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Reading the Tea Leaves: Predictions for Pharma's Future

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30 comments

The human race has one significant weakness. We all want to know what the future holds for us, and we want to know *now* -- hence the popularity of fortune-telling and such "fields" as astrology. In our desire to predict tomorrow, however, we often forget simple cause and effect. What we do today helps determine what happens tomorrow. For instance, every new developed and approved drug, in efficacy and in price, directly impacts company and industry profits.

Despite ongoing product-quality issues, drug companies have been profitable. However, this picture is about to change. Some say that it has already begun to change. Clearly, what we do today will shape pharma's future.

Here are my predictions for the industry over the next five to fifteen years. How do they compare with yours? As you'll note, I see the *status quo* prevailing in some cases, forcing change to come from unexpected places, such as regulatory agencies or outside forces. But what do you think?

1. Pharma companies will have to figure out how to reach the world's masses, rather than small patient populations, if they are to succeed in the long term.

2. On average, the industry's success rate of development and commercialization, for both small molecule and biotech drugs, will not change much from its current level. “Eroom’s Law” still limits pharma's destiny. 3. High drug pricing soon will be frowned upon and discouraged by PBMs (pharmacy benefit managers) and hospitals.

4. Instead of becoming “process-centric,” pharma will stay “regulation-centric.” Process-centricity, if adopted, would allow companies to exceed regulatory requirements, which could also avoid many issues that have created public relations and financial headaches. Current regulatory guidelines and requirements discourage change. Since changing an existing process requires approval, it is still perceived to be a long and expensive step, and something to be avoided.

5. Industry will hedge in adopting many of the internal changes (manufacturing methods, technology, and supply-chain improvements) that could improve profitability and move from the current *quality by analysis/aggravation* to a *quality by design* approach. Again, this is due to regulatory constraints. Short patent lives for the ethical (brand) drugs will impede innovation in manufacturing technologies. At the same time, most generics manufacturers have been in business too short a time for their managers to grasp the value of better technologies and methods.

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6. Since current or higher level of profits can be achieved with the current inefficient practices, industry leadership does not see any value in improving its product development, business, and technology practices. External forces will drive change.

7. With not much forthcoming from the industry to improve its manufacturing and business practices, regulatory bodies will enact regulations that will force the industry to adopt better practices. This tug of war will continue, unless the industry takes the lead.

8. Continuous formulation processes could be a reality in the next five years for new drugs.

9. Continuous API manufacturing is possible, but it will require a different economic and manufacturing model.

A shift is taking place in the global pharmaceutical businesses, whether we like it or not, and is being brought on by generics manufacturers based in developing countries. Pharmaceutical companies will have to take radical measures to retain or increase their revenue streams and profits.

A shift to a new model from the current model in new drug discovery, development, manufacturing technologies, supply chain, conservation, and sustainability requires an “unreasonable man” as described by George Bernard Shaw. ("The reasonable man adapts himself to the world; the unreasonable one persists in trying to adapt the world to himself. Therefore all progress depends on the unreasonable man.")

Significant innovation is feasible in manufacturing and its support functions. For it to happen, though, the pharmaceutical industry will have to move its focus from “regulation-centricity” to “process-centricity.” The industry still appears unwilling to take the steps required for change.

The world and its inhabitants would clearly benefit from better and higher availability of lower cost drugs, while companies would be able to improve their profits from the current levels. I view this as a win-win situation. What do you think?

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