The Changing Nature of Medical Practice
Implications for Pharmaceutical Marketing

By Daniel Hoffman, PhD, *Pharmaceutical Business Research Associates (PBRA)*

US based "customers" will no longer be individual physicians in solo practice or small group offices. Instead, pharma's customers will increasingly be large, corporatized practice groups and their affiliated "franchisers."

Although everyone will be aware of the increasing significance of various "payer" groups (budget holders) in Europe over the last few years, more recently, the U.S. customer base has seen a dramatic shift that is impacting the sales and marketing targets for the industry. Not surprisingly, this will radically change the communication process and the nature of the information that needs to be conveyed.

The trend to consolidation, increased size and corporatized behavior of medical practices will proceed irresistibly and with a growing momentum. What are some of the reasons behind this?

1. ***The demand for cost effective treatment confers an enormous benefit to practices operating with an economy of scale.***
Third-party payers, both private and public, are increasingly under pressure to offer optimally effective care at a lower price. A principal means of addressing this consists of basing compensation to providers on measurable patient outcomes. Local/community practices, for that reason, will be required to base treatments on electronic medical records (EMRs) that commonly contain the electronic treatment protocols (ETPs) of those groups acknowledged as optimally cost-effective providers (e.g., Mayo Clinic, Geisinger, et.al.). Already some of these internationally recognized groups (e.g., Memorial Sloan Kettering and M.D. Anderson in oncology) function, in effect, as franchisers that lend their name and treatment protocols to "interested parties."

While the costs of adopting EMR systems are likely to be reduced in the future as Wal-Mart, GE-Intel, IBM, Microsoft and others enter that business, but, conversion to an EMR system will still require economies of scale that favor larger practices. Furthermore, there is a growing movement for "pay for performance" (P4P) which is designed to reward hospitals, caregivers and physicians for meeting quality metrics. This is also related to outcomes-based risk sharing agreements (OBRA's). Some effects of these factors on various aspects of pharmaceutical marketing are already apparent.

2. ***Larger practices will be able to run on smaller margins as a result of maintaining alternative revenue sources.***
They will operate with economies of scale that allow them to hire more employees capable of generating additional revenue sources. Clinical trials represent one such revenue stream for a practice.

Many practices already seek revenue by offering cash-paying, non-reimbursable services involving elective, cosmetic procedures. Here too, economies of scale favor larger practices.

3. ***Larger practices hold an advantage in pursuing cost-effectiveness by virtue of the fact that more of their physicians can be salaried employees.***

Economies of scale will favor larger practices that can hire professional management rather than physicians as administrators. The work arrangements of employee physicians, for example, will come to resemble those of mid-level civil servants more than those of solo, independent practitioners.

These alterations to physicians' labor status will change the kinds of people (e.g., social class, gender, psychographic and sociographic profiles) drawn to medical practice and will require the full complement of industrial management specialties: human resources, finance, marketing and so forth.

In summary, the environment of outpatient practice is changing more rapidly than it has at any time in the past 60 years. **Pharma companies that are already adapting to this shifting customer base will acquire a sustainable marketing advantage.**

The effect on pharma of this industrial-scale corporatization of medical practice involves nothing less than making pharma's business model obsolete.

Pharma companies have substantially reduced their sales forces in advanced western countries as payers increasingly come to occupy a more important customer role than prescribers. What remains less appreciated is the fact that major alterations to the organization of medical practice portend the need for even bigger changes in pharma's entire business model.

The development of corporatized practice groups removes a key part of pharma's historic business model: "the gatekeeper system."

Instead of physicians who have, until now, lacked a financial stake in purchase decisions, this emerging consolidation/ corporatization gives practice groups a direct financial involvement in choosing a set of products based on "patient outcomes," not unlike the situation in Europe. While the European system often operates at the national level, there are distinct parallels in Spain, Germany and the UK where budgetary responsibilities are also taken at an area or practice level.

The changes we are seeing in the US mean that practices will occupy the role of a "health economic gatekeeper," running their practices or groups of practices with strict financial goals. In this effort they will seek to deliver cost-effective care in a far more deliberate fashion, thereby optimizing the revenues they derive from their third-party payers.

Practice revenue will depend upon the ability to constrain costs while creating optimal outcomes, not unlike the German healthcare "model."

This will lead group practices to rely on comparative drug effectiveness assessments for their therapeutic selection and use. In most cases **this will have the effect of slowing down new product adoption and favoring the use of established, cheaper products**, aside from any directives and formularies set in place by private payers. Many pharma companies will doubtlessly wish to indicate how their product could reduce the incidence of expensive medical interventions and additional therapies, while also decreasing the risks of longer-term sequelae. As pharma has learned over the past twenty years, however, if such putative savings seem too complex to consider, too hypothetical in theirbenefit, or will not occur until a future date that appears too remote, then payers may dismiss such arguments may in favor of short term savings.

The historic information channels that have been in place between manufacturers and high-prescribing, individual physicians contributed to a relatively quick, new-product uptake. Corporatized medical practices are unlikely to be early adopters of new products. Instead they will form a potential barrier, not unlike NICE has accomplished in the UK at the national level.

Another cornerstone of pharma's business model will vanish as the asymmetry of information that historically favored pharma over small providers disappears.

For the most part, office-based physicians acted as passive recipients of data generated by pharma companies regarding the benefits and utility of various therapies. That will change permanently in an EMR environment where the IT capabilities of MCOs and large practice groups, such as Mayo and Geisinger, enable them to slice and dice patient outcomes data in pursuit of cost-effective treatments. The clinical director at Geisinger, for example, proudly claims that his IT budget for refining clinical protocols runs to "tens of millions of dollars a year." Instead of pharma personnel telling providers about the most appropriate conditions and patients for particular therapies, providers and payers will be able to throw back real world results to counter those from increasingly discredited trials.

Some of the derivative effects to pharma resulting from the obsolescence of its business model include explicitly catering to providers' profit-making needs and eliminating reps.

The economic interests of these large, corporatized groups will drive selection and use of pharmaceutical therapies.

This means the communication of product features and benefits will become less important than the business-to-business (B2B) approach required for this new set of customers. As in any other B2B selling environment, pharma will have to base its approach on credibly addressing the P&L needs of the potential customer. Contracting for clinical trials offers an example of an additional revenue stream for customers. In effect, a pharma company's CRO becomes another version of a "sales force," representing a new income stream sought by corporatized practices.

Conventional representatives will become increasingly obsolete.

Pharma's sales personnel will become "account teams" using an entirely different promotional approach. Their objective will consist of persuading decision makers who share responsibility for the practice group's P&L to include the pharma company's products in their formulary. This new

target audience will include the practice group's CFO, IT consultants (that recommend formularies designed to bring the highest third-party reimbursement), the group's pharmacist, a director of clinical studies and possibly an outside health economist acting in an advisory role. Recent announcements about cuts in sales force numbers are not simply the result of the economic climate, but a response to this changing customer base and the need for a different skill set among pharma people who will need to call on new targets.

The nearly total disappearance of primary care reps can potentially change the industry's pricing structure. SG&A currently amounts to approximately 30% of gross revenue, while sales forces plus samples constitute the biggest part of this expense. Dispersing the sales force can substantially lower the industry's fixed overhead and, thereby, lessen the focus on launching potential blockbusters.

The ability of providers and payers to generate optimal usage data will doom pharma's one-size-fits all model of product marketing and require companies to make a substantial portion of their profits from small, niche products.

The days are fading when reps could urge physicians to "try this on your next couple of new starts." Instead providers and payers will continuously produce reams of data on hordes of patients that suggest optimal treatment approaches for ever-smaller segments. That means while market shares between 20-60% will still be possible, such a likelihood becomes much smaller. As generic incursion continues its relentless advance, most brands will have to compete for single-digit shares. The continued existence of pharmaceutical companies as profit-making entities will then depend, at least in part, on their ability to prosper from these small-share products. Whether companies can make acceptable returns on equity from lines of small products, with their capitalizations bloated from a dozen years of mergers and acquisitions, poses a fundamental challenge to industry leadership.

Various Approaches To Addressing The New Provider Landscape

Tactical adjustments

Pharma companies can seek to address the customer base at different operating levels. Obviously the least disruptive approach consists of tactically assessing the altering needs and circumstances of corporatized provider groups in order to market conventional products to them more effectively.

Pharma companies have already used various methods to try to encourage those with budget responsibility to recommend or adopt their product in favor of a competitor. These have included: straight net price reduction, performance-based rebates, product bundling and other methods.

So far these efforts have met with varying degrees of success from pharma's perspective. Each of these programs, nonetheless, bears scrutiny because their impact both to the "payer" and the pharma company can vary according to the nature of the product. In the new environment, each one could substantially impact the budget holder, the disease area, the competitive environment, and many other elements.

Other issues such as economic-based, comparative evaluation, e-prescribing, and reimbursement programs will have an increasing relevance to the new customer base.

Several companies (referred to later) have started to address the business needs of the new customer base by adopting more innovative marketing tactics. However, before embarking on any such action there has to be a fundamental evaluation of the "new" business environment, accounting at a minimum for the following:

1. ***Understanding the requirements of these new practices/ accounts.***

A critical starting point in the process lies in the need to conduct specialized, in-depth interviews of hard-to-reach administrators/ partners and cutting-edge practice groups. Such investigations lead to a better appreciation of: (a) how formularies were derived and agreed upon in the first place (b) what issues can materially influence formulary decision-making, (c) the exploration of how key, corporatized practices (including those with national prominence and others with local repute), influence smaller practices aspiring to implement health economic policies and develop greater budgetary accountability, and (d) which functional areas of pharmaceutical companies (e.g., sales, medical affairs, global product development, outcomes specialists, managed markets, others) would be best suited to lead the account teams of particular pharma companies.

2. ***Evaluating how key competitors are addressing the newly developing customer base.***

Companies can acquire a distinct advantage in assessing and planning for the emerging environment by benchmarking against major competitors. This process, although difficult, offers considerable "insight" that helps identify the "best practices" for dealing with this new environment. Because the US situation has certain parallels in German and Spanish practices, the examination of tactics that have/have not worked in driving successful product adoptions there can help develop a more focused approach in the emerging, payer-driven, US environment.

3. ***What constitutes best practice for B2B selling in the new environment?***

Until now B2B selling has not been a central part of pharma's core competency, although companies will have had some experience in this area due to their approach to managed care organizations. However, pharma sales have been generated largely by representatives that pitch the virtues of various product features and benefits to individual physicians. This has continued, despite the fact that their ability to influence sales has continued to decline, even as the business model of a sales army, with its high fixed cost, becomes unsupportable. At a recent public forum, Genentech's Vice President of Business Development, Joe McCracken, asked, "How long will we be paying sales reps to deliver coffee and donuts into clinics?"

There are a multitude of interpersonal, negotiation skills and new data sources that will need to be integrated into the "new sales team" and, as a result, it is doubtful that many pharma companies maintain the core attributes and/or personality to step into this new role. The assessment of companies in other industries with notable B2B success -- e.g., enterprise software, equipment leasing, and hospital equipment -- again yields a list of best practices that can be evaluated and modified to fit the circumstances of particular pharmas.

4. ***The "para-political" analysis of public policy can provide insight into the nature and timing of how government action will affect pharma in the future.***

When asked why Microsoft has not been more aggressive in developing EMR software for providers, CEO Steve Ballmer replied, *"The situation is just too big, too complex and too unstable for any company to commit substantial resources. We're all waiting on government."*

Most large, multinational corporations maintain active, government affairs departments to assess and/or influence government activity. But there is a need to supplement that effort with an investigative approach that assesses the "masked" economic interests, diversionary ploys and timelines that influence government decisions. This intelligence can be gleaned from Congressional and agency staffs, lobbyists, citizen advocates, journalists and others as needed. Such intelligence can assist both tactical and strategic planning.

Various Approaches To Addressing The New Provider Landscape

Strategic adjustments

As already mentioned, provider organizations in the US will consist of privately owned, revenue-driven ventures. The basis for their revenue growth will consist of improving outcomes that incentivize providers. Because the protocols for various diseases will be driven by "evidence-based outcomes" this will make promotional appeals by brands with little intrinsic differentiation a far more daunting challenge than has been the case to date.

Only a handful of branded products are likely to offer sufficient benefits for payers and providers to recognize their value. Thus, pharma's economic model as a research-driven industry with scientifically based product differentiation and a high-overhead sales force becomes far more precarious, going forward. Accordingly, big pharma companies may find it far more difficult to operate across a wide span of therapeutic categories.

This emerging set of circumstances demands a change to the business model and approaches to drug development that have been in place up until now. In recognition of this reality, some companies have already started to shift their focus. Current moves by Jim Cornelius and his colleagues at BMS signal an effort to become a smaller pharma entity that focuses on high margin, cost-limited, politically safer, specialty categories such as oncology and virology.

This transformation of BMS from a diversified pharma to a quasi-biotech model (what some observers refer to as "Amgen 1995") contains certain, inherent limitations, but also the benefits of positioning the company as an acquisition candidate.

Pfizer, Novartis and Abbott, to varying degrees, seek to make themselves diversified healthcare companies with far flung businesses such as consumer healthcare products, generics, original and follow-on biologicals, vaccines, diagnostics and "orphan" areas.

Andrew Witty (GSK) has indicated that if the company cannot improve on its ability to develop new molecular entities that advance standards of care, it will make money from the drug business as an investor/financier and marketer for smaller companies that possess such capability.

Franz Humer, Bill Burns and Severin Schwan at Genentech/ Roche have clearly demonstrated their commitment to a

diagnostics-pharma strategy in which diagnostics leads pharma by first developing biomarkers that will clue molecular synthesis. The effort is one of identifying those patients most likely to benefit from a therapy, thereby improving ROI on the use of expensive products. Roche's/Genentech's strategy, for this reason, marries a premium-pricing business model to a drug development strategy.

At the 2009 BioPharm America conference in San Francisco, Gwen Melincoff, senior vice president of business development at Shire, noted that that company's business model consists of "Expensive drugs for small populations." By way of illustration, she noted that Shire's gastrointestinal division employs 120 reps to cover the U.S., while the company's orphan drug division requires merely 10 reps.

In conclusion, despite the increasing pace of change in the healthcare market (as discussed above), the downward pressures on prices and declining drug development productivity, pharmaceutical companies need to acquire a fresher understanding of their rapidly changing customer base. Although, that customer base has become increasingly complex, the need for external consultants to assess their needs and appreciate innovative solutions will be paramount. **The need for insightful guidance and solutions cannot be underestimated.**

In this emerging business environment, changes will be so profound and will occur so swiftly that retrospective, large-scale, quantitative assessments of the type generally performed by consulting minions will be little more than post hoc affirmations of what clients already know. The race ahead will instead favor insight, speed, and aggressiveness.

Contact: Dr. Daniel R. Hoffmann
Pharmaceutical Research Business Associates
610-942-7024
DrHoffman@PBRAconsulting.com