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The Widening Gaps in Pharmaceutical Therapies: Cost – Health – Trust

Synopsis of the October 2005 WFS Washington DC Chapter dinner program panel discussion
Panelists: Bill Rowley, Institute for Alternative Futures; Jay Herson, Johns Hopkins University and Mat Salo, National Governors Conference;
Moderator: Eric Garland, Competitive Futures, Inc.;
summarized by Dave Stein and Jay Herson

Pharmaceutical therapies are unquestionably scientific miracles. They address a variety of diseases, offering substantial improvements in health, many of which are significantly better than those offered by any other kind of therapy. On the average, people in industrialized nations are living longer. For its part, the pharmaceutical industry is doing well – so well that a few pharmaceutical giants, themselves the result of massive corporate mergers, invest billions every year in research and development of new therapies.

Yet, these miracles do not come without challenges. Indeed, three major forces are posing an interesting dilemma for US healthcare. First, **healthcare costs (including pharmaceuticals) are increasing faster than wages.** Every year Americans are spending more on pharmaceuticals, paying either through pharmaceutical benefits plans when available or through personal funds otherwise.

Secondly, many new, expensive therapies offer only marginal improvements over generics. Even with the money spent, many pharmaceutical researchers and healthcare professionals believe that the "bang for the buck" is decreasing in healthcare research. Hundreds of millions of dollars are poured into development of drugs that may have marginal improvements on older, cheaper, and equally efficacious generic drugs. Other sources indicate that the number of new drug applications is decreasing, making companies, stockholders, and other stakeholders nervous.

The third challenge is that the American public is becoming increasingly suspicious of pharmaceutical companies, the benefits provided by advanced pharmaceuticals notwithstanding. According to the Gallop "Trust in Institutions" poll, the American popular perspective is often one of mistrust. Instead of seeing an industry that provides revolutionary advances in health, they wonder, why do they profit so much? What information are they hiding about side effects?

In combination, these factors present a dilemma. One might ask how long the US can continue paying more for healthcare while distrusting the industries that provide it. This issue was the focal point of the panel discussion.

PHARMACEUTICAL INDUSTRY FACTS AND TRENDS

Panel moderator Eric Garland began with some drug industry facts and trends. Said Garland, the cost of health care in the US is increasing at a rate far faster than wages are. At the same time, mergers have created corporate giants that dominate the pharmaceutical industry. Concurrently, pharmaceutical research has been increasing at a "breakneck" pace – a seven-fold increase in the past 15 years alone! Impressive as this sounds, the pharmaceutical industry has its challenges, too – not the least of which is the fact that for every 10,000 drugs screened by the Food and Drug Administration (FDA), only ten result in human trials and only one receives eventual FDA approval. In addition, seven years of sales are required to pay back the cost of developing a new drug and to pay the research costs of drugs that fail or that prove unprofitable. Not surprisingly, pharmaceutical companies are highly dependent on "blockbuster" drugs, i.e., those that produce $1 billion or more per year in revenue.

An additional cause for concern is that the FDA perceives that the quality of new drug approval applications is lower, even though it continues receiving a constant level of approval requests. Then, too, the public's trust in the pharmaceutical industry has eroded, partly because of the cost of drugs in comparison with pharmaceutical company profits and partly because of litigation regarding the effectiveness and/or side effects of particular drugs. Reminded Garland, the goal of the panel discussion was to get different perspectives or visions of the panelists on the current state of the pharmaceutical industry.

NEW MODELS FOR BUSINESS AND THERAPY – WHICH FIRST?

First to present a vision of the industry was Bill Rowley of the Institute for Alternative Futures and a healthcare futurist for several companies. Rowley's view is that the pharmaceutical industry world has changed and that pharmaceutical companies must re-invent themselves, to include a new business model. The blockbuster business model used successfully for so long is losing relevance. The new model will not be business as usual, and high profit margins will probably be impossible to achieve.

Panelist Jay Herson of Johns Hopkins University suggested that a big mistake in US healthcare has been to think of the pharmaceutical companies as "private NIHs" rather than profit making entities. Envisioned Herson, the biggest challenge facing the industry is to tailor treatment to each individual patient once we learn more about the fundamental nature of disease, adding that this will take a very long time.

A third perspective was presented by Mat Salo of the National Governors Conference. Cognizant of the balanced budget constitutional requirement of every state except Vermont, Salo noted that the cost of healthcare greatly affects state budgets because the Medicaid program, which covers the cost of healthcare for the poor, currently covers 55 million people and is largely paid for by the states. Put in perspective, the cost of Medicaid to the states is greater than the cost of K-12 education and of higher education. It was also pointed out that with certain Medicaid patients shifting to Medicare drug coverage after January 1, 2006, the issue of who really pays is not completely resolved.

HEALTHCARE SPENDING

Garland then asked the panelists what are the limits on healthcare spending. Rowley noted that the US now spends $1.93 trillion on healthcare per year but that the industry wastes money on

bureaucracy, adding that no healthcare cost cutting measures will be effective until the public reins in its expectations for healthcare. Noting that much of the pharmaceutical industry has moved to the US because the government does not limit drug prices, Rowley anticipates that this will change because of the new imperative to control drug costs. Continuing, Rowley stated that the pharmaceutical companies do care about creating good drugs but that the industry is simply reacting to public demands and expectation, adding that Pfizer, for example, wants to go beyond drugs to provide services that promote health and effective management of diseases.

For his part, Salo addressed the budgetary issues. Stated Salo, **t**he current level of Medicaid spending, 22% of state budget growth, is unsustainable. Many things can be done to limit spending, especially limiting waste. For example, electronic medical records can be used to minimize paperwork, while electronic prescriptions can help avoid prescription errors.

Herson noted that the trend toward mergers in the industry results from the high cost of developing new drugs and the fact that there are not enough blockbuster drugs to otherwise support these costs. There are many failures in new drug development, and the cost of clinical trials is high. Continuing, Herson pointed out that companies in other industries (e.g., in the aircraft industry) do not have the same high failure rates in new product testing because their tests are grounded in the laws of physics whereas there are not yet similar rules to guide pharmaceutical development. An additional point made by Herson is the need for expectation management regarding medical cures, especially in the case of expensive drugs that at best extend lives of terminally ill patients by only a few months.

Rowley then proposed that one way to limit government healthcare costs is to have a two-tiered system like Oregon has. In this system, all beneficial therapies are ranked in order of cost effectiveness as well as in relative benefit to patients and to society. Based on this rank ordering, the state pays for a certain basic level of care, and the individual pays for care above the basic level. Oregon's experience was that good therapies were available for virtually all diseases, but expensive treatments were excluded as not the wisest use of limited funds. Modifications were subsequently made for political acceptability, especially to accommodate children and to provide supportive care for people suffering from incurable diseases. Salo added that Florida has instituted defined contribution levels per individual in its Medicaid program. This provides an incentive for managed care.

NEXT GENERATION PHARMACEUTICAL SCIENCE

Turning from policy and budgetary matters to science, Garland posed the question, "What will happen in the science of drug development?" Herson envisioned that in twenty years, we will have drugs that are based on new developments in genomics and that we will be able to predict their successfulness. Salo suggested that there is a need to avoid over-medicating, citing Governor Huckabee of Arkansas as a case in point. Tremendously overweight, Governor Huckabee was given only a few years to live unless he went on a radical diet – which he did, to the loss of more than 100 pounds, becoming fit enough to run marathons.

Rowley envisioned that there will be biomarkers to indicate the progression of a disease in the patient and how his/her body metabolizes drugs. He further mentioned the possibility of a patch on the head to indicate how well anti-psychotic drugs are working – adding that these developments will require many years. As an alternative to the blockbuster business model, Rowley proposed the possibility of open source pharmaceutical development in a manner akin to present-day open source software development.

Q&A (as best captured):

Q: What would be the global impact of an Indian company producing cheap anthrax medicine?

A: Drug development will have to become more global. Indian and Chinese companies definitely have a role. Considerable progress has already been made in the area of harmonization of national approval requirements that will someday result in same- day approval by many countries. The next Pfizer could be a company based in India.

POINTS FOR THE CLASSROOM *(send comments to forum@futuretakes.org):*

- *According to the **Pocket World in Figures 2005** published by **The Economist**, the US ranks 37th in longevity, even though it also ranks first in per capita healthcare spending as a percent of GDP. What can be learned from healthcare systems in other nations, with respect to both effectiveness and administration?*

- *How serious of an economic stressor are the various entitlement programs, including healthcare, relative to rising energy costs, trade imbalance, and environmental degradation? If entitlement programs are cut back, what are the implications?*

- *In addition to the two-tier system mentioned in the synopsis, several other alternative healthcare paradigms have been proposed – the "Chinese" system (in which patients pay the doctor only when they are well), increased emphasis on preventative healthcare, lifestyle changes (including improved balance between work and leisure, to include time for exercise, healthy meals, family, and friends), and complementary or "alternative" medicine. Which of these alternative systems, if any, are likely to become more prevalent, and why?*

- *How will next-generation pharmaceuticals (genomics-based) change present healthcare paradigms?*

- *The synopsis discusses possible new business models, including offshore (global) development of the next pharmaceuticals and open-source development. How will open-source development, if implemented, impact investment? Specifically, will healthcare no longer be a lucrative investment, precipitating a shift of investment dollars to other industries?*

- *Advances in medicine and bioscience offer substantial promise for improved health and wellness into ripe old age. At the same time, the failure of some traditional retirement systems is forcing some people to postpone retirement and remain in the workforce longer, well into their senior years when the challenges to their health are greater. Delayed retirement affects different people in different ways, providing a social net for some and work-related stress for others. Given these countervailing trends, what can tomorrow's senior citizens expect in health and wellness?*