Original Article

Rethinking commercial strategy – A patient-centered commercial model

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ABSTRACT **That the bio/pharmaceutical industry faces daunting challenges is common knowledge and the subject of debate for some time now. In reaction, leading bio/pharmaceutical firms have re-thought their business models. This article presents the framework, rationale and innards of a new model for commercializing outputs of the industry, given the realities of the difficult marketplace. Growing out of the axiomatic belief that patients are why the industry exists, the model defines a health-care ecosystem, re-specifying and clarifying the roles of seemingly disparate stakeholders in the service of patients. Four interlinked propositions on which the new commercial model thrives are outlined and supported with insights from real case studies and published evidence. Specific examples of tactical programs that exemplify the new model in practice are provided. The new, patient-centered commercial model is far from seeing widespread reality in practice; however, when in play, elements of the new model have consistently delivered the promise of bio/pharmaceuticals.**
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BACKGROUND

As the modern bio/pharmaceutical industry gears up to face a new decade of turbulence, it would do well to recognize a few lasting trends and their implications. Such trends are important in that they have a direct bearing on how firms in the industry organize themselves and function to serve their markets, while staying true to their shareholders' expectations. In other words, these trends call for changes in the fundamental models governing a bio/pharmaceutical firm's business and how it interacts with its customers to fulfill its mission.

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The changing role of the bio/pharmaceutical sales force

In the past 5 years, no single trend has changed the bio/pharmaceutical landscape more than the radical restructuring of sales forces. Companies big and small have shed large proportions of their traditional, physician-directed sales forces to save on

unproductive costs in the short term; but effectively to re-craft the essential role of the sales force. Physician offices no longer represent the most important points of product purchase decisions in a large number of product categories. Large customers such as governments, hospitals, and public and private managed care organizations purchase products on the basis of expectations requiring a selling model distinct from the traditional sampling/detailing driven model. Physicians are increasingly limiting product choice to what is made available to them by such primary purchasers. Patients and consumers – empowered with social networking tools – glean information about upcoming, new and in-market therapies outside the physician's office, often generating a prescription dynamic distinct from the traditional physician-driven model. It is no surprise then to note that the traditional share of voice, physician-focused sales force model has hit a point of diminishing returns to scale. The key is not more size or scale, but excellence in scoping the full customer universe, as diverse as it may seem; understanding disparate decision-making processes, refining targeting strategies and customizing marketing and sales efforts to match idiosyncratic customer motivations and needs as precisely as possible.[1] The need to shift from a product-focused approach to a customer driven one has never been more urgent.[2,3]

The rising utilization of generics

It is estimated that between 2010 and 2012, generics will assume as much as US$59 billion of sales currently accruing to branded products when they lose patent protection in the United States.[4] This shortfall is further subject to loss of revenue from ex-US markets in which the brands may have launched later. Short of requiring the launching of a disproportionately high number of new brands, this trend has a few important implications for new variations of the traditional bio/pharmaceutical blockbuster model. For one, manufacturers of branded bio/pharmaceutical products would need to sharpen their focus on commercializing innovative line extensions and product evolutions (such as pegylations, fixed dose combinations or vaccine formulations) of maturing novel brands which, while serving significant unmet, often unstated, needs of patients such as that for convenience and affordability, require only a fraction of the cost investment demanded by novel, first in class compounds. Such innovations would do well to take advantage of the significant strides in drug delivery and absorption technologies made in the past decade.[5] In parallel, as is increasingly becoming common, buying a stake in the generic industry either through making significant investments in stand-alone generic manufacturers or outright purchase of one is a worthwhile modification to the traditional way of doing business. Manufacturers of branded bio/pharmaceuticals ought to see generic manufacturers not as adversaries but as partners in the larger mission to serve patients.

Declining returns to R&D expenditures

By one estimate, bio/pharmaceutical R&D expenditures are expected to amount to $80 billion by 2014 – rising 400 per cent since 2000 – while the number of new molecules coming to market as a result will go down by half.[4] Pending the widespread adoption of new drug discovery paradigms (such as gene therapy), this radical, not entirely unavoidable trend demands changes to existing models of drug development and, by direct implication, to how such drugs see commercial light of day. For instance, restructuring large R&D organizations into smaller, autonomous, nimbler entrepreneurial units tightly aligned with small customer-focused commercial teams early in the development process holds the promise of encouraging higher levels of market-driven innovation than might be possible otherwise. Another sustainable variation to the existing development model is sharing and collaborating with other firms

(which may have strong, non-overlapping competencies), data and information on select scientific aspects of a line of discovery under neutral supervision, or within the auspices of an independent funding source. Other, more common variants have often been suggested, and sometimes implemented with good results. These include collaboration with or outsourcing development of specific lines of discovery to small, risk embracing, scientifically rigorous start-ups, either on or off shore. Or, working with regulatory authorities, to craft a development program with a strong Phase 4 component, effectively reducing the cost, time and risk associated with pre-launch developmental activities.

THE IMPORTANCE OF PATIENTS

Amidst irreversible industry trends that warrant changes to fundamental business models, another fact of vital importance is cause for a significant reevaluation of how bio/pharmaceutical firms commercialize and market their products. Over the past few years, considerable data have accumulated illustrating the growing dissatisfaction of patients with the ways bio/pharmaceutical products are priced, made available and delivered to them. More often than not, such data imply a deeper problem stemming from perceptions that the focus of bio/pharmaceutical firms has increasingly shifted from the discovery and delivery of effective therapeutics to one of profit taking. In a recent survey, US pharmaceutical consumers expressed considerable dissatisfaction with pharmaceutical firms on a wide variety of issues,[6] implying that the industry was less than trustworthy. Key issues of contention included promoting unapproved use of products, manipulating or suppressing clinical trial results to protect sales and spending too much money and effort attempting to prevent generic firms from competing with branded products. Reports in the media[7] stemming from such surveys have consistently pointed to an erosion of public trust in the pharmaceutical industry.

Coupled with such trends in perception are the consequences on patients' well-being of an overall lack of adequate access to medicines. Complicating such consequence is widespread evidence that access is often a function of patient affordability. Figure 1 highlights key patient problems with the US health-care system as indicated in a recent survey. Figure 2 provides corroboration from a related survey of physicians.

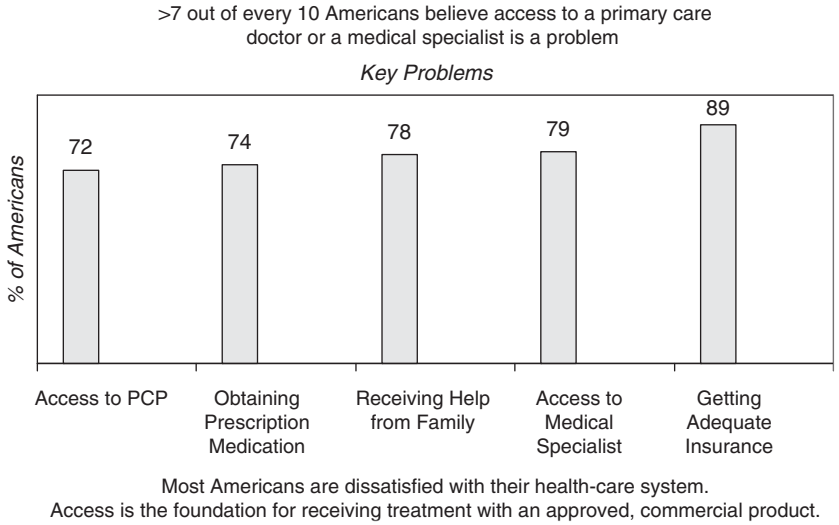

Figure 1: Patient dissatisfaction.
Sources: Anderson[32]; 2008 Almanac of Chronic Disease.

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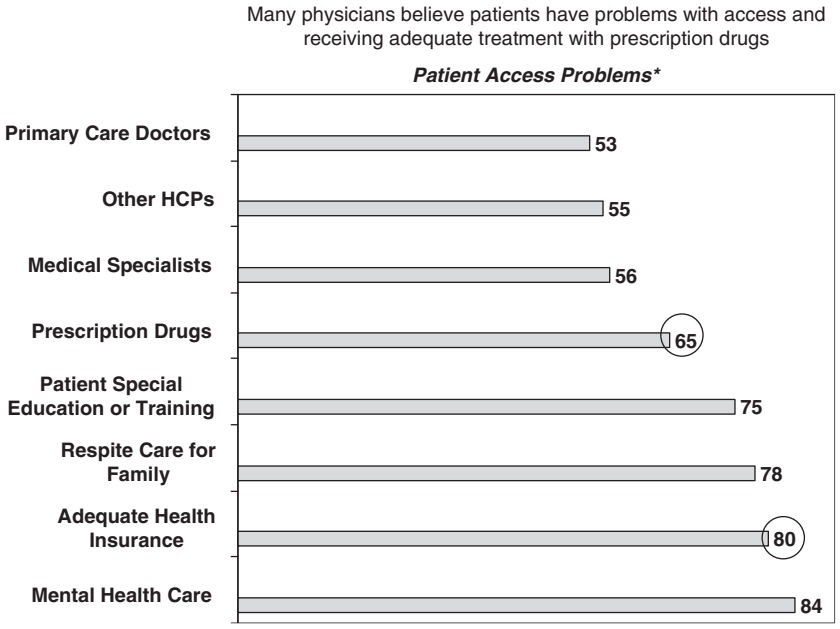

Figure 2: Physicians' view.
Note: * signifies percent of physicians who believe indicated item is a problem.
Source: Anderson[32]; 2008 Almanac of Chronic Disease.

Widespread dissatisfaction with firms in the bio/pharmaceutical industry on the part of its customers, taken in the context of irreversible environmental trends that need to be addressed head-on demand a rethinking of fundamental models that drive decisions about how such firms are organized, the process by which products are developed, and, as in the case of this article, how they may be brought to market and managed over their life cycle. By all accounts, a preponderance of evidence suggests realigning the primary focus of bio/pharmaceutical firms from selling products to serving patients.

A propos, the central premise offered in this article can be summarized in terms of four interlinked propositions as follows:

1. The modern bio/pharmaceutical industry is best viewed as an interdependent ecosystem. Patients are why the ecosystem exists.
2. Key factors driving the survival and successful evolution of such an ecosystem are patient focused.
3. Patients are the un-sung revenue engine of the bio/pharmaceutical industry. Even without innovation, focusing on patients has the potential to radically increase existing commercial revenues. Proven levers of revenue impact include:
   - improving patient access to care;
   - improving patient disease awareness, diagnosis and treatment rates;
   - improving patient medication adherence;
   - improving point of care communication with patients;
   - improving cost of product to patients.
4. Patient-focused commercial efforts are sporadic at best. Tools exemplifying a patient-centric approach have shown promise in solving emblematic problems and improving patient satisfaction.

THE PATIENT-CENTERED BIO/PHARMACEUTICAL ECOSYSTEM

Figure 3 is a schema representing a patient-centric bio/pharmaceutical ecosystem. It envisions a health-care system characterized

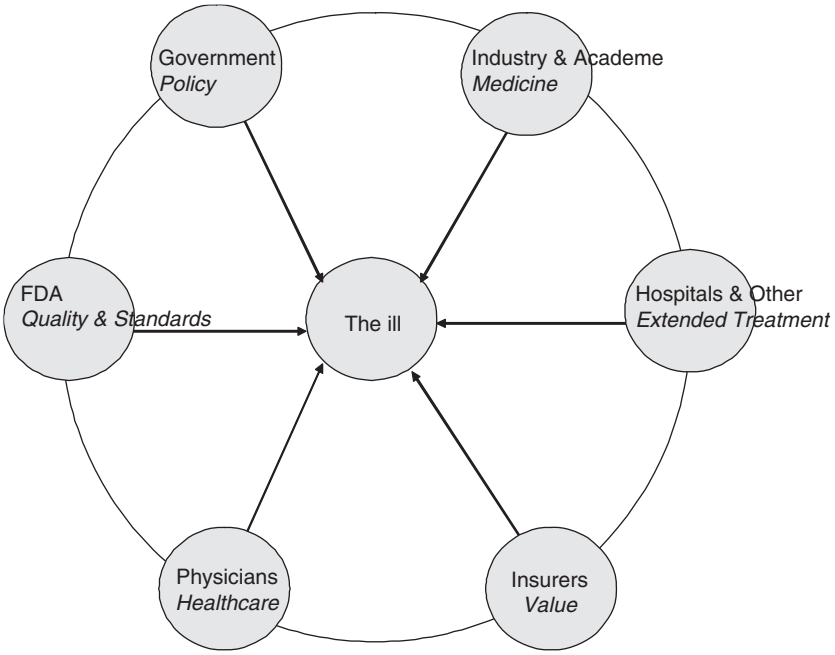

Figure 3: The health-care ecosystem.

by distinct and interdependent business entities focused on serving the ill – not for the sake of principle alone, but also for survival and profit in the broad sense of the term. While such a system may seem similar in some respects to how health care is organized and delivered currently in some developed countries of the world, a succinct explanation of the roles of each actor in the system will clarify differences, outline expectations and serve to inform how a bio/pharmaceutical commercial organization might best aim to interact with it.

Governments

Governments in such a system will assume sole responsibility for setting health-care policy. Key goals of such policy will be to ensure:

- widespread availability of medicines for the ill;
- affordable patient health care over a lifetime;
- wide availability of impartial information on medicines and health care;
- thriving innovation in medicines and methods of providing health care;
- effective competition among suppliers of medicines and health care;
- increasing sense of patient empowerment in dealing with their own well-being.

Regulators

A regulatory authority such as the FDA in the United States will be an autonomous overseer of administrative processes designed to ensure:

- publicly available, science-based proof of medicinal safety and efficacy;
- benchmarks that guide protocols and clinical trials that develop such evidence;
- wide and easy availability of such benchmarks and proofs for easy access and understanding by the public;
- market-based mechanisms that continuously monitor and disseminate information about in-market medicinal safety and efficacy;

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- gradual reduction in the need for an official, overseeing regulatory authority, in favor of market-based mechanisms and impartial, privately funded monitoring organizations.

Arguably, the same regulatory authority would take upon itself the task of evaluating the cost effectiveness of medicines and making such information available to the public.

Care providers

Physicians and related patient care providers would be responsible for patient care through all stages of illness in a variety of sites of care, depending upon disease severity.

In private clinics, physicians would ensure:

- evaluation, diagnosis and treatment of acute and chronic disease;
- prevention of detectable conditions that forebode debilitating diseases;
- dissemination of information on patient conditions, treatment options and care affordability;
- access to ancillary, supportive care either in-clinic or through an affiliated network;
- selective, ongoing education with a focus on prevention and treatment cost escalation.

Hospitals/Emergency rooms

Hospitals and Emergency rooms (ERs) would serve as sites of extended care, ensuring

- evaluation, diagnosis and treatment unavailable in stand-alone, physician clinics;
- a patient mix that is by definition distinct, higher risk and more severe from what is treated in stand-alone clinics;
- highly niched, comprehensive specialized care that – over a network of hospitals in a region – compliments specialization at other, related hospitals;
- effective, highly evolved relationships with regional physician clinics to optimize patient care before and after hospital stays;
- development of longitudinal data on the safety, efficacy and cost-effectiveness of in-market bio/pharmaceuticals and care methodologies.

Bio/pharmaceutical firms

Bio/Pharmaceutical firms would restructure themselves into clusters of autonomous, entrepreneurial business units, each responsible for life-long patient care in a specific therapeutic area and its co-morbidities. Scientific personnel in each business unit would work closely with commercial managers on discovery through all phases of clinical development and beyond. Commercial managers would shed undue emphasis on an Rx product-push model of generating revenue in favor of seeking opportunities residing in patient-centric motives, seeking to understand and serve the full range of patient needs in every site of care, over the full course of disease from the first signs of its manifestation through onset, response and relapse. Such a change to the commercial model would imply

- heightened emphasis on creating and accumulating intellectual property with an outside-in, market perspective; driven by patient needs, both current and foreseen;
- emphasis on creating and accumulating intellectual property that spanned the entire patient care continuum in each therapeutic area of interest, from prevention to evaluation, diagnosis, treatment and maintenance of good health;
- emphasis on developing intellectual property focused not just on bio/pharmaceuticals, but also on innovative diagnostics, devices, procedures, delivery and absorption techniques, and health-care services for every relevant site of care;
- emphasis not just on developing ethical, prescription products, but also on prescription to Over the Counter (OTC)/ Behind the Counter (BTC) conversions, and direct to consumer products if they provided genuine relief and met significant patient need;
- heightened emphasis on informing and communicating with patients on a whole

range of options that impact their health and present revenue generating opportunities for the bio/pharmaceutical organization;
- more justifiable demands for less regulation and open markets worldwide for bio/pharmaceutical firms to build direct relationships with patients – the customers that matter to them most.

Insurers

If and when bio/pharmaceutical firms operate under a patient-centric commercial model, health-care insurers would be required to enhance their existing mandate. They would represent the *de facto* interests of patients who would effectively pay them to do so. Both public and private insurers would deal with bio/pharmaceutical firms on behalf of their member-patients focusing on issues such as

- evaluating detailed performance data on products provided by bio/pharmaceutical firms;
- tallying product costs with estimated benefits to make product recommendations to their patients and their health-care providers;
- enlarging the menu of benefits offered to their patient-members to include services over and above those that might be related to bio/pharmaceutical product purchases;
- offering innovative consumer-directed insurance products which seek to control costs through patient empowerment, rather than by restricting patient choice;
- relating product utilization costs to in-market, patient-related performance by negotiating pragmatic, performance-based product purchase deals with bio/pharmaceutical firms;
- demanding innovative products, diagnostics, devices and synergistic health-care services which drive down costs of patient care over the full care continuum, partly on the basis of a patient-centric (rather than a piecemeal, product-centric) approach to innovation.

REVENUE POTENTIAL: PATIENT-CENTERED COMMERCIAL MODEL

The ability to generate sustained revenue is arguably one of the most important criteria by which the viability of a new commercial model should be judged. As is well known, revenue can be generated through several mechanisms, such as by controlling operational or systemic costs, by selling more of a revenue generating entity or expanding the customer base while maintaining consumption levels per customer. An important proposition that can be advanced in favor of a patient-centric commercial model is its potential to generate such revenue through at least five distinct levers.

Access

There is considerable evidence that efforts to improve access to health care for patients will generate higher demand for goods and services generated by firms in the bio/pharmaceutical industry. Such demand will almost always result in lower costs, higher efficiencies and higher revenues. In forums such as the United Nations, the notion of health care as a human right has received extensive support. In a recent consumer poll, over 75 per cent of respondents agreed with the sentiment.[8]

Under the current model, which seeks to derive economic efficiencies from within the population of patients with access to health care, the system is subject to higher costs for all concerned than would be possible otherwise. Lack of access to health care for a portion of a population of patients results in higher prices for health-care goods and services to those who do have some form of access. Often, lack of access to first-line primary care implies no other option but for the condition to worsen or a costly visit to an emergency room for attention and treatment. Recent data released by the US Health & Human Services (HHS) department indicates that one-fifth of the 120 million hospital-based emergency department visits in 2006 were from patients without any health insurance.[9]

Even when the limited population of those with access seek care under the current model, health-care providers in clinics, hospitals or ERs charge higher prices to patients they treat to make up for those who are unable to pay for treatment they receive.

It is a well-documented fact that health-care insurance – a key enabler of access – can be less costly if more consumers were covered. For instance, it is estimated that Americans with insurance currently pay a hidden tax of $1000 per year in increased insurance premiums to cover for health-care costs incurred by the uninsured.[10]

A recent study[11] of moderate to severe allergy sufferers conducted by the author documented direct and indirect costs incurred by patients who were uninsured or those who lacked the means to visit a physician for their condition. Such patients effectively paid 75 per cent more in direct costs for receiving treatment compared to those who had access to physicians and prescription products. In terms of indirect costs, such patients typically let their condition worsen until they had no option but to seek expensive, un-insured care downstream. Such patients also showed higher levels of absenteeism and presenteeism in the workplace, suffered more co-morbidities and had higher hospitalization rates: in effect providing direct evidence that if they had access to first-line primary care, much of such costs would have been unnecessary; and some of what remained might have been properly channeled toward the purchase and utilization of prescription products.

A cogent piece of analysis supporting the proposition that more access will invariably lead to more demand and revenue from goods produced by the bio/pharmaceutical industry[12] notes that a 13 percentage point increase in the number of people covered by third-party payers (from 67 to 79 per cent) in the United States from 1997 to 2007 has been accompanied by a 72 per cent increase in the number of scripts filled. By that analysis, each percentage point increase in the number of individuals covered converts to a 5.5 per cent increase in scripts. Regardless of the type of coverage afforded to those currently without access, recent analysis indicates that increasing the number of patients with access to health care will invariably lead to a dramatic market expansion for the bio/pharmaceutical industry. For example, the Congressional Budget Office (CBO) analysis estimates that, no matter which version of the pending health-care reform bill passes into law in the United States, proposed changes mandating increases in insurance coverage will result in a 61–72 per cent increase in the number of scripts dispensed over 10 years.

Awareness, diagnosis and treatment rates

It is no secret that considerable revenue potential exists along the path of optimizing sales performance of in-market bio/pharmaceutical products. Opportunities exist in a number of areas such as the breadth of a label, depth of providers targeted for commercial activities, speed of product adoption, type and number of insurers who are proactively engaged to improve product availability and the extent of reach into patient markets globally. In addition, considerable untapped potential resides in the possibility of extending revenue streams of in-market products through longer life cycles depending upon strategy choices that result in line and product extensions, newer doses and formulations, new forms of drug delivery, new indications and in-house genericization. Unlike at any time in the last 40 years, an in-line pharmaceutical product can now be expected to be made available by as broad a base of insurers as is profitable, adopted faster, by as many prescribers and patients as possible, so as to attain peak potential as quickly as possible. The rising number of patients in emerging markets outside the United States and European Union as consumers of bio/pharmaceuticals over the next decade is a fact that emphatically underscores such commercial potential. Even within the United States, the world's largest market for bio/pharmaceuticals, treatment rates for a wide variety of

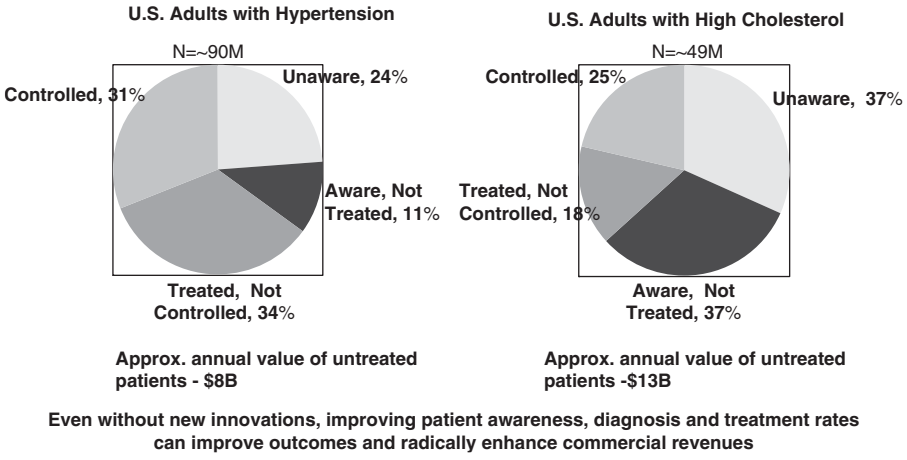

Figure 4: Diagnosis and treatment: The commercial opportunity.
Sources: Datamonitor[33]; *CV Drug Discoveries*[34]; 2008 Almanac of Chronic Disease.

conditions are less than desirable, suggesting untapped revenue potential. For example, only a third of the patients diagnosed with Alzheimer's receive any treatment. Only one out of five HCV-infected patients receive treatment. Similarly, less than half the patients diagnosed with Multiple Sclerosis, Rheumatoid Arthritis or Anxiety receives any treatment. Treatment rates for patients outside the United States are far lower across a wide variety of diseases.[13]

A commercial model that recognizes such potential revenue drivers and prioritizes them on the basis of their value to patients can be an invaluable beacon to shaping commercial strategies.

Figure 4 is a concise representation of untapped revenue opportunities in two of the largest chronic diseases when viewed through the prism of the new patient-centered commercial model.

Key points of note include the following:

- Considerable untapped potential exists in the very basic commercial responsibility to increase disease awareness among those who are already afflicted. Not counting the general, at-risk population – which, as a lot of literature and research point out, can benefit from disease prevention activities – anywhere from a quarter to a third of the affected population is unaware of its respective conditions. It is a well-known fact that benign neglect of either of the two conditions shown can lead to irreversible heart disease, the leading cause of mortality; not to mention associated, avoidable costs to the health-care system. As such, commercial strategists would do well to take a patient-centric view and realize the social and commercial benefits of raising disease awareness.
- Large, future revenue potential exists in good sized chunks of the affected populations who are aware of their condition but for reasons such as lack of access, affordability, sufficient motivation or degree of severity remains untreated. Taking a patient-centric view, an astute commercial strategist would devote reasonable time and effort toward moving such patients into outpatient clinics and under physician care so as to increase the probability of proper diagnosis and treatment with a commercially available product. That enhancing social good, reducing systemic costs and – at the same time – improving the prospects of higher revenue without sizable investments in R&D are all intertwined and aligned in the same direction only attests to the

relevance and attractiveness of such a strategy.
- An even larger revenue potential exists in about a third of the affected populations who are receiving sub-standard or inappropriate treatment resulting in lack of efficacy. Such patients are already under physician care, which increases their value to a commercial strategist, given that no upfront awareness, education or motivational marketing costs need to be incurred. The commercial focus, instead, needs to key on the reasons for lack of disease control, despite treatment. Often the reasons for such an outcome are manifold, such as improper diagnosis, inappropriate selection of treatment, lack of compliance or follow up, the nature of resident co-morbidities or the severity of the condition itself necessitating transfer to alternative sites of care. It falls to the sales and marketing interface, usually a sales representative or a medical liaison, then, to rise above the ambit of his/her usual responsibilities and identify such cases; and to offer solutions – including alternative treatment products with the necessary rationale – that benefit the patient, and in the process also improve the chances of a sale. It is also not unusual for such interactions to generate debates on the comparative efficacies of available treatment options and/or the availability of the right type of clinical data to advocate or refute the use of specific treatments. In other words, taking a patient-centric view of the problem identifies revenue building opportunities even as it suggests opportunities to re-craft value propositions and shape future clinical research designed to provide valuable data supporting appropriate product use.

It is notable that at least three out of every four patients shown in Figure 4 can be the focus of proactive, revenue generating commercial strategies when viewed under a patient-focused commercial model. What is equally important to realize is that the remaining quarter of either pie – representing patients under control – also requires aggressive commercial attention, not in terms described above, but along the dimension of maintaining successful treatment regimens through sustained adherence. While maintaining patients on successful treatment regimens is a highly desired goal in itself, it also represents a sustained source of revenue at very little incremental cost.

Medication adherence

One of the most important sources of lost revenue under current commercial models is directly attributable to lack of adherence. It is estimated that as much as 75 per cent of patients do not take their medications as prescribed. One out of every two patients with chronic conditions fails to comply with prescribed treatment. Four out of five HCV patients are non-compliant. Only one-third of Alzheimer's patients comply with prescribed treatment. Compliance rates for Rheumatoid Arthritis, Multiple Sclerosis or Anxiety are 50 per cent or less. Less than 2 per cent of diabetic patients follow treatment protocols, such as checking fasting glucose levels and taking medication according to prescribed regimen. It is a well-documented fact that commercial efforts to improve adherence rates will plug large gaps in expected revenues. The key challenge is to develop a commercial model that recognizes the importance of adherence or the lack of it as a significant revenue driver, and suggests strategy that seeks to improve medication adherence from the perspective of the patient.

Non-adherence can result from a wide variety of reasons, most of which can be categorized into one of four broad dimensions:

1. relationship with provider;
2. financial reasons;
3. product reasons; and
4. clinical reasons.

Figure 5 provides a breakdown of reasons within each of the four dimensions. It is

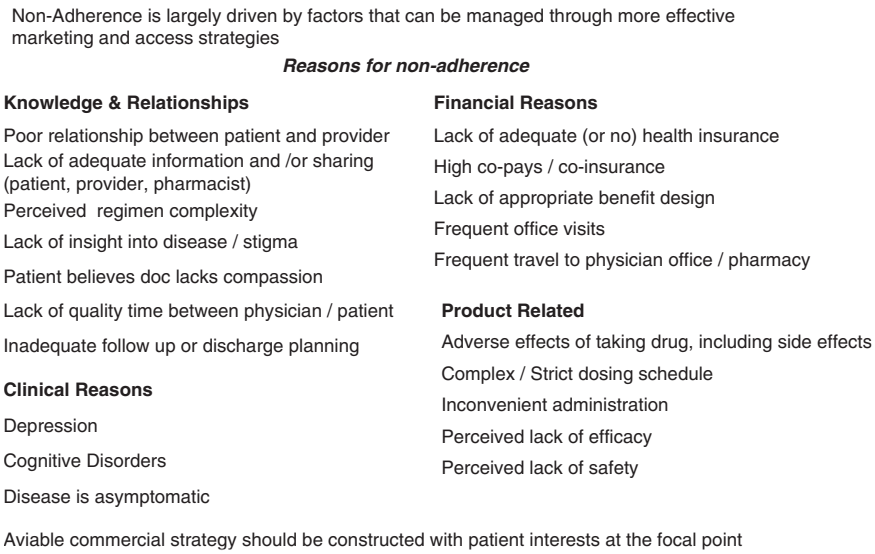

Figure 5: Managing adherence: The commercial opportunity.
Sources: NCPIE[35]; New England Healthcare Institute[36]; PhRMA[23].

instructive to note that a large number of such reasons can be addressed by mechanisms that are directly under the domain of marketing and access strategies. For instance

- Product-related reasons resulting in lack of adherence can be directly addressed by providing appropriate information to patients that clear misconceptions and increase confidence in matters such as product safety and efficacy.
- Financial reasons are mostly related to lack of adequate access, which can be mitigated by providing customized, patient friendly benefit designs.
- Clinical reasons are best addressed through productive dialog with the health-care provider.
- Issues pertaining to poor interpersonal relationships with the health-care provider are best addressed through a combination of patient and provider education initiatives, designed with patient interests in mind. Often, a focused marketing campaign combining direct to patient communication with targeted physician messages during a specific timeframe works well in this regard.
- It is not a stretch to believe that better interpersonal relationships between patients and health-care providers usually also results in the sharing of information that reinforces such relationships while setting the stage for higher compliance.

In other words, it is not unreasonable to expect that a viable commercial strategy executed through effective, patient-focused marketing and access programs can go a long way in improving medication adherence.

The revenue implications of improving adherence are manifold. For example, it is estimated that

- plugging the adherence gap will result in a 36 per cent increase in the number of prescriptions per drug per year, equating to a revenue estimate of $177 billion[14];
- improving adherence will result in an average of three less visits to health-care professionals by those who are non-adherent, resulting in a per patient cost reduction of $2000 per year compared to those who take their medications as directed[15];

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- increasing adherence in the United States could lead to a 10 per cent reduction in hospital visits and 23 per cent decrease in long-term care admissions.[16]

Point of care communication

An important and often under-recognized element of a patient-centric commercial model is the domino-effect-like impact of patient/physician interaction on patient behavior, outcomes and product prescribing at the site of care. Far too often commercial models tend to ignore the potential of encouraging the right kind and frequency of patient–physician interaction as a critical stepping-stone to generating prescriptions, revenue and profits.

Consider the following facts:

- the most common cause of malpractice suits is failed communication of physicians with patients and their families[17];
- in a survey, 83 per cent of Medical Doctors (MDs) believed communication was as important as technical skills in patient outcomes; however, only 18 per cent believed they had had good training in patient communication[18];
- in another survey, 72 per cent of patients were unable to list medications they take; 58 per cent of patients were unable to recite their own diagnosis.[18]

> Social structural barriers impede effective communication, however, and information giving remains problematic. Doctors tend to underestimate patients' desire for information and to misperceive the process of information giving. The transmission of information is related to characteristics of patients (sex, education, social class, and prognosis), doctors (social-class background, income, and perception of patients' desire for information), and the clinical situation (number of patients seen). Doctors' nonverbal communication abilities are associated with outcomes of medical care such as satisfaction and compliance. Regarding the sociolinguistic structure of communication, doctors often maintain a style of high control, which involves many doctor-initiated questions, interruptions, and neglect of patients' 'life world'.[19]

While lack of proper communication abilities on the part of physicians is a problem in itself, its impact on patient behavior is paramount to the success of a viable commercial strategy, viz. to achieve successful patient outcomes. In a large-scale patient study,[20] a person-focused interaction style appeared to be the most congruent with patient reported quality of primary care. Physicians with the person-focused style rated highest on four of five measures of the quality of the physician–patient relationship and patient satisfaction. In contrast, physicians with the high-control style were lowest or next to lowest on the outcomes. Physicians with a person-focused style granted the longest visits, while high-control physicians held the shortest visits – a difference of 2 min per visit on average. The associations were not explained away by patient and physician age and gender.

In a study conducted by the author,[21] patient request and time spent per visit discussing a new biologic drug with physicians were the two most important drivers of product prescribing. Using a non-parametric, auto-regression model on data collected through a survey of patients and physicians, it was clear that physicians who spent

- >38 min per visit with a patient who requested the new drug ALWAYS prescribed the new drug;
- >48 min with a patient who did not request any drug had a 50 per cent chance of prescribing the new drug;
- <38 min with a patient who requested the new drug had a 40 per cent chance of prescribing the new drug;
- <48 min with a patient who did not request any drug had an 18 per cent chance of prescribing the new drug;

- any time with a patient who requested an existing drug had a 0 per cent chance of prescribing the new drug.

To a commercial strategist, lack of new prescriptions for a newly launched drug owing to reasons unrelated to its value proposition is a serious act of needless omission likely to have critical downstream impact in terms of slower than anticipated uptake, lower than desirable adherence and missed forecasts.

Cost of product to patient

Along with the rise in the number of un/underinsured patients, the rising cost of bio/pharmaceutical products has received considerable attention as one of the most important problems facing a multitude of stakeholders in the health-care industry. From the perspective of bio/pharmaceutical manufacturers, however, it should be pointed out that prescription drug costs typically amount to a little less than 10 per cent of total health-care costs, even in a health-care system as large as that in the United States. Even the costs of the more expensive biologic medications total about 14 per cent of all health-care costs.

The key issue isn't the impact of bio/pharmaceutical product costs on health-care systems, but rather one that should be of concern to commercial strategists within bio/pharmaceutical firms. At a micro-market level, rising co-payments for drugs that need to be taken for life to control the consequences of chronic diseases become a burden in relationship to patient affordability, especially for seniors with limited income who form the bulk of the treatment population. In the case of the more debilitating conditions such as cancer, arthritis or a variety of neurological diseases, patient burden of payments for biologic products increase in direct proportion to their list prices in the form of co-insurance payments. A recent poll from the National Council on Aging reports[22] that in 2008, 25 per cent of Americans aged 44 years and older with chronic conditions put off getting their prescriptions or seeking health care because they couldn't afford it. Furthermore, a Kaiser Family Foundation tracking poll showed that 15 per cent of respondents cut their pills in half or skipped doses to make their prescriptions last longer. Even physicians – who purportedly make clinical (not economic) judgments about the pros and cons of treatment options before prescribing one bio/pharmaceutical drug over another – are becoming increasingly sensitive to rising out of pocket costs incurred by their patients. In other words, even within the subset of patients with some form of insurance, more expensive medications are in danger of pricing themselves out of the market that they intend to serve. The issue is magnified several times when seen through the prism of the uninsured.

In a number of studies conducted by the author and his colleagues, such relationships between out of pocket costs to patients and prescription volume are apparent. For example, in a study assessing customer reactions to a new product, making the product available to the patient at an out of pocket cost of $50 versus $20 resulted in

- 11 per cent fewer physicians prescribing the product;
- 13 per cent reduction in the volume of product prescriptions written;
- 50 per cent decrease in the number of patients likely to purchase the product at the pharmacy;
- 50 per cent increase in the number of patients asking the pharmacist for a lower co-pay substitute;
- 40 per cent increase in the number of patients who would consult their doctor for a substitute.

Devising pricing strategy within the rubric of a patient-centered commercial model, then, has never been more critical than now. A business case could very well be made that

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the interests of patients and manufacturers alike are better served by a price that maximizes patient access and adherence rather than short-term product revenue or profit. When viewed over the full course of treatment and the breadth of the patient population eligible to receive the product over its life cycle, such a strategy could also ensure higher profitability. Now, more than ever, considerable value exists in debating the pros and cons of launching a new product with a price to maximize market penetration rather than a year's revenue or profit.

From a systemic, macro-market standpoint, devising a patient-friendly pricing strategy has critical upside potential as well. Numerous studies have pointed out the unintended consequences of putting pressures on patient affordability through higher out of pocket costs or reduction in benefits acquired for the same cost. In an oft-quoted landmark study of seniors enrolled in the United States. Medicare program,[23] for example, a $1000 cap on annual benefits resulted in

- 15–27 per cent less utilization of medications for treating Congestive Heart Failure (CHF), Lipid disorders, Diabetes & Schizophrenia;
- significantly poorer control of blood pressure, lipid levels and glucose levels; and
- significant increases in the costs of subsequent hospitalization and emergency care.

In other words, strategists devising patient-centered commercial models are better served by taking a holistic, systemic and lifetime value view of cost to patient before setting product prices. Such a view also allows flexibility in setting a lower market entry price for the product, which can be recouped through wider access and lower systemic costs downstream.

PATIENT-CENTERED COMMERCIAL PROGRAMS

Initiatives recognizing the importance of patients as the hub of an effective and highly performing health-care system are few and far between. Even in the case of programs that are currently in-market, there is a crying need for more and better co-ordination among key players of the health-care ecosystem (Figure 3) in order for them to succeed in proportion to their promise. There is little doubt that strategists looking to recast or develop patient-centered commercial models will do well to integrate the spirit and intent of such programs into their implementation plans. For example:

1. Progressive legislation such as the US Bipartisan Patient Protection Act of 2001 reflect the well meaning intentions of governments to build a health-care system revolving around the needs of patients. In the absence of comprehensive support from other actors in the health-care ecosystem (such as insurers, in this case) such efforts fail to see light of day. Recent proposals to reform health care in the United States contain elements that aim to restructure health-care delivery in patient friendly ways with implications for how commercial bio/pharmaceutical products may best be delivered to them. As of the writing of this article, such proposals are under congressional consideration.
2. Some insurers, for their part, have launched promising patient-centered innovations of their own which aim to empower patients, reduce costs while increasing access to health care. For example, Consumer Directed Health Plans (CDHPs) empower enrollees through higher deductibles and optional health-care savings accounts, designed, to a large extent, to let the patient decide how and what to pay for their health care. Distinct from other benefits, CDHPs contain financial incentives for enrollees to moderate utilization of health services, while providing them with tools for cost and quality comparisons, in effect aiming to help them become smarter shoppers of health care. CDHPs, however, have failed

to catch on with patients to the extent expected for a variety of reasons. For one, the more well-to-do patient segment with higher education and income relative to the full population of enrollees has shown more enthusiasm in adopting them.[24] The value of CDHPs, however, in improving system efficiencies and lowering overall health-care costs by taking a patient-centric view has been recognized without a doubt. In the recent economic downturn of 2009, enrollment in US-based Health Savings Account (HSA)-linked CHDPs grew by 33 per cent over 2008, as more employers recognized their benefits in saving costs while holding forth to employees the prospect of higher savings.[25]

3. Rising costs (of prescription drugs) to health-care systems have also led regulators in several bio/pharmaceutical markets to scrutinize the true value of bio/pharmaceuticals in terms of improving patient outcomes. In a circuitous way, this has willy-nilly put patient interests at the center of debates on how bio/pharmaceutical products should be priced. As such, *ad hoc* partnerships between payers and bio/pharmaceutical firms – two key actors in the health-care ecosystem – have showed promising signs that patient interests are again coming to the fore in critical issues such as which products would be covered on formularies and at what price. For example,[26] in the United States, Merck pegs what the private insurer Cigna pays for its diabetes drugs Januvia and Janumet to how well Type 2 Diabetes patients are able to control their blood sugar. Merck also offers higher discounts to Cigna on Januvia and Janumet if patients' sugar is better controlled, regardless of whether the improvement comes from use of Merck's products or other medications. In return, Merck's diabetes products are offered preferred positions on Cigna's formulary of drugs meant to treat Type 2 Diabetes. Johnson & Johnson has set what is considered the prototype deal in 2007 with Britain's National Health Service, which had tentatively decided not to pay for the cancer drug Velcade. To avert that decision, the company offered what was essentially a money-back guarantee. If Velcade did not shrink a patient's tumors after a trial treatment, the company would reimburse the health system for the cost of that patient's drug. Another example of a bio/pharmaceutical manufacturer standing behind its products in the interests of patients is that of Actonel, from P&G and Sanofi Aventis. If patients taking Actonel suffered fractures, insurers would be reimbursed by the manufacturers for the full cost of fracture treatment.
4. The desire to control spiraling costs is also a key motivator for two other patient-centered innovations from insurance firms. As with other such initiatives, lack of sufficient enthusiasm and co-ordination among all actors in the health-care ecosystem coupled with seemingly insurmountable operational barriers have resulted in slow adoption. For example:

   (a) Some health plans and employers in the United States have experimented with offering their members value-based benefit designs. In essence, the designs customize benefit designs to the needs of enrollees such that the cost of a benefit is relatively low to one who needs it most. The hope is that frequent use of such benefits by those who need it will lead to heightened compliance and efficacious outcomes, thereby reducing the need for costly hospitalization or emergency care. As part of one such design, the insurer WellPoint offers blood glucose meters to its members with Type 2 Diabetes at no cost. The insurer Blue Cross Blue Shield (BCBS) of Michigan offers its asthmatic members reduced co-pays on seven branded asthma medications in the hope of increasing compliance, reducing dependence on costlier rescue

medications and eliminating hospitalizations. Value-based benefit designs have not become the norm among payers. One reason is the seeming difficulty (and effort) involved in determining who deserves what type of benefit. The notion of micro-segmenting a large, diverse customer base on the basis of debatable criteria has led to widespread inertia in adopting what is clearly a win-win proposition for the patient, the payer and the health-care ecosystem. The time is ripe for the application of state of the art segmentation and targeting methodologies to payer enrollee databases in order to bring the advantages of value-based benefit designs to a much wider patient base than currently.[27]

(b) To address the problem of enhancing patient access to physicians as well as to tackle the growing shortage of primary care physicians in the United States, the insurer United Health Care is partnering with IT leader Cisco to develop the first national Telehealth Network, called Connected Care. Through extensive use of audio, video and telecommunication methodologies, the network will allow rural, urban or hard to reach patients to get in touch with physician services, regardless of geography. Connected Care will make clinics available in the workplace, as well as in rural and retail locations. In-home visits using similar technology will also be introduced to truly bring care to the patient. In a recent employer pilot, 99 per cent of participating employees said they would recommend the program to others. To date, no other insurer has a program similar to Connected Care.

5. Pragmatic bio/pharmaceutical manufacturers and marketers, foreseeing considerable social and business goodwill, have sometimes made increasing product adherence a key objective of commercial strategy. However, the seeming difficulty of continually administering and monitoring the impact of an adherence program over a time frame sufficiently long to realize expected gains on the required investment is often daunting. This is especially true when other investments with guaranteed short-term positive returns – such as increasing sales force reach and frequency – demand a higher share of limited funds. Two examples of notable adherence-encouraging commercial programs include[28]

   1. A program from AstraZeneca Canada in support of increasing adherence to Arimidex (anastrozole), an adjuvant therapy for breast cancer. The program recruits patients through pharmacies (with the help of the e-health organization Rx Canada) and provides them with a series of timed newsletters throughout the 5-year course of therapy.
   2. BP Success Zone – an education and adherence program from Novartis for patients with high blood pressure, wherein patients enroll to receive a series of e mails and direct mail pieces over the course of 12 months, such that every mailing is timed to known treatment drop off curves. In addition to customized patient mailings, the program offers free blood pressure meters and a feedback loop involving health-care providers.

It should be noted that recent advances in marketing research methodologies that enable accurate segmentation, targeting[29] and subsequent performance measurement of marketing programs involving patients and their physicians can solve key conceptual and operational problems which would otherwise prevent marketers from developing and implementing highly focused adherence programs.

Two other concepts merit mention to highlight ideas that illustrate the value of

adopting patient-centric ways of doing business in the health-care ecosystem.

1. *The Medical Home concept*. In existence since its introduction in 1967, this concept has received considerable attention lately in various proposals to reform the US health-care system. The concept advocates a comprehensive partnership between patients, their families and a primary care provider who takes charge of an array of responsibilities to provide acute, chronic and preventive care services to the family. The Medical Home, in essence, is a one-stop center for most medical needs for the entire family. While this concept has yet to find favor among the mainstream patient, physician and payer populations, studies have begun to prove their validity as an alternative, patient-friendly, cost-effective way of delivering health care. A recent study[30] identified three common features of highly effective medical homes in the United States – (a) an exceptional form of individualized caring tailored to prevent ER use and unplanned hospitalization for chronic illness; (b) efficient providing of basic health-care services; and (c) careful selection, and co-ordination with, health-care specialists.
2. *Workplace Wellness Programs*. Given that over 60 per cent of Americans get their health insurance coverage through an employer-offered plan and that the majority of such workers spend the bulk of their waking time in the workplace, wellness programs are a logical vehicle to impact workers' health in ways that are beneficial to the individual as well as to the health-care system overall.[31] Workplace wellness programs have received considerable attention in recent debates about how best to increase health-care cost efficiencies. In a meta-analysis of literature on costs and savings associated with Workplace Wellness programs, it was found that medical costs fell by about $3.27 for every dollar spent on wellness programs and absenteeism costs fell by $2.73 for every dollar spent. Finding common ground between the commercial mission of a bio/pharmaceutical firm and efforts of employers to impact employee health through wellness programs is both a rational and worthwhile imperative.

CONCLUSION

That the bio/pharmaceutical industry is facing daunting challenges is common knowledge and the subject of debate for some time now. This article presents the framework, rationale and innards of a new model for commercializing outputs of the industry, given the realities of the difficult marketplace. Growing out of the fundamental, axiomatic belief that patients are why the industry exists, the model defines a health-care ecosystem, re-specifying and clarifying the roles of seemingly disparate stakeholders in the service of patients. Trends that justify the value of a patient-focused commercial model are presented. Four interlinked propositions on which the new commercial model rests and thrives are outlined and supported with insights from real case studies and published evidence. Specific examples of tactical programs and tools that exemplify the new model in practice are provided. As much of the article illustrates, the new model is far from seeing widespread reality in practice; however, when in play, elements of a patient-focused commercial model have consistently delivered the promise of bio/pharmaceuticals. Much of the content presented in this article can be pondered in the context of an oft-cited quote from George W. Merck, one of the founders and early CEOs of Merck, from a speech he made 59 years ago:

> We try to remember that medicine is for the patient. It is not for the profits. The profits follow, and if we have remembered that, they have never failed to appear.

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