



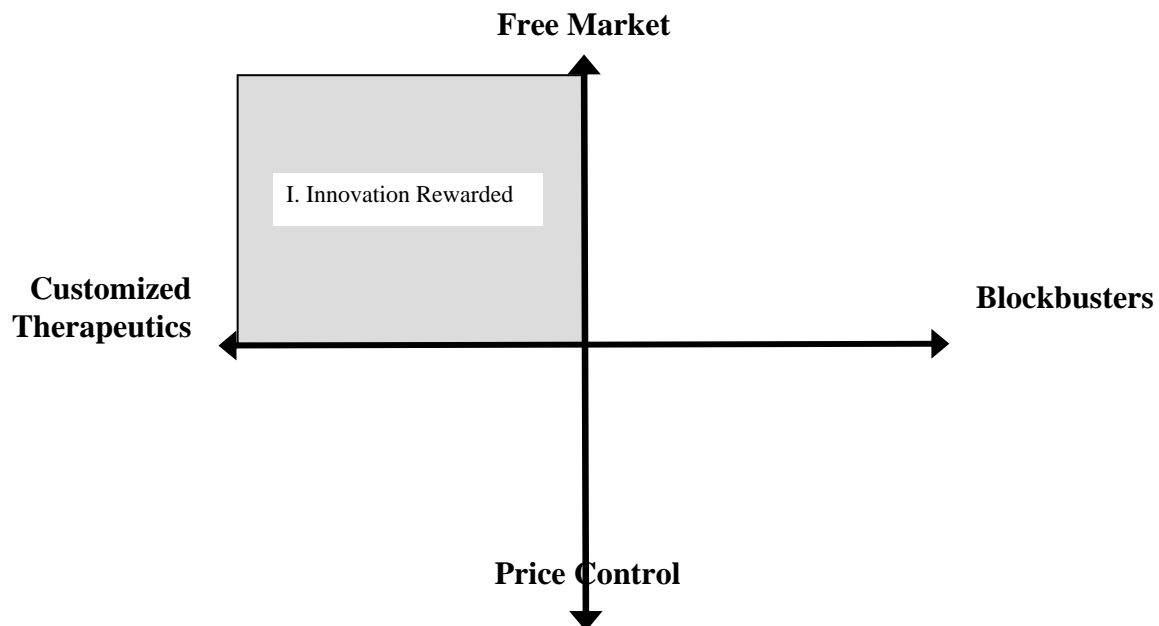
2015: Strategic Considerations for the U.S. Pharmaceutical Industry

The following excerpt is taken from the CHA Advances Report, **2015: Strategic Considerations for the U.S. Pharmaceutical Industry**. In this report, the authors Dr. Ron DiFelice and Sam Tetlow construct 4 industry scenarios based on these variables:

- Customized Therapeutics
- Blockbuster Therapeutics
- Free Market Pricing
- Price Controls

In the following scenario, titled “Innovation Rewarded,” the authors describe a market landscape in which customized therapeutics are introduced in a free market environment. Under each scenario, socioeconomic developments, technological developments, market and regulatory developments, and distribution developments are each in turn considered.

The full report is available from CHA Advances Reports at www.advancesreports.com or by contacting Cindy Ohlman at cohlman@chadvisors.com or 781-547-0202.



Scenario 1: Innovation Rewarded

This scenario explores the effects of the successful introduction of customized therapeutics in a free market environment. The high-risk and high-cost R&D bets placed by large pharmaceutical and biotechnology companies pay off in the form of advanced customized therapeutics that are much more effective than the “one size fits all” medicines of the early 21st century. The industry has been laying the groundwork for customized medicine over the past decade, and technology

advances combined with a greater understanding of the human genome lead to big strides. While the public still pressures legislators to do something about the high cost of healthcare, price controls are avoided by the industry because of a deceleration in the growth of healthcare costs that is largely due to the increased effectiveness of the new therapies. In addition, customized therapeutics prove their cost effectiveness when looking at overall, long-term costs, and they demand and receive premium prices. In particular, the wealthy in the US turn to personalized medicines because they are so much more effective than traditional treatments. The industry remains highly profitable, and even more money is funneled to R&D.

Socioeconomic Developments

- Medicaid and Medicare reforms passed by Congress make healthcare more affordable for lower-income patients, but this group does not realize the benefits of advances in customized therapeutics. Government benefit programs are slow to act on the fact that even though price points are high for new customized therapies, the overall effect is that healthcare costs are actually lowered because of the higher efficacy of products. But within five years, the cost-benefit evidence is overwhelming, and government administrators begin to offer customized therapies. The elderly, however, resist the change to personalized medicine because they distrust the new therapies, and for the most part they continue to rely on traditional medicines. Consumers are still unhappy about the high cost of healthcare, but the escalation of prices has slowed enough to prevent outright government price controls.
- Outside of the US, few countries can afford to implement the customized healthcare model, and international sales are minimal. Generics and traditional medicines are largely ceded to developing countries, and the image of US pharmaceutical companies abroad continues to decline as US companies ignore diseases and price-controlled countries that are not profitable. The developing world suffers from lost access to US drugs.
- The integrated medical registration card is introduced and gives patients more control by making it easier to change doctors, hospitals, or healthcare plans. The delivery of customized therapeutics relies heavily on the use of this card to diagnose, manage, and track patients.

Technological Developments

- Huge investments in new technologies pay off and result in new customized therapeutics that combine diagnostic tools with treatment. Instead of developing a single “cure all” for the entire patient population of a given disease, focus has shifted to developing therapies based on the genetics of smaller patient populations. New technology enables an emerging field of predictive medicine—assays are commercialized for defining the potential susceptibility of individuals to chronic and acute diseases. Advances in science and information technology that combine genomics, biostatistics, informatics, and medicinal chemistry enable this movement. It starts broadly and is initially implemented as a safety tool, enabling physicians to spare patients from adverse and dangerous side effects. But soon the tools are being used to optimize responses.
- The new technologies are developed and introduced primarily by biotechnology companies; the large pharmaceutical companies resist customized therapies because they cannot realize economies of scale and their organizations are not well designed to profit from this new business model. But large pharmaceutical companies eventually see the opportunity that customized therapies represent, and scramble to enter into partnerships and collaborations with biotechnology companies. The biotechnology companies wield much more negotiating power because of the effectiveness and potential of the new therapies, and so they strike lucrative deals with their pharmaceutical partners. “Virtual” organization models emerge that facilitate knowledge sharing and further speed technology development. Because of the lack

of government price controls, customized therapeutics are highly profitable and their success funds even more R&D, which feeds the cycle.

Market and Regulatory Developments

- Increased competition results as companies scramble to establish a foothold in customized therapeutics. But eventually, the market segments, and a leader emerges for each specialized disease category. Companies begin to vertically integrate to offer complete solutions from diagnostics to actual treatment, and they exit markets where they do not have competitive products. First-mover advantage becomes important in order to shape this nascent field, and large pharmaceutical companies rush to partner with/acquire biotechnology companies and healthcare providers that can help deliver custom treatments.
- Pharmaceutical companies narrow their focus to provide the high-end gene therapies almost exclusively to the US market. Many companies spin off their traditional pharmaceutical “pill” businesses to focus on more profitable total solutions offered by customized therapeutics. To make up for the loss of international sales and reduced volumes, firms continue to push for price hikes and get them. The competition from generics in the US is minimized because customized therapies, by their nature, cannot be easily replicated. Furthermore, the infrastructure required to deliver customized therapies is too large and expensive for generic competition this early in the life cycle of customized therapeutics.
- On the regulatory side, the FDA institutes stratified clinical trials—smaller, but more focused trials that proceed to market more quickly and with greater safety. These controlled launches into certain stratified markets offer well-defined therapeutic benefits and also require the FDA to develop new monitoring processes—pharmacovigilance surveillance and safety monitoring become important and extend beyond clinical trials.
- A discrete number of emerging biotechnology companies bundle a diagnostic and drug for a safe, effective, and highly valuable combination. These firms focus on large therapeutic areas and earn early success through execution of their business model and serendipity. The value of these firms exceeds that of medium and large biotechnology companies.

Distribution Developments

- Customized therapies are initially too expensive for government benefit programs and for bare-bones insurance providers, and traditional drugs are distributed in the same way they are today. However, distributing customized therapeutics requires a new model that includes new diagnostic and treatment centers.
- Pharmaceutical companies vertically diversify to capture more value in the supply chain. This helps to compensate for the fact that they are targeting smaller market segments with their expensive new gene therapies. They venture into health services to diagnose and administer customized therapies, and new specialized distribution businesses are created because pharmacies do not have the resources to deliver customized treatments. The pharmaceutical companies need a very well-regulated channel to deliver customized therapies, and thus they demand more control over distribution. The lack of price controls induces competition, but prices escalate (at the expense of hospital revenue) as the industry ultimately competes on results and not price. Direct-to-Consumer advertising sees a higher success rate as marketers effectively tailor their message to specific populations.