Impact of Incorrect Forecasts on New Product Launches

AN INDEPENDENT EXECUTIVE RESEARCH STUDY BY ORC INTERNATIONAL

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Pharmaceutical companies around the world are under tremendous pressure—from regulators, legislators, payers, and patients—to reduce the cost of drugs. In response to the outcry for cost-cutting, pharmaceutical company leaders are examining every aspect of their business to determine where they can derive savings, particularly when planning for the launch of a new product. Pharmaceutical company marketing executives have become more accurate in positioning their new product in the marketplace, profiling prescribers, and understanding and responding to the reimbursement landscape. What is still a quagmire for pharma companies is predicting the actual demand for products and the timing of that demand.

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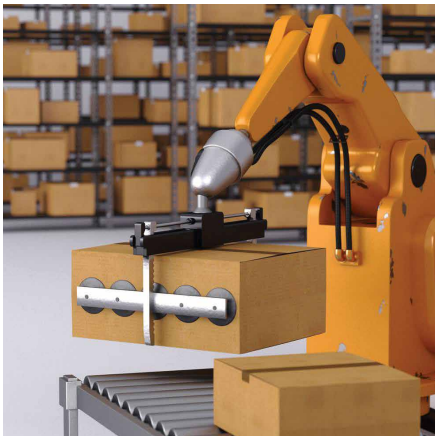
In today's drug manufacturing environment, demand forecasts provide critical input that ultimately affects pharmaceutical companies' decision-making processes[1]. Pharmaceutical companies utilize drug forecasts to design clinical programs, position sales force resources, allocate geographic resource distribution, and obtain company or licensing assets[2]. However, achieving accurate forecasts is extremely challenging, especially for new drug launches. Although drug forecasts combine an assortment of scientific, clinical, regulatory, and commercial data, it is difficult to capture a new drug's potential with a single numerical value because countless factors influence and contribute to that drug's demand[3]. Each new drug is susceptible to variations in the external environment, the uncertainty of drug development, and the unpredictable actions of competitors[4]. As a result, drug forecasts are often significantly inaccurate[5].

This implies that many companies depend on inaccurate forecasts for in-house production of product, hoping that they can manage fluctuations in demand. For those companies relying completely on outsourcing manufacturing, it means procurement of "too much or too little" capacity. One study found that greater than 60% of drug forecasts over- or underestimated peak revenues by more than 40% of the actual peak revenues[6]. In fact, a substantial number of forecasts were overly optimistic by more than 160% of the actual peak revenues of the product[7]. Other studies find that about two-thirds of the new drugs fail to meet prelaunch consensus expectations for their first year on the market[8]. Moreover, drugs that fall short during their first year on the market continue to fall short for the following two years[9].

Drugs that fall short during their first year on the market continue to fall short for the following two years.

When Lipitor launched, its peak sales were forecasted at $800 million per year[10]. However, the drug generated $12.8 billion peak sales, making it the highest-selling drug of all time[11]. Sanofi and Regeneron set the price for their colorectal cancer drug, Zaltrap, at $11,063/patient/month[12]. But the company was forced to cut the price in half when oncologists at Memorial Sloan Kettering Cancer Center refused to prescribe Zaltrap because cheaper alternatives already existed[13].

Incorrect forecasts have serious consequences for operational efficiency and for the bottom line. When a company is unable to meet demand, the lack of inventory can result in loss of sales, product risk, and overworked employees. It's estimated that a delay in launch costs an average of $15 million per drug, per day[14]. The variance in peak sales estimates was still 45% versus actual peak sales 6 years after the drug has launched, reflecting continued uncertainty even as new information becomes available.



On the other hand, overestimating demand results in mis- appropriating capital[15]. Manufacturers may be forced to mark down the price of the product, destroy inventory and/or close plants and lay off employees. This means that a company would lose the roughly $500 million it cost to acquire its pharmaceutical plant. In each scenario, worker morale is low, product quality suffers, and reputation is damaged[16].

Pharmaceutical companies will launch some 400 new products in the next three years, up 146% from 2005[17]. Inaccuracies in demand forecasting, combined with increases in complex manufacturing processes, are driving the need for more choices in manufacturing solutions. In fact, 60% of new compounds entering development need unique manufacturing processes due to their formulation or delivery system[18]. These growing demands demonstrate that there is a fast-growing market in need of alternative, more flexible manufacturing options.

To better understand the issues that pharmaceutical companies face when it comes to forecasting accuracy, we conducted both phone and online surveys with 50 pharmaceutical executives who consistently utilize launch forecasts to predict manufacturing planning and volume. The surveys aimed to address current processes around forecasting, key issues that arise from inaccurate forecasting, and how forecasting needs will change over the next few years due to evolving organizational needs.

Demand forecast is a primary decision-driver

The single most important factor that influences manufacturing decisions is demand forecasting. Almost all respondents agree that the demand forecast influences manufacturing decisions regarding capital cost and outsourcing for product commercialization a great deal. There is broad recognition that failure to appropriately predict demand has real consequences on a firm's reputation and bottom line.

> "Launching a new product requires a fully defined approach and strategy, for which we need to address unfulfilled needs in a disease area, which is a challenge. Secondly, we need deep insight into the customer in order to differentiate in the market. To execute in both of these ideas, we need accurate information on market demand, which is really difficult because we are not sure whether our product will be approved, and if it is, to what extent it will be accepted by doctors and consumers."
>
> **Director—Marketing, Large Pharmaceutical Company, United Kingdom**

Variable factors in predicting demand

A number of factors influence and contribute to a drug's demand. In order to accurately forecast demand, pharmaceutical companies need to feel comfortable with and confident in the data they have for all of the variables used to calculate demand. In speaking with industry professionals, it was apparent that there is a split in how they view different demand-driving variables.

Manufacturing: Predictable costs, unpredictable processes

Certain hard costs, like manufacturing expenses and raw material costs, are fairly easy to predict. Respondents also felt confident in their understanding of their unique products, from the formulation processes to pricing structure. These areas represent costs with little expected variation, and are mostly in the control of the business as they can seek lower-cost ingredients or other raw materials. Companies can also look to alternative formulation processes or consider insourcing or outsourcing their manufacturing. However, options can be limited in such a complicated environment.

> "I would say that the manufacturing cost that would be incurred during the whole process is the most predictable one, and one can expect to have the least amount of variances here. But as you know, it's a very complex thing and we solely don't have control over it, so sometimes it has become uncontrollable in the past."
>
> **Associate Director—Global Business Development, Large Pharmaceutical Company, United States**

While the overall cost of the manufacturing process is relatively easy to ascertain, predicting the exact levels of active pharmaceutical ingredients (API) and general manufacturing capacity needed are more challenging variables to address. It can take a significant amount of time to acquire and test the quality of an API prior to launching production. Lead time is also a struggle to predict, as manufacturing sites need some notice to be able to have the capacity to incorporate the production of a new product, and companies will generally need to place orders before seeing actual market demand.

Without knowing the overall market appetite for the product or the rate of growth it will experience, it can be tremendously difficult to appropriately budget time and resources for manufacturing the product.

> "Material sourcing and manufacturing capacity are the two variables that are most difficult to predict for launch products, since the market demand of the product changes rapidly depending on the product's acceptance in market by consumers."
>
> **Associate Director—Research & Development, Specialty Pharmaceutical Company, United States**

Market uptake is erratic

The variables that tend to be most difficult to forecast are more intangible predictions around the levels of market uptake, physician propensity to prescribe, and out-of-pocket costs for patients. These are areas where companies have struggled to develop new thoughts on how to broach the calculation challenge, as historically most have relied on using the incidence of a particular disease in a region and applying a potential market share to estimate the potential demand. This method fails to accurately gauge the acceptance rate among physicians and patients.

> "You'd expect a certain type of doctor to use a product, but you find out in the end that doctors don't really want to prescribe it, because they are committed to using the alternate drug for something … Companies obviously do a lot of research to see what kind of doctors they should be going after for prescribing things, but sometimes there's an unknown and that's just that certain doctors are trained to do certain things, and they see value in the amount of training that they have, and they may not want a simple alternative."
>
> **Senior Director of API Manufacturing,**
> **Mid-Size Pharmaceutical Company, United States**

In estimating demand, companies must be cognizant of the willingness of the market to adopt a product, but also of what their competitors are doing in the marketplace to realistically predict their potential market share with a new product. Pharmaceutical companies are participating in a highly competitive market. Competitors can respond to new product launches in different ways that can be difficult to predict, especially because of the lack of structure in today's reimbursement environment.

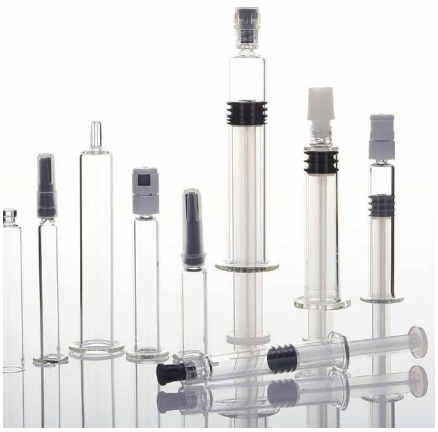
Integrating demand forecasts into production plans—adaptability is key

Many companies have developed strategies to deal with the hurdles to accurately predicting demand. When they feel comfortable with their estimates, they face their next challenge—incorporating the demand forecast into their full commercial production plan.

As demand forecasts are made during the initial phase of drug development when there is little clinical information to base sales projections and reimbursement strategies on, companies need to be prepared to make adjustments to their expectations as new data comes to light and as they face variations in supply chain patterns. It is best to look at the production process as a balancing act between changing demand forecasts and real manufacturing capacity. As one Operations Director put it, there "… should be perfect coordination and communication between manufacturing and products team in alignment with the forecasting team so that we are updated on the demand in market."

Respondents often cited difficulty in coordinating different teams to meet timelines, but failing to do so can directly affect market share and brand reputation. Again, a long lead time is necessary for production to develop appropriate plans, allocate

resources efficiently, maintain schedules, and minimize waste. Some respondents noted that it takes about two years to completely develop a product after electing to move forward with its production.



This level of planning and lead time can be managed, but it is hard for many companies to be agile enough to adapt their practices and make adjustments as demand forecasts change. This often leads to situations of overestimating or underestimating demand.

> "The biggest challenge is being able to meet the demand forecast. So obviously when you do your annual projections, everyone's very optimistic at the beginning of the year, but once you start to realize your sales, it may be 35, 40, 50% of your forecast and you have to make adjustments, so that was the hardest thing."
>
> **Former Senior Manager of Global Supply Chain Operations, Specialty Pharmaceutical Company, United States**

When facing these challenges, companies have to evaluate the benefits of producing their new product in-house versus outsourcing manufacturing, based on their demand forecasts. This is simplified if a company has a good sense of its future sales volumes and can clearly determine whether production can fit into an existing contract manufacturer. If capacity seems inadequate within an existing structure, a company would need to decide if a capital acquisition would be worthwhile and cost-effective versus finding an alternate partner. It can be time-consuming and costly to alter manufacturing processes, so it is imperative that demand forecasting be as accurate as possible.

Forecast overestimation or underestimation is the norm

Pharmaceutical respondents surveyed report high rates of overestimation and underestimation with demand forecasts. Companies err on both sides of actual demand, both underestimating and overestimating the uptake of a new product, leaving them to deal with a distinct set of consequences on either end. When a company is unable to meet demand, the lack of inventory can result in loss of sales, product risk, and overworked employees, while overestimating demand results in a misappropriation of capital.

> "If you're preparing for a big launch and then it looks like the launch didn't go as well as planned, then the question is, do you end up having to reduce your manufacturing capability because you just don't need what you're doing so far? And then the flipside is, if you don't get the forecast right and you don't have enough product for launch, you don't want to stock out, because it's a problem that ruins companies' credibility, and the FDA really doesn't like it."
>
> **Senior Director of API Manufacturing, Mid-Size Pharmaceutical Company, United States**

The majority of companies are over- or underestimating demand by up to 25%, though instances over 50% were reported. Respondents cited that they often

overestimate demand when there is greater market volatility or when they were overly optimistic in their forecasting. Generally, underestimating resulted from not having enough background data to support forecasting information. One respondent speculated that the therapy area served could also contribute to the variation between forecast and actual demand.

> "Depends on the product in the portfolio. Primary care, which is more generics, I think there's a little bit of overestimation, and for other fields, where there is like an orphan indication, I won't say underestimated, but appropriately estimated because those are a little easier to predict since the population is much smaller than for something more generic."
>
> **Associate Vice President—Research & Development, Mid-Size Pharmaceutical Company, United States**

Incorrect forecasts have serious consequences to operational efficiency and to the bottom line. As stated, adverse effects of over- or underestimation often center on reputational damage. Particularly in cases in which demand was underestimated and production fell short, a company can face a fair amount of backlash both internally and externally. Investors and employees often lose trust in management, while suppliers and customers face disappointment with not having a new therapeutic option.

If companies lose market share as a result of their estimation error, that too can damage their credibility, as competitors take advantage of the position and bolster their own reputations.

Operationally, there are costly consequences of poorly estimating demand. When adjusting production to new sales forecasts, companies can lose days of production. This may force them to change orders to their suppliers and waste available capacity at manufacturing sites.

> "I've paid penalties. Some of my CMOs have had lost days of production that they had planned and committed to us that they had to cancel, and couldn't find someone else to fill the slots. In my previous company we had biologics that had really long cycle and lead times that had commitments that were way out and it's hard to rebook that time in the short term if it's already committed. So yeah, there's been production time loss with forecasts."
>
> **Director—Supply Chain, Specialty Pharmaceutical Company, United States**

In many cases of overestimation, companies have to destroy inventory when either their raw materials or their completed products surpass their shelf lives.

> "We had a few product lines that had long lead times so we didn't have to produce them as often, but as a result of that, sometimes we would have to destroy expired material."
>
> **Former Senior Manager of Global Supply Chain Operations, Specialty Pharmaceutical Company, United States**

Overall, overestimating and underestimating demand are costly misjudgments that are too common in the industry. They can regularly impact a brand's reputation.

Avoiding layoffs and negative patient health outcomes as a result of demand forecasting is essential to reputation preservation. While neither of these issues transpire as often, the occurrence of either resonates longer with a broader population, sometimes leaving irreparable brand damage.

> "I'd say one of the challenges is getting the forecasting right. So if it's a brand new product and there's nothing else like it on the market, then at least in the experience I've had so far, we've tended to over-forecast, and as a result, that means that for manufacturing, at least in one case, the increased staff to prepare for launch and launch didn't, just didn't have the uptake that was originally forecasted, and as a result, a year later, we underwent layoffs. So that to me is probably the worst that I've seen so far."
>
> **Senior Director of API Manufacturing,**
> **Mid-Size Pharmaceutical Company, United States**

Combining insourcing and outsourcing for optimal efficiency

To address forecasted demand for a new product, most companies will first consider their in-house capabilities. It allows more control over production standards and mitigating changes if the projected demand does not exceed the production capacity.

Companies will outsource for a number of reasons. If they do not have in-house capabilities, they will need to locate an alternative site. The costs to build and maintain manufacturing facilities are significantly higher and riskier than working with an outsourcing facility. More commonly, companies outsource because they do not have enough available capacity in their own sites to include a new product.

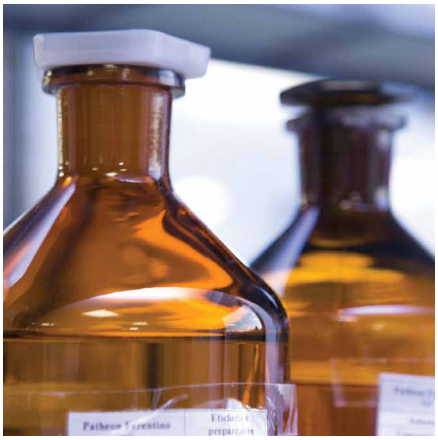
> "It actually depends on the product because sometimes we have the facilities in-house, or even if we don't, we tend to build a facility and repurpose the existing lines. But in the case when it's hard to maximize the facilities, then definitely we go for outsourcing."
>
> **Associate Director—Research & Development,**
> **Specialty Pharmaceutical Company, United States**

For that reason, a large number of companies are using a mix of both in-house and outsourced production to maximize their options. It is fairly easy for some companies to extend their lines to include similar products that do not require entirely unique supplies, equipment, or skills. Outsourcing for these companies is generally reserved for the products that would have too many associated costs to begin production or instances when there is simply not enough capacity to produce in-house.

There are a number of factors to consider when deciding where to produce a new product.

> "This decision is made after considering various aspects, like the facilities, resources, capabilities, equipment, cost etc. and also uncertainty regarding demand and market size. On the basis of all these factors, we tend to outsource the manufacturing."
>
> **Associate Director—Marketing, Large Pharmaceutical Company, United States**

Forecast uncertainty drives outsourcing



One of the biggest motivators to outsource is a higher degree of forecast uncertainty. In fact, more than three-quarters of respondents noted that the less certainty they have about demand, the more likely they are to outsource, even if they do have the capacity to produce the item in-house. As demand forecasting remains a significant hurdle, nearly all respondents claimed to have unused or underutilized facilities in their network, though underutilization was generally kept below 25%. The decision to outsource is made at a high level to mitigate risks from incorrect demand forecasts.

Various departments and roles collaborate on the decision to outsource, including medical and regulatory heads, manufacturing and production teams, the director of research and development, the head of marketing, and those involved in planning and business development.

In order to make decisions based on the efficiency of supply rather than the degree of certainty in demand forecasting, companies need to develop concrete strategies to address the variability in demand forecasting and reduce the margin of error. Companies throughout the United States and Europe recognize this need, but have long struggled to develop any such proven strategies. Those strategies that are often employed were identified by respondents as not always effective.

> "The general strategy includes inspection of the facilities, system, procedure required to outsource the product and raw material and if it fits in the regulatory compliances. It does work most of the times, but in rare cases when we launch a unique product, it might happen that our general strategy does not work. In that case, either we outsource it or we come up with a new product differentiation and new market segmentation strategy."
>
> **Associate Director—Production/Manufacturing, Mid-Size Pharmaceutical Company, United States**

Some companies tend to approach demand forecasting as a risk management task. In such, they look to resolve their errors in prediction by mitigating risk and outsourcing production. Others will establish a second production line as a back-up, which could be within their existing contract manufacturer's portfolio or with another external vendor.

> "To avoid the risks and uncertainty, we choose to outsource in case of any new product launch. Once we have the capabilities and forecasting tools by which we can minimize the level of inaccuracy and errors, we would manufacture the product in-house and come up with a general risk strategy to minimize the risk."
>
> **Associate Supply Chain Director, Specialty Pharmaceutical Company, United Kingdom**

Finding partners that can help mitigate the enormous risks developers must assume may be the most critical step of all

Companies are looking to outside partners to enhance outsourcing strategies for better optimization of the launch planning. And in the increasingly complex, capital-intensive, and multi-step process of getting new and ever more sophisticated drugs to the patients that need them, finding partners that can help mitigate the enormous risks developers must assume may be the most critical step of all.

1-7 (Cha, Rifai and Sarra, “Pharmaceutical Forecasting: Throwing Darts”, Nature, 2013)
8-9 (Ahlawat, Chierchia, and van Arkel, “The Secret of Successful Drug Launches”, McKinsey & Company, 2014)
10-13 (LaMattina, “Why is it so hard to predict sales of new drugs?” Forbes, 2013)
14 (Noffke, “No Time to Delay”, PharmaExec.com, 2007)
15-16 (Cha, Rifai and Sarra, “Pharmaceutical Forecasting: Throwing Darts”, Nature, 2013)

A call to action for CMOs

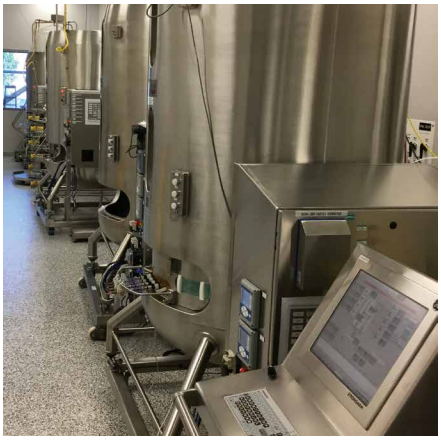
A perspective from Jim Miller, President, PharmSource

Forecasting is central to manufacturing operations and supply chain management. It drives scheduling, raw material ordering, inventory levels and many other decisions that ensure an uninterrupted market supply of finished product.

However, forecasting really doesn’t work very well when planning the manufacturing requirements for new product launches. It has to be done so far ahead, and take into account so many variables, that it is often wrong—at great cost in lost revenues or misspent capital expenditures.

Manufacturing and supply chain planning must begin four to five years before actual product launch, maybe even longer if the manufacturer makes Phase 3 clinical trial materials. If manufacturing is to be done in-house, engineering

studies and plans must be completed, facilities built or modified and equipment ordered, installed, and qualified. If production is to be outsourced, CMOs need to be identified, contracts negotiated, and, if special capabilities are required, the CMO must examine its engineering and capital investment program. In either case, processes must be transferred and validated, and stability batches manufactured. All of this demands an extended manufacturing and supply chain planning cycle.



This means the manufacturing planning timeline runs well beyond the timeframe in which forecasts can be expected to be reliable. Even if the product is successful in clinical trials, there are simply too many variables that can change the sales outlook over that five-year period, among them the time it takes to complete clinical trials, adverse events that could limit the size of the target population, time to approval in various regulatory jurisdictions, the performance of competing products, payer willingness to reimburse, and the rate of physician acceptance. While marketers will refine and improve their demand forecasts as product launch nears, those projections always will be too late to meet the needs of manufacturing and supply chain operations.

The traditional CMO business model compounds the uncertainties that surround long-term capacity planning for product launches by locking in manufacturing arrangements based on those unreliable early demand assumptions. To a considerable extent, contractual relationships with CMOs are driven by forecasts, especially critical elements like pricing, capacity availability, and financial terms like “take or pay.” Consequently, faulty forecasts can lead to unfavorable pricing, financial penalties, and inappropriate capacity.

Further, in the traditional model, CMOs are driven to commit and utilize capacity as fully as possible. So the sponsor may find that the CMO doesn’t have reserve capacity available to increase production if the product performs better than the launch forecast.

CMOs do have some tools to increase responsiveness to marginal forecast variances. New manufacturing technologies such as single-use bioreactors and continuous manufacturing trains are somewhat more flexible than traditional fixed tank and batch manufacturing technologies. Also, CMOs that supply both the drug substance and the drug product, so-called one-stop shops, may also be more responsive because they control more of the supply chain and are more integrated into the sponsor’s operations. But neither new technologies nor the one-stop shops can accommodate the wide variances that can result from traditional forecasting errors.

Solving for the uncertainty

Sponsors can improve their product launch plans by running multiple scenarios that establish broad parameters rather than the single-point estimates of traditional forecasts. Having multiple demand scenarios and parameters can enable manufacturing and supply chain professionals to develop more flexible sourcing strategies that can adapt to a range of possible launch outcomes.

For their part, CMOs must be more innovative in their sourcing arrangements, i.e., they must offer manufacturing arrangements that can adapt to the market as

it responds to the new product as it is rolled out. The traditional CMO business model, with multiple clients sharing the same tightly scheduled production trains, is not adaptive; it is a one-size-fits-all solution.

More innovative approaches can be built on the traditional CMO advantages of being able to distribute capital and operating costs across a broad base of products and clients. However, what and how costs would be shared could be tailored to the requirements of specific products and sponsors. Further, CMO experience and know-how in process develop- ment, facility engineering, and equipment procurement can be leveraged to develop solutions specific to the product and sponsor—a far more cost effective approach than building a dedicated full-function facility for all of them.

Take, for instance, an arrangement under which a sponsor pays for a suite (or suites) and related equipment dedicated to its product (or products). The sponsor contributes certain capital costs relating to the suite, including dedicated equipment, and pays a periodic fee to cover a share of the ongoing expense of operating the facility in which the suite is located. However, the sponsor gets the benefits of a dedicated manufacturing operation that it can operate as needed to meet its supply requirements while sharing high-cost capital and operating expense functions such as water and air handling systems, warehousing, shipping and receiving, security, QA, and QC.

Sponsors must appreciate the risks associated with uncertain launch forecasts.

If sponsors and CMOs are to do a better job of matching manufacturing capabilities to uncertain launch requirements, there must be an attitude shift on both sides of the table. Sponsors must appreciate the risks associated with uncertain launch forecasts. Typically, they focus on the hard cash costs of manufacturing—capital, validation, the unit costs of goods and inventory—and are likely to neglect or under-appreciate the broader costs of potential lost market share, or the damage to a company's reputation because patients cannot get a promising drug. The profit that vanishes due to lost sales, and the resulting drop in stock price that can wipe out hundreds of millions of dollars of shareholder values, far outweighs the costs of more appropriate manufacturing arrangements. Spending a little more on dedicated facilities is an insurance policy against the risks of unreliable forecasts.

While this may seem obvious, current sponsor behavior suggests that many don't get it: a recent PharmSource analysis of newly-approved new molecular entities (NMEs) found that less than 15% had established dual sourcing arrangements (i.e., two approved manufacturing sites), a simple and long-established practice for managing supply risk and assuring adequate product supply.

But CMOs also need to get with it. They need to be more open to innovation in the business arrangements they will consider. They have to understand that today's industry environment, marked by new products that are more technically challenging, produced in smaller volumes, and subject to greater market uncertainty due to competing therapies and growing reimbursement risk, requires new solutions to supply chain management.

CMOs can bring a lot of assets to bear on the challenges of new product supply in the face of uncertain forecasts. Those assets are not just their physical facilities and equipment; they include their expertise and experience in process technologies, engineering, procurement, operations, and risk management. By using those assets in creative ways, sponsors and CMOs together can develop the innovative manufacturing solutions that will ensure successful product launches.

How to live with uncertain demand forecasts

In discussions with pharmaceutical industry leaders, it's clear that regardless of company size, product type, or market, the challenge of demand forecasting is significant. In October 2015, Patheon CEO James Mullen addressed it in "Does Pharma Demand Forecasting Keep You Awake at Night?" for *Life Science Leader* magazine. The problem, he wrote, is that to estimate future needs, "Pharma companies develop forecasts, and often quite sophisticated ones, too. But, by definition, forecasts are never 100 percent right. And it's especially difficult to predict sales in markets that are likely to see the introduction of numerous competing products."

Mullen's article resonated, and led to a number of discussions with our clients about how to address the challenge. To understand the prevalence of demand forecast inaccuracy— and the struggle to bring new products to market—Patheon commissioned ORC International to conduct in-depth interviews with 50 pharma industry executives with experience creating or implementing demand forecasts for commercial launches.

The study confirms Mullen's assessment. Every respondent said their forecasts either over- or under-estimated demand—indeed, future demand, they said, was the most difficult variable to predict. The majority of respondents said they over- or under-estimated demand by up to 25%, with some indicating that they were off by 26%-50% or even 100%. Nearly all respondents said that demand forecasting influences manufacturing decisions "a great deal." They also noted that the consequences of inaccurate demand forecasting can be reputational damage, market share loss, lost days of production, destruction of inventory, and layoffs.

A large majority of survey respondents said they plan to invest in improving their forecasting tools; almost all said they will be honing their inputs and assumptions

over the next few years. And as long as there's a satisfactory rate of return on investment, pharmaceutical companies should continue to try to improve the accuracy of their forecasts.

But that's not all they should be doing.

The roots of forecast inaccuracy

Demand forecasts are often wrong because they are developed to inform manufacturing commitments as many as four to five years before product launch. Naturally, between the forecast, and when the drug goes into production, variables and market conditions change. Several years out, it's impossible to say what competing products may enter the market. The regions and populations for which the drug will be approved cannot be known for certain, and any constraints that will be imposed by payers can only be guessed at.

As contractual relationships with CMOs are driven by forecasts—especially critical elements like pricing, capacity availability, and financial agreements such as take-or-pay contracts—inaccurate forecasts can "result in unfavorable pricing, financial penalties, and inappropriate capacity," according to Jim Miller, President of PharmSource, a pharmaceutical industry contract manufacturing intelligence firm.

Everyone in the industry is trying to improve their forecasts, but there is a limit to how good they can get. As long as they have to be developed several years before launch, they will never be 100% right. Nearly all respondents noted that the absolute most unpredictable variable in the demand forecast is the estimate of market demand. When you're trying to project market behavior three years in advance, even the most sophisticated forecasting models will suffer some level of variability.

This is why Mullen wrote, "Instead of forever seeking more-certain forecasts, I believe we should be talking about how to provide flexible, scalable capacity that can accommodate the uncertainty. With sufficient flexibility, the need to accurately forecast demand for a product that does not yet exist is relaxed."

The results of the ORC International's research validate the changes Patheon has made to our commercial contract manufacturing services. Our new suite of outsourcing services, which are unique in the pharmaceutical CMO sector, provide flexible and scalable capacity—what Patheon calls "adaptable capacity."

Many pharma companies—including virtually all of the top 25 global players—have more than one product launching within the 18-month planning window. Some products are global, others regional; there are a hundred variables that determine the optimal manufacturing solution. Based on the client's needs, Patheon now offers a variety of adaptable manufacturing arrangements for the industry:

Dedicated Capacity. Companies that have multiple products in similar formats (vial, capsule or tablet) launching within 18 months need a dedicated facility, or line, so they can modify their manufacturing schedule until they can understand the exact market demand for each product. Within the dedicated capacity, a customer can determine how much is used for each product, and can transfer technology in and out of the line without additional fees.

Fractional capacity. For companies that don't have the budget (or the volume) for a dedicated facility or manufacturing line, Patheon builds a single CMO facility or line for two or three clients, providing flexible capacity for each. This model is less expensive than the dedicated line, but still provides flexibility and scalability.

Flexible network access. For regulatory purposes, global companies often need manufacturing capabilities in North America and Europe. Or they simply may want on-demand access to capacity without preference for location. This model assures the client anytime access to a specific type of capacity within Patheon's global network within a specified period. Clients can adjust the product mix with the assurance they will have the right type of capacity when they need it.

Condominium capacity. A fully customized solution for a company introducing a new product with unique characteristics (e.g., complex formulations or delivery systems) that cannot be manufactured on a conventional manufacturing line. Patheon provides design services, works with equipment suppliers, validates the process, builds the line, and manages operations on behalf of the client. Overhead is shared, and the line can operate as needed to meet demand.

Enterprise. A solution for companies that own facilities in need of operational improvements. Some facilities may need to repurpose existing equipment; some should be closed. Patheon can manage these facilities to accomplish those goals while allowing companies to focus on their core competencies.

These five scenarios are points on a spectrum. Patheon also can customize solutions to match specific client needs.

ORC International's research reflects some of the uncertainty pharmaceutical companies face today. In response, Patheon offers a range of models that accept the reality of uncertainty, and provides flexible and scalable approaches. Our solutions can't eliminate risk, but they will help mitigate it.

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+1 919 226 3200 • thermofisher.com/patheon • pharmaservices@thermofisher.com

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