BABSON INSIGHT

SPECIAL ISSUE / LIFE SCIENCES AND HEALTH CARE

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Greetings:

This special issue of *Babson Insight* presents the latest Babson thinking on Life Sciences and Health Care, sectors distinguished by breakthrough innovation but also costly complexity.

Today, more than ever, businesses in this space face unprecedented levels of uncertainty. How should health care costs be managed and linked to performance outcomes? In which areas of health care is social and regulatory innovation critical? Which business models are right in Big Pharma given a changed landscape? And, which new decision frames should be adopted?

In the following 10 featured articles, we present readers with a proposed way forward through these and other tough questions that require insight and smart risk-taking.

At Babson Executive Education, we believe that a corporate goal of preventing all downside risk is unattainable, and may well sow the seeds for the destruction of shareholder value by simultaneously eliminating opportunities that can lead to growth. To ensure successful growth, management can learn a lot from entrepreneurial leaders. Good entrepreneurial leaders recognize and manage risks. They understand the essence of the situation, take actions, learn from them, and recalibrate. They discover or create opportunities. Through our programs, consulting, and other learning solutions, Babson Executive Education provides a dynamic learning laboratory where our clients experiment, learn, and create new opportunities for growth and value creation.

As you read through the articles in this issue, we hope you discover ways to act successfully in the face of complex and uncertain operating environments. Please don't hesitate to contact us to find out how we can help you and your organization.

Best regards,

Gaurab Bhardwaj, *Associate Professor and the Louis J. Lavigne Jr. Endowed Term Chair in Strategy and Planning at Babson College*

Elaine J. Eisenman, *Dean of Babson Executive and Enterprise Education*

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Can Pharma Find the Right Course?

Factors transforming Big Pharma and why its business model must change *by Bill Lawler*

The pharmaceutical industry is in the middle of a perfect storm. First, what has been termed a patent cliff has materialized with more than $150 billion in drugs coming off patent worldwide in 2011–2014. This is particularly disastrous for the industry.

With gross margins around 90% of revenue for established drugs, and sales and marketing at 30%, every dollar of lost revenue impacts operating profit by about $0.60. For example, Lipitor, at its peak a $13 billion drug worldwide for Pfizer, lost patent protection in the U.S. in November last year. With almost $8 billion in U.S. sales, this means a potential negative impact on operating profit of well more than $4 billion, approximately 30% of Pfizer's 2011 operating profit. In that first week in November, off-patent, U.S. Lipitor sales plunged by more than 50%.

Companies have weathered patent issues in the past, but this one is more troubling since R&D productivity, the value driver of the industry, has dropped precipitously. In a 2008 Goldman Sachs industry report on Big Pharma companies in the U.S., it was noted that in the past 10 years R&D spend had increased threefold while new molecules introduced to the market had decreased by 40%. This resulted in two outcomes. In the short run, the product pipeline development process was not robust enough for the pharmaceutical industry to weather the looming patent cliff. Of equal importance, however, was the long-run impact—the cost to discover and bring a new drug to market was increasing dramatically. The report concluded by stating that the business model for Big Pharma was broken.

This brings us to the third aspect of this perfect storm, the business model issue. How has the industry responded? Some players have responded the old-fashioned way—investing more resources in R&D hoping to fill the pipeline. Eli Lilly has taken this a step beyond by moving to a more open innovation model partnering with firms in emerging markets to broaden its research and development capability—what it terms "more and better shots on goal." Others have taken more drastic steps via mega-acquisitions. Pfizer acquired Wyeth for $68 billion. Likewise, Merck, with close to 80% of its revenue stream at risk due to the patent cliff, followed suit acquiring Schering-Plough for $41 billion. This clearly helped with pipeline issues but at what cost?

Andy Grove, past CEO of Intel, wrote an interesting reflection on his time at the helm of Intel, titled *Only the Paranoid Survive*. In it, he talked of the importance of recognizing inflection points in an industry's life cycle—that point in time when the old ways of doing business no longer hold. A business model has three balls that must be juggled constantly. First, one must **create value** by meeting the needs of a targeted market segment in a manner such that the value in the mind of the customer is greater than the offered price. Then, one must **deliver this value** by marshaling and aligning resources to support processes necessary to meet the targeted customers' needs in a manner that competitors would find difficult to imitate. And, finally, the last ball is to **capture value**. All this has to be done in a manner that results in increased investor value. Simply put, the cost to the company to deliver the value must be less than the price—that is, the target customers' willingness to pay. When these three balls are juggled correctly, it results in profitable growth. Unfortunately, the perfect storm factors described above are changing the nature of the industry fundamentally, making this process of value creation, delivery, and capture extremely challenging.

The long-practiced business model for the pharmaceutical industry can be described as The Search for the Next Blockbuster. Find a large patient population with an important therapeutic need, spend on average about $1 billion to discover, develop, and launch a drug in the market, ensure strong patent protection, convince the market of the drug's benefits by promoting it heavily, and then hope that annual sales exceed $1 billion (a blockbuster drug is one that has sales of at least $1 billion annually). When this business model works, the rewards are enormous. The large market size is essential since the costs incurred are so high and the process is highly risky since a large majority of attempts at drug discovery fail. This risk is

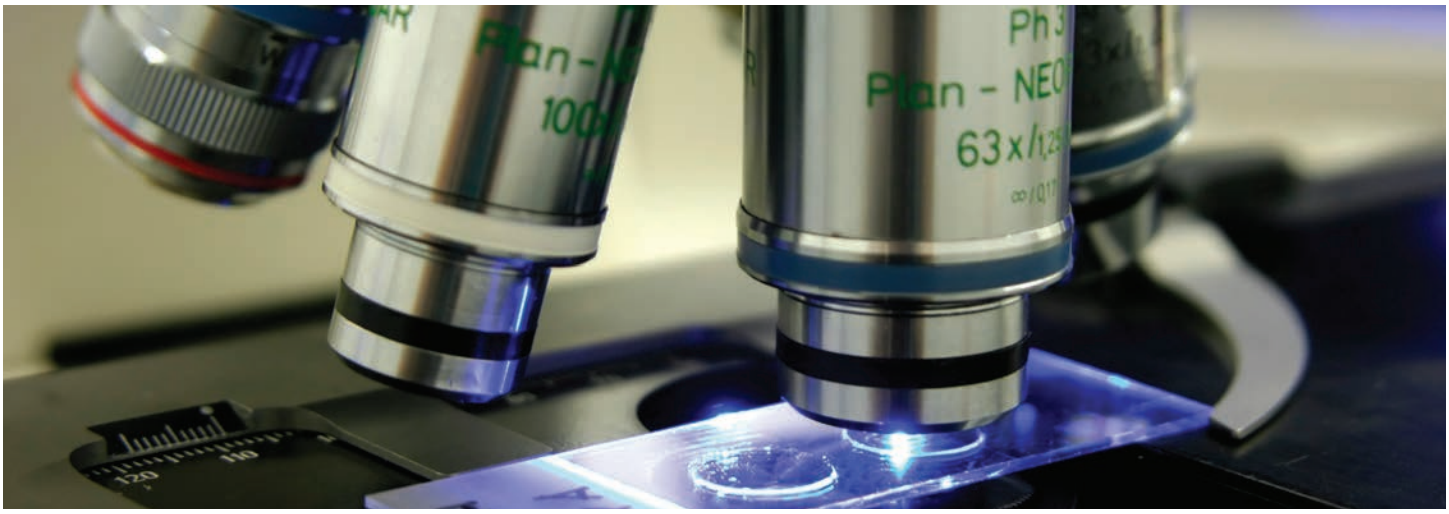
justified only if the return is large enough. As mentioned above, in the 14.5 years Lipitor enjoyed patent protection, it generated some $125 billion in sales for Pfizer resulting in an estimated $80 billion in pre-tax operating profit. This is what researchers in the industry dream about every night. Although this is the extreme example, many other drugs have had success returning 40X to 50X the cost of development.

This blockbuster model did not work perfectly for all medical needs of society. What happens when the patient population or sales potential of a particular therapeutic need is small and so cannot justify the cost and risk of creating a treatment? Rational economic thought says these are not viable options for development. In the U.S., this industry-wide business model was abridged in the 1980s with passage of the Orphan Drug Act where pharmaceutical companies were given liberal tax incentives and market exclusivity for focusing on rare diseases with target populations of less than 200,000—a market segment size that held too high a risk for the traditional blockbuster model. But market exclusivity led to firms attaining monopoly status resulting in astronomically high costs for orphan drugs. The potential return had to be increased artificially to incentivize the development of these orphan drugs.

Targeted therapeutics are causing this inflection point today. Breakthroughs in genome mapping now allow drugs to be targeted at the molecular level. For instance, in the past chemotherapy treatments for a cancer type were nonspecific thus applicable to a large target group (i.e. market segment). But, by now focusing at the molecular level, these treatments can be much more specific. This holds great promise for patients since it is more effective with fewer side effects. But, how will these be developed given the now much smaller target market segment? Can economic logic justify current levels of R&D expenditures for smaller markets? The level of risk remains high, although some feel it is lower than for the blockbuster model. Still others suggest the government might need to step in and have a hand in this new era of drug discovery, as it did in the 1980s with orphan drugs.

With health care costs now about 17% of GDP for the U.S. this will be a challenge. Payers such as insurance companies and governments cannot afford prices akin to orphan drugs. Wall Street is now waiting. Pharmaceuticals were downgraded as a portfolio option a number of years ago due to the three factors discussed above, and there has been little upward movement since then. Pharmaceutical firms will have to chart a new course to once again be the foundation of investment strategies.

Professor William Lawler's teaching and research focus on two areas: financial footprints of business unit strategy and the impact of new technologies on cost systems design.



SIX MODELS FOR STRATEGIC SUCCESS IN MEDTECH

By developing insights from pharmaceuticals, tomorrow's winners in medical technology will adopt six strategic building blocks *by James Gilbert*

The pillars that supported the historic pharmaceutical industry business model of "global/fully integrated/blockbuster/primary care-focused/small molecule products" have been disrupted in the last decade. The result is that the new leading companies are those that have adopted a variety of alternative business models, by which they have been the beneficiaries of differentiated shareholder value expansion. For example, leaders in specialty drug franchises, generic commercialization, large-molecule (biotech) discovery and development, functional process outsourcing, and PBMs all have outperformed the traditional Big Pharma business model.

During the next decade, the traditional medical technology business model—characterized by customer value proposition, key business processes and capability, and profit model—is likely to experience the same type of adjustment as has occurred in pharmaceuticals. This change could lead to current market leaders (absent leading the next-generation of winning business models) getting displaced by companies that lead the creation of new business models that are consistent with future market requirements for differentiated customer value provision.

There will likely be six key strategic process and capability building blocks, with alternative approaches in each, that future winning customer value propositions and profit realization models will build around. (See Exhibit 1.) I describe each one below.

1. Innovation Model. For existing, clinically proven franchises, the focus of R&D will need to shift to a focus on creating good enough global value product platforms versus iterative premium product cadence. Instead of the historic focus of adding potential clinical benefit irrespective of the cost, good enough products are designed to meet the core clinical needs of the majority of the target users as economically as possible, factoring in all the health care system costs of providing the procedure. A number of companies, such as GE Healthcare (part of General Electric Co.) in ultrasound and X-ray, have started to leverage R&D programs focused on China, India, and other emerging markets as a basis for creating first local, and then global, good enough products. Also, investments in comparative effectiveness studies may be needed in certain franchises to support penetration, and offer the potential for differentiated claims to support share gain in others.

For the therapy and diagnostic areas where medical technology holds significant new potential, R&D and business development investments to lead the creation of major new medical technology therapies with the potential to demonstrate cost-effectiveness at high price points to important patient groups will cost more, take longer, and be higher risk. This will put pressure on ROI expectations and make leveraging existing global commercial, development, and operating capabilities more critical. Success will require a commitment to exploring a range of technology options working both internally and with VC-funded startups, investing in the comparative effectiveness data and in developing the space, all of which will require multiple years of patience. Although Edwards Lifesciences Corp.'s stock price is currently getting rewarded for its position in percutaneous heart valves, this is hardly an overnight success; one cannot overlook the years of investment in building this innovative evolution of the valve market that has taken the company to this point, or the large uncertainty as to how the development of the U.S. market might yet play out.

2. Commercial Model. As the role of the physician changes in the product development and adoption process, the commercial model will likely need to change to scale the intensity of the physician contact to what is permitted and appropriate, based on where the product is in its physician adoption life cycle. Analogous to the transition that is being experienced by the pharmaceutical industry, there will be pressure and ROI justification to expand sales forces to the point at which it becomes clear to everyone that the current model is broken.

Globally, payers and providers will become increasingly important in the product utilization decision-making processes. This will require the creation of value propositions as well as selling capability to cost-effectively address the needs of both of these groups. The traditional medical technology pricing model that has taken advantage of physician price insensitivity and that has been based on pricing for each customer and in each market based on what is the maximum price that can be realized, will be replaced by a structure with increased payer and provider decision-making roles and global price transparency, requiring the development and disciplined implementation of worldwide price strategies and account level pricing decision rules.

With the U.S. becoming increasingly less central to the profit economics of medical technology companies due to profit margin and growth constraints in the U.S. and the increased growth of markets in China, India, and other developing countries, commercial resource investment will need to be optimized globally with the model and investment level tailored to each market's decision processes and profit potential. To support changing decision-maker roles and criteria, globalization and margin pressures, alternative channels versus direct sales representative contact will become increasingly important, including e-channels, along with vendor neutral comparative effectiveness and physician education organizations. While many companies are experimenting and piloting a number of these new business model approaches, so far the experiments and pilots are additive to historic commercial approaches, as opposed to being used to displace current commercial infrastructure.

3. Building New Capabilities. The changing regulatory mandates and associated required changes to companies' business models will necessitate they build a broad range of new capabilities, including alternative commercial channels, comparative effectiveness data, and provider sunshine compliance. To avoid having a company's profits eaten up by the building of these new capabilities, it will be critical to group the new capabilities into those that are price-of-admission capabilities, where low-cost capability adoption is critical, versus those that will be the basis for building competitive advantage, where investing to create the appropriately differentiated capability will be high payoff. Building these required new capabilities will require conscious investment, optimization of make-versus-buy decisions, and the development and evolution of the internal team, as well as recruitment of new skills from outside to manage these efforts.

As the global health care systems shift from payment for procedures and interventions to payment for managing patients' conditions or disease states, there will be increased opportunities shift from product selling and servicing for a procedure to getting paid for providing the products and services that facilitate more cost-effective total patient management. Historically, the services provided by medical technology companies have largely been included in the product price paid by the hospital at implant, even when (as is the case in the cardiac rhythm management business), the service is provided for the patient product utilization life for free to physicians, despite distinct reimbursement to the physicians for monitoring the patients. Delivering and making money off of playing an expanded role in patient care management will require a number of new capabilities to support this very different business model, but might become critical to profitability as the procedure product model gets increasingly commoditized.

4. Significant Reduction in the Cost Structure. It is likely that only a few companies in this changing environment can maintain high growth rates and margins based upon an innovation-focused strategy that delivers differentiated products that require high levels of physician engagement and field support. For the majority of the companies and product franchises, globally rationalized pricing, along with the cost pressures from building the required new regulatory and strategic capabilities, will necessitate 30%+ cost reductions (about 10% of sales) in the majority of traditional functional activity areas to offset the likely 5% or more of sales gross profit compression and around 5% of sales of added investment in capability.

While cost has become an increased area of focus (especially during the global financial crisis), to date it has targeted 10% to 15% improvements versus the likely required 30%+ targets. Despite being painful and requiring superb execution, there are a broad range of demonstrated tools and actions that can be used to realize 30%+ cost reductions, including low value added activity elimination, process redesign and IT/e-enablement, and outsourcing/offshoring/shared service center creation. To achieve the sort of cost reduction that will be required, the corporate center needs to rethink its model and structure to be consistent with the strategy and business model approach taken. As an analog, in pharmaceuticals, the corporate offices and practices of a generic company are very different from those of a similarly sized innovation-focused company.

5. Global with Emerging Market (versus U.S.) Focus. The majority of global medical technology companies are based in the U.S. with U.S. citizens making up the large majority of the senior management teams, driven by the U.S. historically accounting for more than 50% of their global sales and profitability, despite comprising only around 5% of the world's population and health care needs. With non-U.S. markets, especially emerging markets such as China and India, increasingly responsible for the majority of future market growth, shifting the whole organization from a U.S.-centric to a global mindset will become foundational. This will require distributing globally at least some key business and functional activity, along with having the development path for key future leaders include significant non-U.S.-based assignments.

Historically, the requirements of the U.S. market have set the standard for the design and development of products, functions, and processes. Although the U.S. will continue to be the most important market for the next decade plus, increasingly, emerging and other non-U.S. markets should both set the base level requirements and become a base for operational activities, such as manufacturing, shared services, and R&D.

6. Business Consolidation and Leadership. The historic profitability of medical technology has allowed the number four, five, and six players in markets to earn sufficient returns to stay in and reinvest in the business. This has been particularly true in orthopedics, vascular, and a range of other markets. The majority of businesses in the world at large tend to have at most three competitors that earn sufficient returns to create shareholder returns for required reinvestment levels. As the future of medical technology plays out, picking a basis of focus for competition and leadership will become more important. Each medical technology company should evaluate its business/regional/functional portfolio and decide which areas it wants to focus on to sustain and become a leader versus which areas it should evaluate selling or harvesting to free up capital to invest in the selected areas of focus.

Getting Started by Selecting a Strategy

Many medical technology companies may be tempted to believe that they can build on their historic success by experimenting with and adopting only incrementally many of the elements of the building blocks discussed here. Such an approach could open the market to disruptive entry from nonconventional, likely non-U.S.-based competitors. Traditionally, the physician-driven premium price adoption of the U.S. market created sufficient scale and profitability to allow competitors to manage the rest of the world, based upon marginal economics.

Sale of global premium products at the price levels they have been sold at in Germany and other low-priced markets historically has been supported by the price level and scale of the U.S. covering all the fixed investment costs and a lack of global price transparency and migration. To the degree that the growth of emerging markets, constraints in the U.S., and the migration of low price points such as those that typically exist in reimbursement-constrained countries such as Germany create low-cost good enough global competitors (analogous to generic competitors in pharmaceuticals), a strategy of incremental business model changes will unlikely be sufficient for a device company to remain profitably competitive in many product areas. Like many industries before it, the medical technology industry will likely move from one primary winning business model with multiple companies all being successful, to multiple winning models where picking one and being a top player is critical to creating shareholder value. Historic success and strength of current strategic assets will not be a guarantee of future success.

To get out front and build profitable market leadership in this changing medical technology world, companies should:

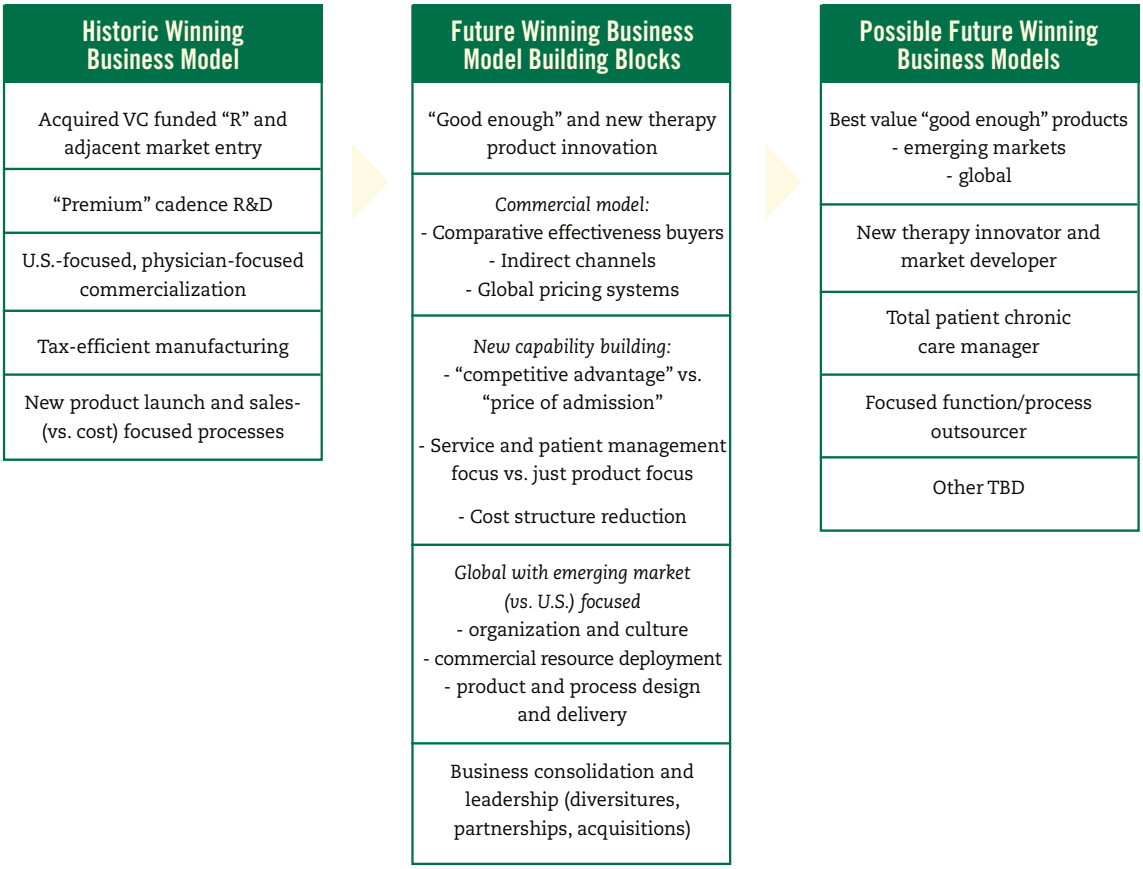
1. Develop an objective, fact-based view of their business situation today and how it might evolve, given a forecast of future market dynamics (not the reality they wish, but the one that is and likely will be).

2. Focus on creating a long-term strategic view and plan on how to win given future market requirements of winning versus just optimizing for the next few quarters. The updated strategy and associated business model should include an aligned view of the target customer and value proposition, supporting key business processes and capabilities, and profit realization model.

3. Take an agile and flexible approach that leverages pilot programs and experimentation to support continuous transformation consistent with the strategic vision and plan. Pilots and experiments may need to be separated from existing businesses to support the level of change required.

The medical technology arena is one of the few industries where U.S. dominance has increased during the last few decades, but given the current and future dynamics and the need to shift business models, U.S. dominance will be challenged. Since the U.S. and other developed countries will maintain their interest in being the global hub of a healthy medical technology industry, in addition to each company working to create its own winning approach, the industry as a whole—and on a global scale—should be working with industry associations to create a common voice to advocate for more supportive government-driven regulation and industrial policies (or at least to head off misconceived new regulations and policies). By adapting business models to a changing environment, device companies and the industry itself will increase the likelihood of successfully evolving to meet these new challenges and maintain their competitive profile.

Exhibit 1 / THE EVOLUTION OF MEDICAL TECHNOLOGY BUSINESS MODELS



The author is an adjunct lecturer in the Management Division at Babson College and was an executive vice president at Boston Scientific Corp. This article is adapted from Gilbert, J. "Creating a Winning Medtech Business Model for a Post-Reform World." In Vivo, 28 (7) (2010): 46-51.

Moving the Spotlight from Innovation to Problem Solving in Pharmaceutical Companies

An industry facing uncertainty and change must adopt new decision-making frames *by Gaurab Bhardwaj*

How Mental Frames Affect Decisions

We simplify the complexities of our world with mental frames. They determine what aspects of the world we see. Frames bring some things to the forefront of our attention and push others in the background to be given less attention or none at all. Frames affect what we think about, the choices we make, the resources we allocate. Frames include beliefs, assumptions, concepts, predispositions, what is taken for granted, and views about what drives success. Often, we are not conscious of the frames we use in our thinking, and how powerfully they may be driving our choices. Because they can lead to both good decisions and bad ones, it is important to be aware of the frames we use and judge whether they are best suited for the circumstances facing us. If not, then we should consider new frames.

In every industry, some frames come to dominate conversations, thinking, and work. They emerge largely from successes. Media coverage and interactions among industry professionals disseminate and reinforce them. While no frame can unerringly lead to good decisions, the ones that gain dominance are seen as driving success. Among pharmaceutical companies, the dominant and long-held frames include innovation, unmet medical needs, first-in-class drugs, and blockbusters. In recent years, emerging markets has been added to the list.

The question is whether these dominant frames are still the most suited as the world of pharmaceutical companies continues to change in fundamental ways. The example of U.S. automakers in the years following the oil shock of the 1970s and market entry by Japanese automakers underlines how old frames can lead to competitively damaging decisions. The continuing struggles of Sony in consumer electronics and music and the many extinct computer firms further illustrate the value of adopting new frames when industries transform. New frames can illuminate the changing world in new ways and facilitate better decisions. But they also can be wrong, as the dot-com era of the 1990s amply demonstrates. Adopting new frames to replace or complement old ones needs careful thought.

The World of Pharmaceuticals Is Changing. Should Its Frames?

In the last few years, the world of pharmaceuticals has been changing in ways that appear fundamental rather than transient. Most are, by now, widely acknowledged. Price pressures and rising health care costs already were evident before the global recession made the situation worse. As governments in high-income countries find their budgets stretched, so do those in emerging economies in their attempts to provide health care to millions more citizens. Globally, governments and individuals who pay out of pocket remain the leading payers. Price pressures are likely to continue. The greater emphasis by pharmaceutical companies on emerging economies is a long-term bet. Although growing rapidly, in the near term these are relatively smaller markets with modest margins. They have large patient populations, but a great majority cannot afford to pay for medicines they need. Emerging markets also are the source of new competitors with global ambitions. The patent cliff arrived but R&D pipelines were not adequate to replenish the steep drops in revenues. Mergers and acquisitions helped revenues but brought with them other costs. Still the question remains of how to get R&D productivity to desired levels medically and financially.

During the next few years, demand for medicines will rise globally due to aging populations, obesity-related illnesses, and rising life expectancy and incomes in emerging economies. How this increasing demand will affect the economics of the business is uncertain. Scientifically, the industry is moving toward personalized medicine. It will make treatment more effective but will shrink the patient population relative to the one-size-fits-all approach of the conventional blockbuster model. Costs for discovering, developing, and marketing personalized medicines may not decline, but it may be difficult to charge substantially higher prices to offset the smaller markets. While the blockbuster model is frequently criticized, there is little agreement on what might replace it effectively.

These are some of the factors reshaping the landscape. Jointly, they present many scenarios but there isn't room here to enumerate them. However, they do raise the question of whether the long-used decisionframes in the industry are right for this new, uncertain reality. The need for changing frames is reflected in Eli Lilly's lucid call to reinvent invention. The search for new frames is under way.

Dominant Frames in Pharmaceuticals

The most influential frame in pharmaceuticals is innovation, which is appropriate as new or better medicines have to be discovered using long-term, high-risk R&D. But, innovation is viewed and practiced in varied ways across different industries. From looking at industry conversations, media reporting, and what is celebrated, one can surmise how innovation is primarily viewed and practiced in pharmaceuticals rather than how it should be or occasionally is.

Innovation in pharmaceutical companies is generally equated with novelty and pioneering discoveries. Hence, the prestige accorded to targeting unmet medical needs and creating first-in-class medicines.

Just about every pharmaceutical and biotechnology company says that it targets unmet medical need. What does this framing of innovation actually mean? With this statement, the companies are announcing that they approach research in novel ways, and work in new scientific territories. This is believed to make it more likely that they will discover novel medicines that can be patented and sold at a price premium. It is mainly a signal to scientists and investors about uniqueness and being at the cutting edge of research.
A contrasting frame, one that I have not seen used, is unmet patient needs. The two frames highlight different factors. Unmet patient needs has little to do with the research undertaken in labs but has everything to do with the patient's experiences—medical, economic, others. With many orphan and neglected diseases needing treatments, very different emerging market settings, and moves toward personalized medicine, unmet patient needs is a useful frame to adopt.

First-in-class drugs are accorded prestige in innovation that is far above that conferred on the remaining drugs, often called me-too or, more kindly, follow-on drugs. The labels that frame these types of medicines say it all. Such labels make sense from a scientist's perspective because being first in making discoveries and advancing knowledge brings status and prestige. Scientists want to be seen at the cutting edge. From a patient's perspective, the picture is different. First-in-class drugs provide treatments where none existed or they may be big improvements over existing remedies. But, that does not mean that me-too drugs necessarily provide only incremental benefits to patients. The best-selling drug in the history of medicine is Lipitor. It was the fifth statin to be launched and was almost not developed for being a me-too drug[1]. Similarly, Zantac was launched a few years after the first-in-class Tagamet and quickly became the best-selling drug of its time. The overwhelming majority of drugs approved by the FDA are me-too or follow-on drugs. Many succeed well in the market because they effectively address **unmet patient needs**. Scientific primacy is not always congruent with treatment effectiveness, market performance, and investor returns. Patients celebrate medicines that make them better, whatever be their launch order and scientific status.

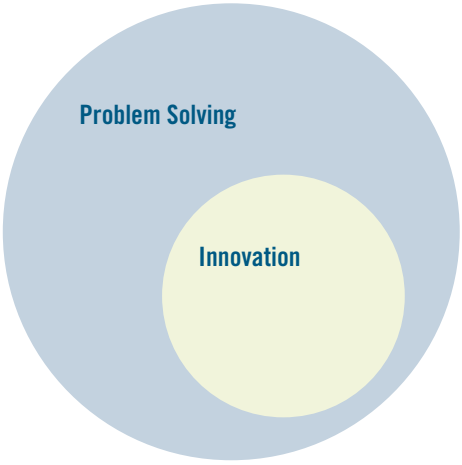
Since no medicine is perfect, patients hope for better ones to come along, whether they are follow-ons or first in new classes. Decision making would benefit by according more status to follow-on drugs. And, personalized medicine would require looking not just at classes of chemistry but also patient segments based on genomics. For an era of repurposed medicines, combination therapies, growing ability to identify which medicines work best for which patent sub-populations, biosimilars on the horizon, and promise of emerging markets, we need different frames to influence our thinking and decisions.

The conventional dominant frames create blind spots in a complex, changing, uncertain, ambiguous world. There are so many unsolved problems in the life sciences and health care ecosystem that we need more frames so we can see more, take the perspective of different ecosystem players, and expand the objects of innovation from products to services, processes, systems, practices, business models, behaviors, and mindsets. I propose adopting a problem solving frame for more effective decision making. It does not replace

innovation, but encompasses it (see figure). It enables viewing innovation as problem solving. And, it broadens the scope of thinking.

The Problem-Solving Frame

A problem can be conceptualized by three elements from the perspective of an individual (e.g., a patient, payer, physician, scientist, sales and marketing personnel): current state, desired state, and the path separating the two. Solving a problem requires a thorough understanding of the two states and the specifics of what is required in going from the current to the desired.



The problem-solving frame is about identifying the right problem to solve. It brings to the forefront of our attention the following fundamental questions:

1. **Whose problem should I (or my organization) be solving?** Consider the range of people and organizations that are part of the life sciences and health care ecosystem. Also, consider people, functions, and business units within your organization.

2. **What problem should I (or my organization) be solving?**

3. **Does the intended beneficiary want this problem solved?** Will they (or someone else) pay us to solve this problem? In other words, can this problem be solved profitably?

The problem-solving frame (PSF) and the innovation frame (IF) differ in what they emphasize.

1. PSF can be applied by anyone in the organization. IF is generally used by those formally engaged in innovation (e.g., scientists doing drug discovery).

2. PSF can be applied to a wider range of situations than IF. Moreover, if innovation is seen from a problem-solving perspective, it expands the focus from medicines to services, processes, systems, activities, practices, business models, mindset, and behavior.

3. PSF spotlights the problem, IF spotlights the solution.

4. People often fall in the plunging-in decision-making trap—they start gathering data, analyzing, and developing solutions without carefully determining whether they are solving the right problem and solving it in the right way. PSF reduces the chances of falling in the plunging-in trap. IF does not specifically deal with it.

5. PSF's success metrics are whether the right problem has been solved, and how well it has been solved. IF's success metric is the novelty or innovativeness of the solution.

Conclusion

Changing times call for new frames to think about the world differently. Moving the spotlight from innovation to problem solving will better assist pharmaceutical companies profit and grow as the life sciences and health care ecosystem continues to transform.

Gaurab Bhardwaj is an associate professor and holder of the Louis J. Lavigne Jr. Family Endowed Term Chair in Strategy and Planning at Babson. His research, teaching, speaking, and facilitating expertise are in strategy, innovation, corporate entrepreneurship, and decision making in biotechnology, pharmaceuticals, and other life sciences and health-related businesses.

[1] *John L. LaMattina, Drug Truths: Dispelling the Myths About Pharma R&D (Hoboken: Wiley).*

SECTION 2: GETTING THE MOST FROM YOUR TALENT IN LIFE SCIENCES AND HEALTH CARE

IDENTIFYING AND INFLUENCING KEY STAKEHOLDERS

Identifying and managing critical stakeholders—beyond physician and payer—will lead to better decision outcomes; not doing so can be deleterious *by Allan R. Cohen*

A key issue for life science and health care companies is identifying and managing the multiple stakeholders who can affect business outcomes. These stakeholders can include internal managers and scientists, regulators, university scientists, sources of financing, Wall Street and financial analysts, legal experts, patient and other advocacy groups, scientific experts in particular fields, the Food and Drug Administration (FDA), and so on. Each stakeholder or stakeholder group has its own vision, set of objectives, concerns, and hot buttons. Even when identified, it can be difficult to appropriately influence them. And, failing to identify critical stakeholders can lead to extremely negative consequences and large financial losses.

Let me cite an actual example—disguised but accurate—that set a new biotechnology company back several years and millions of dollars.

HemoSeptrix was created in 2001 to use the mapping of the human genome to develop a cure for a deadly blood disease that had no good treatment option. As with all such companies, everything was pointed toward eventually getting FDA approval for the drug. The entire process, from early stages of discovery to clinical trials to market launch, can take up to 12 to 15 years.

The company had been founded by Dr. Desmond Baker, a brilliant but extraordinarily difficult and irascible researcher in hematology, and Dr. Walter Beckman, a former professor and prominent venture capitalist. Baker's discoveries at Case Western University showed promise of being able to stop the course of sepsis in postsurgical patients, and, if it worked and was approved by the FDA, would become a blockbuster product surpassing $1 billion per year in sales.

Through some of the early difficulties, Baker had become even more difficult, and publicly attacked a young researcher who dared to question some of his research findings. As a result, he was thrown out of his own company.

After overcoming many challenges, HemoSeptrix made it through Phase 3 trials after four more years, with good but not great or unambiguous results. The 10,000-page application went to the preliminary advisory committee of the FDA, which wrestled with it (at least in part because of the controversies about the data analysis), but finally sent it to the FDA with a positive recommendation. This kind of recommendation results is typically followed by FDA approval.

Nevertheless, two key opinion leaders (KOLs), who had been infuriated by the behavior of Baker, mounted a campaign against approval even though Baker was long gone. The two were known to the company, but ignored because of the excitement of the advisory committee recommendation. As a result, the decision was delayed for two years, calling for more studies that cost many millions of dollars.

In retrospect, company insiders acknowledged that they could have done a great deal to mitigate the reactions of the KOLs. They might have talked with them about the reasons for Baker's dismissal, provided them access to the data, listened hard to their objections and shown willingness to address them, and so on. None of this would have been inappropriate, and the skills required were well within the capacities of the executive team if they had been paying attention.

As this case suggests, the ability to influence powerful stakeholders is critical. Like all influence, it involves a form of exchange and reciprocity, in which the targets gain some of what they care about in return for what is desired. This kind of "currency" exchange happens at all levels, but it is difficult when the influence target is very powerful. When there are large power discrepancies, the powerful usually care about things that are

quite different from those who are less powerful. They may have longer-term concerns, think more broadly, underestimate the potential and value of lower power players—or as in the HemoSeptrix case, have personal concerns about the influencer(s) that might even override the specific science involved, or color it.

Ironically, most powerful stakeholders display very visible evidence of what they care about, through speeches, blogs, printed materials, conferences, and so on. But if the party desiring influence doesn't even identify the stakeholders, or knows what they care about but disagrees with that particular set of concerns, potential influence may be reduced or completely lost.

It isn't always simple to manage a complex set of stakeholders, but sophisticated organizations figure out how to do it. For example, John Maraganore, CEO of Alnylam, talks about managing 10 large pharmaceutical partners, each of which may have different concerns and styles. Two of those partners are Novartis and Roche. With Roche, the partnership was struck with the CEO, Franz Humer. With Novartis, most of the negotiations were done with Mark Fishman, the head of science. Their different backgrounds, ages, and nationalities—older Swiss businessman and younger American academic scientist—require different approaches. Alnylam takes partnerships with major stakeholders so seriously that it has "an internal head of alliance who is part of our management team; she attends weekly meetings, reports what's going on, issues, gaps" with all of their partnerships. "We give each of our employees the responsibility to do whatever they need to do to nurture a specific relationship—dinners, breakfasts, lunches, whatever—since we are the junior party and they are the senior party. Over time, our counterparts begin to see us as peers; we develop relationships based on mutual scientific, business, and human interests."

Learning to diagnose the interests and currencies of myriad stakeholders, the style of interactions they prefer, and find legitimate ways to respond and to sustain relationships as peer-like partners, will be an ever-increasing component of organizational success.

Professor Cohen is the Edward A. Madden Professor of Global Leadership at Babson College.

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LEVERAGING THE TALENT OF WOMEN IN LIFE SCIENCES AND HEALTH CARE

A look at what companies can do to reduce bias and maximize talent *by Nan S. Langowitz*

Women in technology fields historically have been underrepresented, and this is no less so for women in the life sciences, health care, and biotech industries. But, would it surprise you to know that women are catching up quickly?

In 2008–09, women earned nearly 40% of the biomedical and medical engineering degrees in the United States, according to the National Center for Education Statistics[1]. Not quite half, but certainly much improved from bygone days. Similarly, the percentage of women attending medical school is now nearly equal to that of men. It can no longer be argued that women lack the technical and scientific expertise required to be active players in the health care and life sciences arenas. But, how do they fare in the workplace? Matching the pattern in many industries, we find that women comprise roughly half of the employee base but are visible in far lower numbers in managerial roles. According to the 2007 Healthcare Businesswomen's Association *E.D.G.E. in Leadership* study conducted by Booz Allen Hamilton, 34% of midlevel life sciences company managers and just 17% of senior executives are women[2]. This study recommended that companies need to do more to attract and retain talented women, including taking a merit-based approach to career advancement and compensation as well as using metrics to track progress on talent retention of women.

What might companies do differently? Surely merit is always the core of how companies evaluate and promote individuals. According to a 2011 report on women entrepreneurs by the Kauffman Foundation, the impact factor of published scientific research is identical among female and male scientists. In other words, the science they do is equally valued. Similarly, patent productivity in the life sciences industry is nearly identical among men and women. Yet, analysis of patent productivity by Professor Kjersten Whittington at Reed College points to the possibility that a "fatherhood premium" is active in providing contacts and opportunities to male researchers as compared with their female counterparts[3]. Men appear to have more commercialization and career advancement opportunities as a result of an implicit positive frame that associates fatherhood with stability, drive, and reliability.

On the opposite side of that bias, women seem to experience a motherhood penalty that frames their parenting as a tug away from their potential focus on career, and seems to result in a protective or distrustful instinct against offering them new opportunities or challenges at work. We know that in many life sciences companies there are dual career tracks, on the science side and the managerial side. Even if women are experiencing a subtle bias on the science side, there should still be opportunity on the managerial side. Yet, the statistics noted above paint a different picture. Wouldn't all of these organizations say they were using a merit-based metric?

Undoubtedly, yes. So what's going on? As has been found in numerous other contexts, it seems that merit may be in the eyes of the beholder. That is, inherent and subtle cultural cues and implicit bias in organizations may influence the advancement of talented women (and perhaps others who inherently differ from the norm).

What can organizations do to erode the potential for implicit bias?

- **First, they should look to organizational mechanisms.** Review any mechanisms your organization uses to allocate resources, e.g., lab space, opportunities for travel to conferences, access to developmental training, to be sure that there are no hidden criteria for allocation. For example, some HR systems have a check box in performance dashboards in which managers note an employee's willingness to travel. Are you sure all of your managers are actually asking employees about this? Perhaps they are simply assuming who is available for travel. A manager's good intent of wanting to protect an employee with young children from traveling may actually be harming the employee's opportunity to develop, and eroding the company's investment and long-run return from the employee. (As Professor Whittington's research shows, this tends to harm working mothers more than working fathers, but it is an issue to be considered either way.) Or, consider how task force team assignments are done. Do managers sit together over coffee and think about "who would be good for this product development assignment?" Do they tend to choose the usual suspects, and are all of those chosen typically male? Such a system can create a self-fulfilling cycle, the male employees get the opportunities and the experience, thus they have the chance to perform well, and they get the chance to be chosen as good for the assignment based on that past product development experience.

- **Second, they can monitor advancement.** Evaluate the level of data your organization tracks on the advancement of women in the organization. Do you know where your women employees are and what they contribute? Are there any discrepancies in their patterns of advancement compared with their male counterparts? As with so many other issues, it's hard to make progress without knowing where you stand and measuring how things may be changing. A baseline to use might be to see where your company stands in comparison to the Healthcare Businesswomen's Association benchmark noted above. Leading companies also have found that making an explicit connection between the advancement of women and senior executive evaluation and compensation is a must to giving the policy teeth. It signals to senior executives as well as to the rest of the organization that leveraging the talent of women is a priority for all.

- **Third, they can use networking and mentoring.** Consider the level of support available to aspiring women employees in your organization. Are there visible women senior leaders to serve as role models? Is there a network through which women can exchange information, tips, and opportunities? Are mentors readily available and accessible to women employees? Companies with strong track records for women's leadership and advancement support their women employees with affinity groups, mentoring opportunities, and professional connection.

One example of a company that already has put many of these suggestions into place is Abbott, the only health care and life sciences company named a Top 10 company on the National Association of Female Executives list in 2011. The company has particularly focused on moving women into roles with profit and loss responsibility. Abbott is tracking the number of women in senior-level roles both overall and on a country-by-country basis, and has used its women's affinity group to support and develop professional skills to develop and advance women leaders. Twenty-seven percent of Abbott divisions are led by women executives, and 16 percent of its corporate executive leadership team consists of women, meeting or exceeding the HBA study benchmark. Overall, the number of women managers at Abbott has increased by 90 percent during the past five years. In addition, Abbott's affinity group for women partners with the companywide mentoring program to ensure that women employees interested in mentoring are connected not only within their local context but also globally.

Not all life sciences or health care companies are large multinationals, however, and anecdotal data suggests that women scientists and managers more readily advance in small- and medium-sized firms. One explanation is that in smaller firms, with limited resources and bureaucracy, demand for good ideas,

energy, and valuable contribution trumps social bias or politics. Growing companies should be aware of the potential for organizational process and culture to develop that might erode their ability to leverage the talent of women. When companies are in high-growth mode, leaders have a tendency to focus on product delivery, financing, and simply making the trains run, and can easily forget to focus on building an organization that values diversity of talent. Once size overtakes intent, it's easy to lose the transparency and connection that were built in when the firm was small.

For growing firms, it's essential to consider how you will build your team and organization in order to best tap diverse talent and leadership. Again, looking to organizational mechanisms, holding individuals accountable, and finding ways to create communication and connection are key levers for success.

The author is professor of management at Babson College and served as the founding director of Babson's Center for Women's Entrepreneurial Leadership.

[1] *National Center for Education Statistics Homepage, last modified on September 17, 2012, http://nces.ed.gov/.*

[2] *"HBA E.D.G.E. in Leadership Study," Healthcare Businesswomen's Association, accessed September 17, 2012, https://www.hbanet.org/hba-edge-in-leadership-study .*

[3] *Kjersten Bunker Whittington, "Mothers of Invention? Gender, Motherhood, and New Dimensions of Productivity in the Science Profession," Work and Occupations 38(3) 417–456, accessed September 17, 2012, doi: 10.1177/0730888411414529 .*

SECTION 3: VIEWS ON HEALTH CARE COSTS

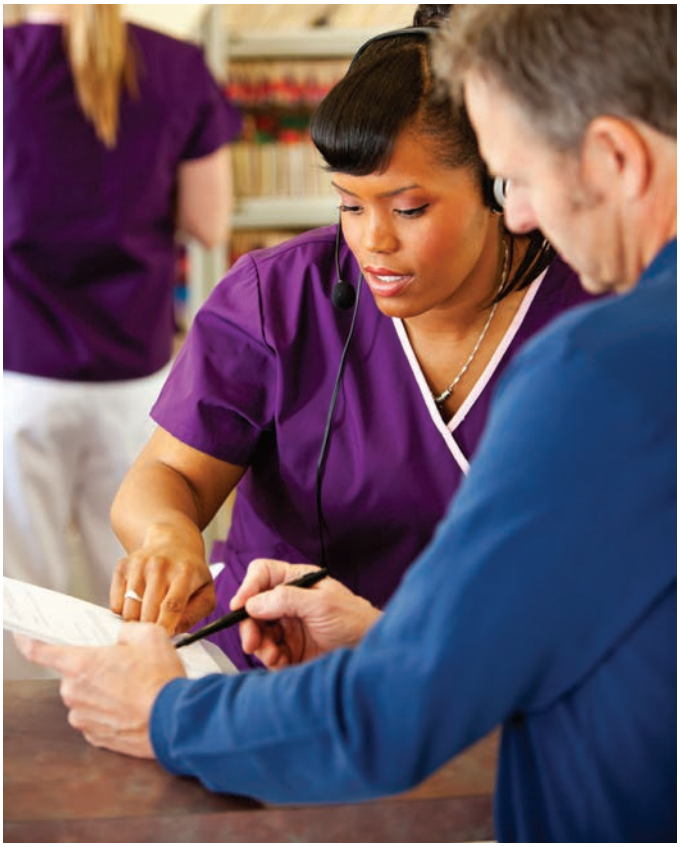
MANAGING COSTS IN HEALTH CARE: WHY IS IT SO HARD?

Some reasons why attempts to control rising health care costs have had limited success or have failed *by Mike Bell*

For many years now, rising health care costs have been one of the loudest cries from both the business and government. In many cases, the only issue addressed is the cost of health care. For those who do not have health insurance or access to health care getting taken care of is their justifiable concern. For those involved in the provision of health care, bureaucracy, and unreasonable intrusion on their time and judgment is often a target of hostility.

This is all the more interesting as many very well intentioned and intelligent people have made enormous efforts to correct some or all of these problems. (There also have been some not so well-intentioned but we can address those later.) Initiatives by various medical, insurance, business, and government groups have been met with limited success and sometimes outright failure, with the associated vitriol that so often accompanies failure.

In this article, I will try to explain the causes of the failures, and the risks of not making significant changes to the entire system. The word "entire" is dangerous, as it brings back bad memories of "Hillarycare" from President Clinton's first term. I make no pretense to have one all-encompassing solution as that actually may border on the impossible. What makes everything so hard, and why so many failures have occurred, is the lack of explicit recognition of the multiple agendas and how they are often diametrically opposed. In order for any real progress to be made in the areas of cost, access, and quality of care, everyone is either going to have to compromise or be forced to give something up. That is not to say that the U.S. cannot have the highest quality, most efficient health care system in the world. To the contrary, I believe that we have to lead the world in health care. No one else has the abilities, talents, or creative skill that we have here. But, we do need to do a few major things: Encourage and fund entrepreneurial ventures that fix some of the problems that exist, and find a few politicians who have both the courage and leadership skills to do the obvious, but unpopular things that need to be done.



So to start with, let's lay out a few facts to indicate just how disingenuous many of these warring factions have been. First, health care represents about 17 percent of GDP now with no good reason to believe that number is going to significantly change or stop climbing and start dropping[1]. The projections on the new health plans only make sense if you think you can predict the weather in 50 or 75 years. That is beyond my planning horizon and we will have a catastrophe in the system way before then.

Second, approximately 70 percent of the health care system cost in this country is driven by 10 percent of the patients[2]. The statistic is startling for two reasons. It shames the 80/20 golden rule of business by over a factor of 2, no easy feat. The other shocker is that this is not a secret within the health care world. Many people have similar sets of numbers and even know how to make changes that impact the ratio dramatically. They have been stymied at

every turn by an opposing constituency, and the people who lead are more concerned with the politics for a few rather than the answers for the great majority.

Third, approximately 30 percent of the entire health care spend is put toward paper[3]. By that I mean administration, processing, financing, and the systems that in theory control all of them. Anyone who has had a problem with the system turns purple in rage when discussing insurance claims, hospital forms, lack of "how to" information or "where do I go" questions. Can this be changed without unicorns? Of course, but we can't keep doing things the way we have been doing them and expect big changes here. (The definition of lunacy is doing the same thing over and over and expecting a different result.)

Fourth, many smart and sophisticated people seem to labor under the impression that doctors are hatched. That is, they go to medical school, graduate, and the next day are handed scalpel to perform brain surgery with a perfect surgical success rate. Yes, that is ridiculous; they have to be trained practically in a good clinical environment. Guess what? That is not free either. So, we need to find that money without harming patients or crippling the system.

Fifth, the fact that doctors are created, not born, holds true when you talk about medical research. Yes, the government spends a lot of money on it, as do the academic and clinical institutions. Guess what, again. All the money going into basic research does not cover all the costs, and we have to find that money somewhere. A thinking person does not have to spend too long pondering the value of research. Whether it is improving the odds of curing cancer, doing surgery with lasers, finding drugs that cure the problems people could not fix before, everyone implicitly knows the need for and value of basic medical research. We need to pay for it.

Sixth, all patients seem to feel entitled to all the best possible care at all the times when they might need it. That form of entitlement is simply not affordable. The benefit of all of our great science is clear. What is equally clear is that the money for every patient to get everything does not exist and to think it does means people are either irresponsible, or do not understand the basic arithmetic around the problem. Does everyone get a Maserati simply because they exist?

Seventh, the government claims to be our friend and protector in health care. But, it is not. Without getting into mysticism and voodoo, I won't even begin to discuss government numbers at this stage. What I can say, is that while government programs do many things well, arithmetic is not one of them. For all intents and purposes, Medicare is broke now and we can watch it slowly unfold like a bad movie. Medicare was started in 1965 when overall life expectancy was around 70 years old. Is there anything that works the same or costs the same as 40 years ago?

I trust you are getting the point by now. There are at least partial answers to all of our health care problems available today, I mean right now. As noted earlier, the various players all have to give a little bit for the benefit of the whole, or the people who can't afford basic care, or to fill the gaps needed for teaching and research, etc. Perfection is the enemy of the good and what we want here is a good affordable system for all that permits us to do the things we need to do to be the best health care system in the world.

The author is an adjunct lecturer at Babson College. He is a managing partner and founder of Monitor Clipper Partners, a private-equity firm located in Cambridge, with more than $2 billion under management and currently investing out of its third fund.

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CONTROLLING COSTS OF PROVIDING CARE STARTS WITH UNDERSTANDING THOSE COSTS

Managing costs requires measuring them correctly and relating them to outcomes. Health care organizations lag in this capability and can learn from other industries

by Paul Juras

A June 2010 report from The Commonwealth Fund (www.commonwealthfund.org) states that "(d)espite having the most costly health system in the world, the United States consistently underperforms on most dimensions of performance, relative to other countries." That situation continues today, and one can conclude that the high cost of U.S. health care is not due to its superior quality.

So what accounts for this high cost?

The answer is not a simple one. The demographics of the population, the health care reimbursement system, the incentives within the health care system, and the advances in technology and treatments all contribute to costs. According to Kaplan and Porter (2011), however, there also is a source of rising costs that does not attract as much attention, an apparent inability to understand how much it actually costs to treat a patient and then relate those costs to outcomes. This dynamic is similar in several ways to what has occurred in the manufacturing sector.

While some may cringe at the thought of comparing the process of providing care to that of manufacturing a product, there are certainly concepts that can be adapted from the manufacturing sector to help improve the understanding of the process and the cost of providing care. One does not have to look too hard to find examples of this type of adaptation. One of the most notable examples may be the Virginia Mason Production System, which was created by Virginia Mason Medical Center (www.virginiamason.org). It is an adaption of the Toyota Production System which focuses on lean production techniques. If manufacturing production methods can be used to improve the delivery process, perhaps manufacturing costing methods can be adapted by health care providers to improve the understanding of the cost of the delivery process.

I am not suggesting that improved cost measurement has to translate into cost cutting. Rather, I am suggesting poor cost measurement can lead to dysfunctional behavior and lost opportunities on the part of health care providers and administrators. Consider the simple example of when there are two operating-room procedures that are routinely performed within a hospital. Hospital administration wants to attract more patients who need one of the two procedures, but does not have the capacity to increase patient demand for both. Which patient population is administration likely to target? The obvious answer is the population that needs the more profitable procedure. The next question has to be, which procedure is more profitable? If costs are not clearly understood, one procedure might be undercosted and the other overcosted, thereby distorting the profit level of each and possibly leading to an incorrect decision and a missed opportunity.

How does this happen? Think of it like squeezing a balloon. Just as the hospital in the simple example has a certain level of costs, a balloon is filled with a certain amount of air. If you squeeze a balloon the total amount of air does not change, but one part of the balloon gets smaller and another part bulges out. The same is true for costing of procedures. If fewer dollars are assigned to one procedure (the squeeze), then more dollars have to be assigned elsewhere (the bulge).

Sure, each procedure has some unique costs, but many costs of the hospital in this example are fixed, just like the air in the balloon. Think in terms of nursing salaries, the operating room equipment, the beds, machinery, and even support services such as admissions, discharge, and patient transport. The staff, equipment, and facilities are all resources that are acquired and combined in some way to provide patient care and will be there no matter which of the two patient populations is targeted, and all

these resources come at a cost. The assignment of some of these costs to each patient is part of the function of the costing system and if the underlying demand for resources, and their related costs, cannot be understood, any analysis that relies on the cost numbers becomes suspect. There is no question that payer mix, the respective power of the payer and the provider in reimbursement negotiations, are among the factors that would enter into the analysis, but those are factors that impact revenue, and the concern here is with understanding the cost of providing care.

In summary, all resources have a cost, and a clear understanding of how the resources and their related costs are consumed is an important step in controlling costs. Perhaps the health care sector needs to start looking to other sectors of our economy, like manufacturing, that have made advances in understanding their costs in order to better align them and their related resources with the strategic goals of the organization.

The author is a professor of accounting at Babson College.

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APPLYING HEALTH ECONOMICS TO MANAGERIAL DECISION MAKING

Cost reduction and incentive creation *by Yunwei Gai*

The main objective of health economics is to create incentives for individuals (and, thereby, for nations, as a whole) to achieve the highest level of health for each dollar of care purchased. Reaching this goal is trickier than you might expect because it requires adjustments of various inputs in our health care system, and one of the most important adjustments is the resource we allocate to prevention vs. treatment. In general, it is our unwillingness to address and accept compromises that has become a major source of our health care problems of the 21st century.

Look at the numbers. Each person in the United States spends about $7,500 per year in health care, which cumulatively amounts to more than 17 percent of our GDP[1]. This spending is far more than that of any other country in the world, and it might be justified if the United States were the healthiest nation in the world, but it is not. In terms of life expectancy, we rank 50th among other nations[2]. There are many explanations, and high on the list is U.S. inefficiency caused by its low emphasis on prevention and heavy reliance on treatment.

It is difficult to understand why basic principles of management, which are used readily in most other industries, have not been adopted by the health care industry. Most managers realize that goods can be produced using varying combinations of inputs, such as labor and capital. The mixture chosen depends on their relative prices and respective levels of output. Prevention and treatment are two inputs in the production of health, whose proportion in the health production process also should depend on their relative prices and levels of effectiveness, but it is not.

An example may help to clarify the problem. Based on data from Centers for Disease Control and Prevention (CDC), 24/7 Wall Street estimated that in the United States during 2010, the top 10 causes of death accounted for 75 percent of the nearly 2.5 million deaths and cost more than $1.1 trillion to treat them[3]. There are many underlying causes of these deaths such as environment, genetics and lifestyle. Some of these underlying causes can be prevented, thereby reducing the expenditure for treatment. Among preventable causes, you will often find them to be poor diet, physical inactivity, misuse of alcohol, and smoking[4]. The common denominator among them is that they are behavioral (not congenital)—and, therefore, preventable. Think of how much it costs each year to treat ailments such as coronary heart disease, Type 2 diabetes, and hypertension. Then, think of what else could be done with this $150 billion in annual spending if we can find a way to reduce these preventable diseases[5].

While you are thinking of costs (and I hope you are thinking big costs), consider the additional benefits that prevention offers by improving workers' health, well-being, self-image, and productivity. Reputable studies suggest that health-related reductions in productivity can be two to three times larger than the direct costs of treatment. If this is true, then the yearly knock-on benefits of prevention amount to almost $450 billion[6]. Anecdotal stories are plenty. In 1991, Bank of America initiated a health promotion program among its retirees at a cost of $30 per retiree per year. During a 12-month period, retirees in the program lowered

their insurance claims by $164 per person, while those not in the program had an increase of $15 per person in their claims[7]. In 1994, Citibank started a comprehensive health management for its 11,194 employees. Evaluated over 38 months, the program generated savings between $4.56 and $4.73 for every dollar spent on the program[8]. In 2002, Highmark launched a comprehensive health promotion program to its employees. In the course of a four-year period from 2002 to 2005, the program cost $808,403 and led to total savings of $1,335,524 in health care expenses, yielding a return on investment of $1.65 for every dollar spent[9]. A recent study summarizing past employer-provided wellness and prevention programs found that, for every dollar invested during a three-year period, the return on investment ranged from about $1.40 to $4.70[10].

Without effective prevention and lifestyle changes, 42% of Americans seem destined to be obese, and 11% will be severely obese by 2030[11]. Despite the dire consequences, both in terms of financial burden and decreased quality of life, only 2 to 3 percent of health care spending is used for prevention, which is a miniscule amount compared to spending on treatments for condition that could have been prevented[12].

You might be asking yourself, if we know that the problem's cause is an incorrect resource allocation on prevention and treatment, then why can't we come up with incentives to correct the distortion? One of the main reasons is that health care is a complicated system, composed of many players such as insurance companies, federal and state agencies, healthcare providers, employers, individual employees and patients. To correct the distortion requires changes for each player as well as coordination among them.

For example, health insurance companies in the United States often face a high turnover rate. That is, their enrollees change insurance providers, mainly due to switching jobs or employers. Although preventive care brings savings to insurance companies eventually, the financial benefits accrue in the future over a period of time. When enrollees change health plans, some of the financial benefits to an insurer will be lost and the insurer may end up paying the costs of preventive care without fully enjoying the benefit[13]. As a result, health insurance companies may hesitate to provide and reimburse preventive care services.

Another major player in the system, namely, health care providers including nurses, physicians, and hospitals, may provide less than ideal amount of preventive care because they are generally reimbursed for their services on treatment while prevention-related services are either compensated at low levels or not at all. Another bottleneck for increasing the utilization of preventive care is the shrinking supply of primary care physicians, whose time already is stretched thin. While other developed countries have at least 50 percent of their physicians specialized in primary care, the U.S. has less than 30 percent. During the past decade, less than one in five U.S. medical graduates chose primary care medicine[14]. Even with the introduction of free preventive services under the *2010 Patient Protection and Affordable Care Act*, we will not increase the use of prevention significantly without addressing the reimbursement system and the supply of primary care physicians.

Although workplace wellness and prevention programs have respectable returns on investment, adoption of such programs has not been universal. While 77 percent of large manufacturing companies offer formal health and wellness programs, less than 30 percent of small businesses offer some of them because they (and other similar preventive care services) often require substantial up-front costs, but their benefits may be uncertain and are likely to accumulate over time, rather than immediately[15].

Given the low survival rate of small businesses and their employees' high turnover rate, return on investment from such programs is likely to be small or even negative for some small businesses. Herein lays another distorted incentive. Although workplace wellness and prevention programs improve workers' health and create long-term social benefits, small business owners are unlikely to offer them. One solution to this impasse is for owners of small

businesses to seek external funding, for example, from insurance companies, as well as local and federal governments. This funding could cover some of initial costs and allow the businesses to enjoy benefits without hurting their bottom lines. Insurance companies, such as Blue Cross Blue Shield, already offer wellness programs at no cost or very low cost to small businesses, offering lower insurance premiums or cash awards for participating businesses. Many states offer support for these programs through partial reimbursement or grants. To this end, the *2010 Patient Protection and Affordable Care Act* authorized the appropriation of $200 million for small businesses to create comprehensive workplace wellness programs.

What types of wellness and prevention programs should be offered at the workplace is another key issue. Although studies have shown that diet counseling, increased physical activity, tobacco-use screening and intervention, cancer screening, and immunization are among the most cost-effective preventive services and wellness programs, there are no clear answers on the optimal design for different industries and firms. Labor-intensive manufacturing industries clearly face different health and behavioral risks than office-based workplaces. Until we accumulate more information, this heterogeneity remains, somewhat, a trial-and-error process.

Another important incentive question managers need to consider is how to properly motivate employees to participate in these programs, which often requires difficult behavioral changes such as healthy diets, more exercise, and less smoking. These lifestyle changes are, typically, harder to follow than taking a regular flu shot or measuring for high blood pressure. Many firms offer cash incentives, gift-card rewards, or reduced insurance premiums for employees who participate and achieve certain outcomes. Safeway, for example, differentiates employee contribution in insurance premiums based on their tobacco usage, weight, blood pressure, and cholesterol levels. Although Safeway's approach and incentives adopted in other companies are not without controversies, their experiences do demonstrate that properly designed workplace wellness and prevention programs combined with right incentives improve employees' health and productivity; reduce direct and indirect health-related costs; and create social benefits by altering the combination of prevention and treatment in health care production.

Transitioning the United States from a treatment-based to a prevention-based health care system is a difficult task (some would say forbidding) but, at the same time, offers a golden opportunity for business and social entrepreneurs to exercise and demonstrate their limitless ingenuity. People respond rationally to well-designed incentives; so the key is finding the proper mixture of incentives to accomplish the broad-based goal of moving the United States from where it is now to where it could be. Clearly, the stakes are high because they have life-or-death consequences. In my opinion, the implications and resulting actions of this effort are among the most important we face and also among the most rewarding that we as a society should strive to accomplish.

The author is an assistant professor of economics at Babson College. His current research focuses on insurance gaps and chronic condition management; impacts of health insurance on entrepreneurship activities; and the importance of preventative health care.

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SECTION 4: RETHINKING HEALTH CARE AT THE END OF LIFE

REPUTATION, PUBLIC POLICY, AND CONSUMER CHOICE: LESSONS FROM THE NURSING HOME INDUSTRY

How nursing homes are changing and new business models for elder care are emerging *by Michael Cummings*

The nursing home industry can provide us with an object lesson in the intersection of public perception, public policy, and consumer choice for health care delivery business models. We can draw four key lessons from the history and current environment (both regulatory and economic) within the skilled nursing facility industry.

History

The nursing home industry experienced rapid growth in the 1960s and '70s, principally due to the creation of Medicare in 1965. Simultaneously, and as far back as 1962, the U.S. Senate was conducting hearings into quality of care issues. During the next 45 years, congressional hearings were conducted into quality of care issues at nursing homes, focusing on poor care, inadequate physical plant, and access issues. The negative public perception of nursing homes and the ensuing regulation correcting the deficiencies (actual and perceived) were emblematic of the conflict between societal expectations and nursing home performance. Periodic undercover press coverage detailing substandard care gave rise to public outcry for regulatory reform. By the 1990s, regulatory monitoring of facilities led to the imposition of punitive sanctions against offending nursing homes, including the publication of infractions. This inevitably led to further deterioration in the industry's reputation. Ironically, as the industry's reputation among the general public has suffered, the result of efforts to correct nursing home quality has been that:

- Quality has improved remarkably. Among many other positive metrics, approximately 90% of Massachusetts family members indicate they were pleased with their relatives' care[1].
- Just as facility quality is improving, public policy initiatives are reducing the need for nursing home beds by shifting patient care to alternative, less-regulated sites.

The first lesson from the industry is that the penalties associated with a damaged reputation are likely to have negative consequences far in excess of the actual damage caused by fines and sanctions. The nursing home's place in the continuum of health care[2] is threatened by the negative perceptions associated with quality of care issues.

Public Policy

Elder Care advocates have long pushed for care alternatives for the elderly. Some of the most promising alternatives were, until recently, not available to the vast majority of the elderly due to cost. Assisted Living Centers were developed during the last 30 years as residential alternatives to nursing homes that provide a less institutionalized and less medically driven health care alternative to nursing homes. Many of the original founders of Assisted Living Centers gained their experience in the nursing home industry. The lessons from the nursing home industry of a heavy regulatory burden and public oversight paired with difficult-to-manage public contracting via Medicare and Medicaid[3] was not lost on the founders. Eschewing public funds, the industry largely developed along a private pay model. With private rates starting at a minimum of $2,500 a month and reaching much higher rates in many centers, this option is closed to the vast majority of elders.

The second lesson is that public policy initiatives designed to correct the failings of one part of the health care ecosystem will impact other parts to the system. The sheer size of government funding, combined with shifts in public policy can have a powerful effect on changing the competitive environment. Elder care advocates' work in creating the regulatory and reimbursement environment within nursing homes have inadvertently led the largest sector of alternative care to place a high price on their service, pricing out many elders.

With Assisted Living Centers unavailable to most elders, advocates next turned to home care as an affordable alternative to institutional care. Through intense lobbying, advocates have developed programs funded through Medicare and Medicaid to pay for home care. There is a wide dispersion of services available, and programs vary widely by state. Levels of care can begin with just a few hours of assistance per day or include payment for full-time, live-in caregivers, depending on the program. Although data is scarce, the anecdotal perception among both federal and state government officials is that home care is both more effective and efficient.

As alternative models develop for elder care the consequences for competitors in the health care ecosystem are only now being realized. In addition, government oversight of these models is lagging far behind their growth. Looking back on the rapid growth of the nursing home industry in the 1970s, government regulators realized only after the fact that there were widespread financial and care abuses taking place. Recently, we see history repeating itself as the Justice Department has arrested large numbers of home health care providers and others caring for elders in the home, accusing them of defrauding Medicare. In addition, both federal and state government regulatory agencies are woefully unprepared to monitor the quality of care provided in an elder's home by home care providers.

The third lesson is that new, potentially effective models require carefully monitoring from the beginning. The realities of elder vulnerability have not changed in the last 50 years, and careful monitoring is essential.

Consumer Choice

Public policy initiatives combined with market demand for alternative care options have greatly expanded consumer choice. The critical questions now facing consumers are access and cost. As the health care ecosystem expands and includes new care models consumers face an often bewildering array of choices and the various consequences for the elder's care associated with those choices. In many cases, options are closed to elders due to cost; in others alternative care does not provide the level of care required for the truly infirm. In still other situations, choice can be limited simply due to the availability of programs in specific geographic regions.

The fourth lesson is that choice, while important, must be accompanied by education and the ability to understand the consequences of those choices if the ecosystem is to develop effective and efficient care.

Implications for Nursing Homes

In the short and intermediate term, nursing homes are likely to experience deterioration in their performance. Currently, nursing homes provide two key services: short-term rehabilitation for patients requiring acute care after hospitalization; and long-term care for residents unable to live alone. There will be a marginal decline in rehabilitation services as insurers such as Medicare and private insurers attempt to shift rehabilitation services into the elder's home or provide care on an outpatient basis. This change in demand patterns is, however, likely to run into severe headwinds as Medicare begins to impose penalties on hospitals for unnecessary readmissions. Anecdotal evidence suggests that

while more expensive than home care, admission to nursing homes for rehabilitation have better long-term health outcomes that lead to fewer readmissions. The efficacy of the nursing home approach requires both data developed over time and a realization by public policymakers that home care is not a panacea.

The second service nursing homes provide, long-term care, will experience an extended period of decline as consumers choose home care as their preferred option. The impact on the industry will be a period of overcapacity leading to facility closures to match market demand to industry capacity.

Finally, as public policymakers attempt to reduce spiraling health care costs, nursing homes will offer the health care ecosystem a place for short-term admission that in past decades would require an admission to an acute care hospital. In other words, nursing homes will provide short inpatient admissions for sub-acute elders requiring 24-hour care for a short term at a cost per day that is substantially less than that at an acute care hospital. The advent of Accountability Care Organizations will help fuel this need.

The Health Care Ecosystem: Lessons from the Nursing Home Industry

Emerging health care delivery business models should pay heed to the lessons of the nursing home industry. Reputations are critical in health care. Once an organization or an industry begins to lose its reputation, the lack of legitimacy can lead to public policy initiatives that reallocate public resources to business models deemed more worthy. Heightened regulatory enforcement reduces the flexibility to innovate and consumers will seek out alternatives perceived as providing better care. If alternatives are not themselves effectively regulated, or consumers are not fully apprised of their choices and the consequences of these choices, then we risk repeating the cycle again.

Nursing homes will continue to have a place in the ecosystem. Having squandered their initial reputation, they entered a cycle in which they always operate under close regulatory scrutiny. The industry therefore has lost much of the vital ability to innovate and meet changing consumer demand.

The author is a lecturer in management at Babson College and the founder of LTC Group, a Massachusetts corporation that owns and operates long-term care facilities.

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[3] *Medicare is Federal Health Care Insurance for those older than 65 and the disabled. Medicaid is a state-managed health care program for those with incomes below a predetermined level.*

MOLST: THE CASE OF AN INNOVATIVE PROGRAM FOR THE END OF LIFE

A new voluntary program in Massachusetts that facilitates discussion, planning, coordinating patients' end-of-life decisions *by Margaret Ann (Peg) Metzger, JD*

Many believe that the American death-denying culture inhibits achieving the best health care for those approaching the end of life. Ellen Goodman, working with The Institute for Healthcare Improvement, has kicked off a national initiative called The Conversation Project in an attempt to promote conversations about death and dying in order to narrow the gap between what people say they want as they face death and what really happens[1].

The goals of The Conversation Project are enabled and advanced by MOLST (Medical Orders for End of Life-Sustaining Treatment), a Massachusetts program designed to assure that each person's end-of-life preferences are expressed and can be honored across all medical settings. MOLST statewide expansion started on April 1, 2012.

Background

A person born in Massachusetts in 2008 has an average life expectancy of 80.4 years[2], 35 years more than a person born in 1900 when the average life expectancy was 45. Before antibiotics, people tended to die quickly, either of infectious diseases or accidents. Today, only a small fraction of the population dies suddenly.

By dramatically increasing life expectancy, modern medicine has changed what we die from and what we live with before we die. Individuals live longer but often develop chronic, life-threatening illnesses. Notwithstanding medical advances, everyone remains mortal. Doctors have a range of options that can prolong the dying process but "[i]n the course of a progressive illness, there almost always comes a point when more treatment is not better care.[3]"

Approximately 53,000 people die each year in Massachusetts; the largest number of deaths is among people age 85 or older and almost 80% of all the people who die are at least 65. These deaths touch friends and families deeply but most are not unexpected. Patients have typically received care from many caregivers, often in multiple treatment settings, for many years. It is not unusual to have little coordination between the patient's clinicians, little discussion with the patient about the patient's prognosis, and little planning with respect to the patient's goals for care. Families confront a barrage of medical decisions with little context and great uncertainty about what their loved one would want.

MOLST

MOLST is a standardized form that translates a seriously ill patient's preferences into **valid medical orders that can be honored by all health care professionals across care settings**, whether in the home, hospital, nursing home, rehabilitation facility, hospice, or in transfer by ambulance when emergency medical personnel are called.

MOLST is one possible outcome of ongoing, advance-care planning discussions between a patient and the patient's health care providers and loved ones. Completing a MOLST form is voluntary. MOLST is suitable for patients of any age with advanced illness including, but not limited to: life-threatening disease; chronic progressive disease; dementia; life-threatening injury; or medical frailty. MOLST instructions are effective immediately and reflect the patient's current health status and preferences.

When approaching the end of life, MOLST can be more effective than a living will or other expression of final medical wishes. Since there is no statute in Massachusetts that expressly authorizes living wills or other expressions of final wishes, such documents can serve as evidence of a person's wishes, but have no particular legal authority. A MOLST form contains valid medical orders that are effective immediately and can be honored by health care providers in any setting.

MOLST does not change the need for health care proxy. All adults (age 18 and over) in Massachusetts should complete a health care proxy form to appoint a health care agent who is authorized to make health care decisions on their behalf in the future should they become incapacitated. While it may seem self-evident that seriously ill patients would benefit if medical orders could be honored by all medical personnel across care settings, unfortunately, that is not how the current system works. Typically, clinicians only honor orders written by other clinicians working at the same institution. Without express authorization not to administer cardiopulmonary resuscitation (CPR) on the Comfort Care/ Do Not Resuscitate Verification Protocol (CC/DNR) form created by the Department of Public Health's Office of Emergency Medical Services (OEMS), emergency responders have been required to attempt CPR. Under current guidance from the OEMS, emergency responders can honor either a MOLST form or a CC/DNR form.

MOLST represents a standard of practice with respect to documenting and communicating patient preferences for care at the end of life. MOLST builds on and enhances CC/DNR because it (a) can be honored by all clinicians across treatment settings (not just emergency responders), (b) includes the option of refusing or requesting treatment, and (c) creates valid medical orders about CPR, intubation/ventilation and transfer to a hospital. MOLST also serves as a communication tool to facilitate expression of a patient's other preferences by indicating the extent of the discussions that have occurred. This allows clinicians to continue conversations that were started earlier.

MOLST was first authorized in Massachusetts under Chapter 305, Section 43 of the Acts of 2008. That legislation directed the Executive Office of Health and Human Services (EOHHS) to test implementation of a physician order for life-sustaining treatment paradigm program (see www.polst.org) to assist individuals in communicating end-of-life care directives across care settings in at least one region of the Commonwealth and to make recommendations for establishment of a statewide program. Clinical practice settings in the Greater Worcester area were selected as demonstration sites for implementation of MOLST. Based on the demonstration project, an initial cohort of Massachusetts hospitals and nursing homes are currently engaged in training and preparation to proceed with the steps required to implement MOLST. These steps include recruiting clinical champions, revising institutional policies and procedures to incorporate MOLST, and the challenges of training staff. Key findings developed during the demonstration project and the expansion recommendations are contained in a report available on the EOHHS website.

Statewide MOLST expansion has been endorsed by the Board of Registration in Medicine (and the Boards of Registration for nurses, nurse practitioners, and physician assistants), the Massachusetts Medical Society, and the Massachusetts Expert Panel on End of Life Care, and many institutions have expressed interest in participating in MOLST training. Current efforts are under way to scale up to be able to respond to all of the requests for training and individualized coaching. In addition, efforts are needed to assure that clinicians who feel ill-equipped or uncomfortable with discussions about end-of-life health care options can get support and training. Public outreach efforts also are being planned since MOLST can satisfy the desire of many patients and families to control the treatment that they receive at the end of life. However, there is a great concern that clinical systems be given time to prepare in order to be able to adequately respond to patient demand.

A seasoned attorney and health care consultant, the author is an adjunct lecturer in the Management and the Accounting and Law divisions at Babson College.

For more information about MOLST, go to www.molst-ma.org.

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