial side has seen a similar decline in productivity. Physician details have become almost twice as expensive, evidenced by the drop in sales representatives' productivity of nearly 50% over the past seven to eight years.

Without a new model, costs will likely continue to rise. The overall cost of manufacturing and supply operations will grow further, owing to the increasing expense of regulatory compliance as well as the growing complexity of the molecules manufacturers are producing. And while costs rise, mounting payor price pressures and aggressive patent challenges limit the total revenue potential of the average drug.

In recent years, these productivity declines for self-developed products have made in-licensing more attractive. Companies have increased their investment returns by licensing drugs developed elsewhere and putting them through clinical trials. As price competition for in-licensing of compounds has sharpened, however, the average expected returns for Phase III in-licensing have dropped, from 12% for the period between 1995 and 2000 to about 6% today *(See Exhibit 3.)* Falling success rates of Phase III trials have also played a role in driving down the expected returns of in-licensed compounds.

In the long term, productivity could improve–and thus so could the viability of the blockbuster model. One source of improvement is scientific: development of more predictive preclinical toxicology screening could increase success rates and reduce expensive failures in the later stages of development. Similarly, the increasing adoption of pharmacogenetic profiling could benefit clinical trial design, recruitment and outcomes. Another source is technical: Increased automation of clinical trials plus earlier regulatory involvement could reduce time to market and total cost. Further still, new IT-enabled approaches supporting physician, payor and patient sales could reduce launch costs, increase peak sales and reduce sales and marketing costs. But all these improvements together are unlikely to yield returns greater than the industry's cost of capital. *(See Exhibit 4.)*

Story Continued from Page 4

Building Blocks

The drug business isn't the first industry to face a radical—and ugly—transition when the old model shows diminishing returns. The shift is usually characterized by prolonged doubt and sharp debate about the next model, along with significant shifts in capital markets investment and stock valuations. The steel industry in the 1970s, retailers in the 1980s and personal computer makers in the 1990s all experienced this form of turbulence.

Big Pharma won't abandon its old model easily. The blockbuster model has served the pharmaceutical industry well, generating over 13% annual growth in market capitalization between 1992 and 2002. What's more, pharmaceutical companies have built a large infrastructure around the blockbuster model, including 80,000 sales representatives in the US alone, trained and paid to focus on the one or two breakout products in a company's portfolio. Organizations of that scale carry considerable inertia, as US Steel, Sears and IBM all discovered.

Despite this inertia, the laws of risk and return still apply. Big Pharma will need to experiment in order to create a new model, managing the inherent risks through a sound strategy and a thoughtful approach to execution.

No one-size-fits-all solution is likely to emerge. Instead, companies will probably craft a tailored model constructed from four inter-related building blocks. Today, niche companies are using each of these blocks to compete successfully among the giants of the industry.

1. Shift from opportunistic to focus.

Every company has had its own "*Viagra* experience"—creating one blockbuster from an R&D program focused on an altogether different therapeutic area. Breakthroughs like these have led pharma companies to both invest in a wide range of R&D programs, independent of their experience level in the category, and to gear up their sales and marketing investments in anticipation of scoring primary care blockbusters. While this approach may have worked in the past, the increasing cost and complexity of clinical trials and declining industry economics mean this

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opportunistic model is losing its appeal.

In fact, history has overemphasized these lucky breaks. Seventy percent of all blockbusters have been created by companies with significant prior experience in the relevant drug category. Lilly's ability to create three major CNS products—fluoxetine *(Prozac)*, olanzapine *(Zyprexa)*, and the yet-unlaunched anti-depressant duloxetine *(Cymbalta)*—is a case in point. *(See Exhibit 5)*. Prior experience helps companies design superior trials and conduct them with greater speed and higher likelihood of success. Market forces are also driving companies to focus their efforts. Increasing knowledge of diseases, competition in clinical trial patient recruitment, specialization among physicians, and payor focus on demonstrated outcomes all lend weight to the argument for companies to narrow their scope.

Pharmaceutical companies may choose to focus on a number of possible dimensions. In science, for example, Genentech has picked one area—biologics—while **Vertex Pharmaceuticals Inc.** has focused on a structured approach to drug design, both with significant improvements in research productivity. Other companies might choose to focus on particular patient/physician groups (disease or therapy area), as Novo has done with success in diabetes. Still others, such as **Genzyme Corp.**, have created successful businesses by combining multiple dimensions of focus—in Genzyme's case, by focusing on biologics, on specific areas of science (lysosomal storage disorders, for instance), and on very small patient populations treated by a small set of physicians.

The economic arguments in favor of narrowing scope are also compelling. Whatever the dimension, focus not only increases the likelihood for finding or creating a blockbuster in that area, but also dramatically lowers the cost of developing and commercializing a drug. In the past, Big Pharma has avoided focusing on specialists, believing such markets offered limited revenue and profit potential. In reality, smaller drugs can be highly profitable in specialist areas that do not require large primary care sales forces. Indeed, given the size of some specialist products—within a year or two, there could be three large-molecule rheumatoid arthritis drugs with sales of greater than $1 billion—companies can generate more dollars to the bottom line with specialists than they can earn with far more expensive-to-market primary care therapies.

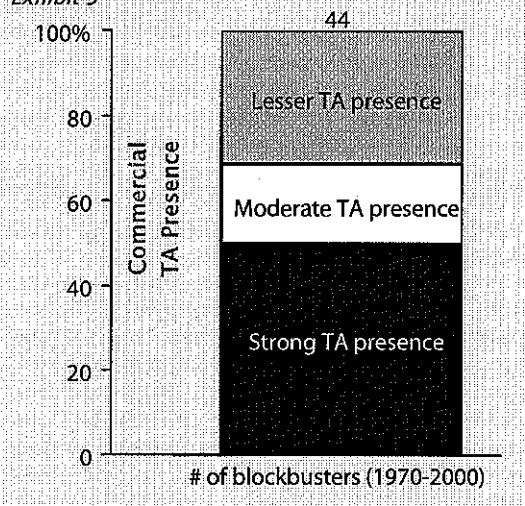
2. Shift from a fully integrated pharma company model (FIPCO) to using partnerships to manage risk and return.

Today, Big Pharma is largely based on a FIPCO model, with each company running its own discovery, development, manufacturing, marketing and sales for the majority of its product pipeline and portfolio. External relationships tend to be opportunistic, for example, buttressing the sales force for a new product launch through marketing agreements, clinical trial support or discovery pipeline in-licensing. Trying to do everything within the company carries a high risk with increasingly significant investment.

On the other hand, partnerships can lower risk and volatility. Big Pharma can learn a lesson here from the oil and movie industries, where players use partnerships aggressively, picking those elements of the business model that can build competitive advantage and entering collaborations to combine skills and diversify risk. The majority of blockbuster movies, for example, are brought to market by a partnership of multiple studios, with large numbers of independent contractors providing key capabilities (screen writing, directing, acting, producing special effects and so on). Thus the studio shares both the rewards and the costs of blockbusters, and it also shares in the production of more profitable movies per year.

COMPANIES WITH STRONGER TA PRESENCE CREATE MORE BLOCKBUSTERS

Exhibit 5



SOURCE: IMS, Analyst Reports, Bain Analysis

Most obviously, drug companies should outsource capabilities that aren't central to their strategy—perhaps IT, administration and manufacturing. But the major firms could also make use of partnerships more aggressively in joint development and commercialization of product pipelines. A company making a discovery in a non-core area would partner with a company whose area of focus matched the discovery in question. So, when a company focused on specialist-led disease categories finds a primary care product, it would partner with a firm that has a large primary-care presence.

Partnerships should be evaluated to improve commercial productivity, especially in accessing primary care physicians (PCPs). PCPs will continue to write a disproportionate share of prescriptions in the future. But pharma companies need new commercial models to reach PCPs, beyond the one-size-fits-all, massive armies of detail reps. This is true for both large and mid-size players.

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Selling reach and frequency have worked well in the past, but will no longer be sufficient to sustain growth even for the largest companies.

One promising alternative focuses selling efforts on products or classes that tend to be led by sub-specialists and using partnerships when necessary to access the broader PCP community. In fields such as atherosclerosis and schizophrenia, sub-specialists influence the writing behavior of the broader PCP community. Finally, forging partnerships with other companies that have strong commercial capabilities in individual drug classes can create attractive returns, especially when factoring in the very real opportunity costs for the product's owner of taking a sales force away from its core audience to sell to a brand new one.

The transition from a FIPCO approach to a less integrated model presents a daunting prospect for senior management. Executives' concerns will be both visceral and practical. Companies will need to shrink the number of their employees, generating plenty of concern both from the workers who will have to find jobs elsewhere and managers who will be losing major parts of their power base. In an integrated corporate world, few managers have built the skills to ensure the quality of outside partners now responsible for work once done by insiders.

These concerns match those of management teams that moved away from fully integrated models in industries such as automobiles, fashion, financial services and information technology. In reality, many companies have liberated latent energy in their businesses by focusing in areas where they can add the most value. Nike, for example, focused from the beginning on the design and marketing of their athletic footwear and accessories and on supply chain management, and left many other functions, notably manufacturing, to partners.

Big Pharma will need to assess which of its capabilities are most strategic, or, viewed another way, which can earn the greatest returns on capital. Executives will need to develop new skills in partner management. But the likely outcome is the emergence of new, better-capitalized businesses that will make attractive partners, focusing on specific aspects of the pharmaceutical value chain, such as technical operations, sales and drug development.

3. Shift from science-driven provision of specific drugs to providing customer solutions.

Historically, the pharmaceutical industry has focused on selling therapeutics that address diseases, but don't necessarily cure them or meet the patients' full needs in managing their condition. The high profitability of the drug itself suggested that incremental investment should always focus on maintaining existing brand franchises or discovering the next blockbuster. But the declining fortunes of the blockbuster model argue that this strategy may no longer be valid.

After a decade of mixed results from disease management experiments by pharmaceutical companies, some players have experimented successfully over the last few years with a range of complementary products and services that improve the therapeutic value of the pill. Albeit rarely so far, diagnostics have been combined with clinical studies on responder profiles to get the drug to the right patient at the right time—the combination of Genentech's trastuzumab *(Herceptin)* and the Her2-neu gene diagnostic being the best-known case in point. We've also seen combination pills such as HIV cocktails that deal with multiple symptoms. Better forms of delivery, aided by technology, may also improve or expand a drug's therapeutic profile, as they have in diabetic drug delivery devices, for example, or drug-eluting stents. Some focused initiatives aimed at improving compliance and managing diseases more effectively have shown promise, as well. Early data seem to support the potential of therapeutics complemented with nutrition and alternative medicines such as dietary supplements and over-the-counter products.

Pressure for better solutions is growing with increased payor and consumer influence over treatment. For the next several years, the pill itself will likely retain the most profit. But over time the industry can expect to see some shift in profits, just as profits in the computer industry shifted into ancillary products and services from the traditional boxes. As in computers, providing the best overall solution can affect product penetration and market share, improve the odds of bringing the next generation of products to market and provide a less volatile additional profit source. While providing customer solutions is not the top imperative today for most categories, it will be an increasingly important source of value and profits in the future.

4. Shift from a functional to an integrated business organization model.

Traditionally, Big Pharma has organized itself along functional lines, with separate functional units for each stage of the drug development and marketing process. In such an organization, each function aims to operate efficiently, making the best use of scale,

building competence and coordinating with other related functions.

This functional structure maps well to the blockbuster model. R&D operates with a distinct focus on creating blockbusters, which are then handed off to a flexible, commercial operation for launch. Other functions work to support R&D and commercial functions effectively and efficiently, with marketing serving as the bridge.

However, as Big Pharma grows to an unwieldy scale the industry would do well to look at companies such as Dell and **General Electric Co.** to assess the advantages of more decentralized organization models based on discrete business units. These companies continue to grow profitably, each with recent annual revenues more than $30 billion, by pushing responsibility for profits down to smaller business units. These units are held accountable for making integrated, cross-functional, customer-focused decisions rapidly.

Pharmaceutical companies could also benefit by organizing around integrated business units based on their therapeutic, customer or scientific areas of focus. These business units share central or outsourced services such as manufacturing and information technology. Integration can provide tighter coordination and more rapid decision-making around each area of focus. Integrated business units will also create the opportunity to push down P&L accountability, and put in place new metrics that shift the focus from overall product revenues to business-area profitability, return on investment and functional productivity.

Indeed, Big Pharma needn't look as far as Dell for examples of integrated structures in action: the medical technology industry has long used business units focused on groups of customers or types of technology. **Medtronic Inc.**, with multiple technology and physician-focused business units, has succeeded with more sequenced and rapid product innovation cycles than pharmaceutical companies have managed. Admittedly, this difference is facilitated in part by different regulatory requirements—but these are rapidly converging with pharmaceutical requirements, as more and more new medical products must satisfy drug-like requirements for pre-market approval.

While no major company has yet restructured fully, a number are experimenting with alternatives. **Novartis AG** has successfully deployed an organizational model with relatively integrated specialty business units, such as oncology, along with a primary care structure that has separated out mature brands, supported by shared services. **Johnson & Johnson** has been the most successful of the Big Pharmas since 1999, in terms of stock appreciation, based in part based on the company's radically decentralized structure.

Putting the Building Blocks Together

While each building block can create value by itself, their full value is likely to emerge when companies integrate them coherently. For example, focus might lead a company to target specialty areas and reduce its dependence on primary care. Partnerships become necessary, then, for pharma companies to augment their core strengths. Improved focus also leads companies to try to create complete solutions, bringing science closer to the customers who will benefit from more comprehensive therapies. For companies to strengthen the coordination between science and customers in the areas of focus, they would need a more effective organizational model based on business units instead of functions. On their own, the building blocks are less powerful than when applied in concert.

Smaller players, out of necessity, have moved ahead of the majors in finding successful new business models that make use of these four building blocks, and the results are beginning to show. Genentech, for instance, has focused almost exclusively on large molecules, using partnerships to build on a research core and to increase access to capital to fund up-front research. Other companies have responded to narrow patient targets and relatively high drug costs by focusing more on providing patient solutions, as **Biogen Inc.** did when it launched its interferon beta-1a (*Avonex*) for multiple sclerosis. Organizationally, these companies are smaller, more integrated and less bureaucratic entities.

Other examples of companies making use of the building blocks include those focusing on specialty franchises, such as Novo Nordisk and **Schering AG**. These companies have chosen to exit non-core product lines and filled out their offerings through in-licensing or co-promotions. They have also built solutions to meet the needs of their target physician and patient populations. Novo zeros in on people with diabetes and their doctors, while Schering focuses on women as well as their obstetricians and gynecologists. Both companies have organized around largely integrated business units focusing on their core disease areas.

Larger pharma companies will need to come up with their own approaches geared to their situations and aspirations.

First, they have to decide which areas they should focus on, given their unique capabilities and strategic assets, in order to access and launch drugs most profitably: certain areas of science, targeted customer groups and needs or some combination of both.

Once they've chosen their focus, they'll need to identify the relevant capabilities, build-

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ing those that provide key advantages and outsourcing others.

They'll also need to figure out where they can profitably add value for patients beyond providing any particular moelcule.

And finally they'll have to structure the new organization to speed decision-making, increase accountability and reduce cost.

Given the high costs of shifting to new models, companies would do well to experiment in a controlled fashion before committing fully. Inevitably, there will be failures along the way. The key is to contain the risks within the experimental phase and to learn quickly for the next round. Companies also should expect to spend time developing the capabilities they need before pursuing a new approach. But once the experimental phase is complete and capabilities are in place, the organization must commit fully to its new direction. Executives who act now to build a new strategy, constructed from tested building blocks and making best use of their companies' capabilities, stand the best chance of emerging from the coming period of change as winners.

Jim Gilbert is a director of Bain & Company Inc. in Munich. Preston Henske is a Bain vice president in New York. Ashish Singh is a Bain vice president in Boston.



Comments? Send an e-mail message to the publisher at rlongman@windhover.com

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