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Can Gates/Clinton Save Pharma?

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21 comments

In the pharmaceutical industry today, the predominant mood is one of negativity. General discussion in the press focuses on drug shortages, recalls due to quality problems, or contamination or problems with new drugs and clinical trials. The average reader understands these topics as they relate to him or her.

Even in the publications geared to industry professionals, and presentations at industry events, the overall focus seems to be on risk mitigation, rather than on proactively doing whatever will result in better product quality.

What's missing is any discussion about active pharmaceutical ingredients (APIs), the most important element of a drug, and their manufacturing and formulation. Is it due to our lack of understanding or our inability to create repeatable processes? APIs have become the orphans of the industry, even though they cure diseases and keep us healthy and alive.

Regulations have been proposed that will cause API supply disruptions and force some manufacturers out of business.

Is this a bad thing? Clearly, we are spending a great deal on API production and formulation, and are doing so very inefficiently. This inefficiency results from lack of economies of scale and some of the time and effort that is spent by every company in bringing a generic drug to the market, and subsequent testing during production. And yet, such testing offers no guarantee that quality will be achieved, as we've seen with the recalls.

Having many companies produce the same generic drug not only affects R&D and manufacturing, but has an impact on the entire supply chain, including the APIs and excipients that are used in formulation. This is also true for brand drugs.

Each company buys its APIs and excipients from different suppliers. Lack of economies of scale also raises regulatory burden on both sides of the fence.

Overall, we are raising costs. Customers do not know this, and many might not care, as they are willing to pay more for what they perceive to be valuable. However, the industry's inefficiency affects those, such as the uninsured or those on fixed incomes, who must often choose between food and medicine.

Besides pharmaceuticals are there any other businesses today where inefficiency costs are passed on to consumers? Regulatory bodies developed current good manufacturing practices

(cGMPs) to maintain basic levels of product quality. But, if we look at cGMPs, they are neither current nor good, and yet, they appear to be challenging some of the world's largest pharmaceutical manufacturers today.

If companies were crossing every "T" and dotting every "I" there would be minimal citations and/or recalls.

Profitability has assured a culture where inefficiencies are ignored.

Increased competition could turn this situation around. Yes, it will mean that some companies won't survive, but perhaps they shouldn't be in business anyway. Reducing the number of companies producing the same drug would bring economies of scale. This, in turn, would reduce the development time, time to market, improve the overall business process, reduce regulatory workload, and result in safer and more sustainable API and formulation processes.

Who will bring about the “creative destruction” needed for this to take place? Only organizations that challenge the status quo can bring real change.

Foundations, including those established by Bill and Melinda Gates and Bill Clinton, along with various governments, have been helping many in developing countries secure drugs for neglected tropical diseases (NTDs) and HIV/AIDS. They have already succeeded in reducing the prices for some drugs, compared to prices in the developed countries. However, there is still room to lower drug costs (about 30 to 45 percent) through better manufacturing technologies and economies of scale.

Since these foundations have already worked with pharma companies, they could be the ideal change agents. Initially, they would have to focus on a few selected APIs and their formulations and a select group of manufacturers, to show what might be possible with better technologies. Each success would extend the reach to an additional 20 to 30 percent of people living in any given region without the need of additional funding. Success with these drugs could then gradually spread across the total pharma landscape.

Such efforts would improve profits and lower healthcare costs across the board.

There could be short-term disruptions, but long-term, everyone would benefit. Lower costs would increase drug usage, and a 10 percent global drug use increase could add about 600 million people to the industry's customer base.

What will it take to pay attention to the orphans of the pharmaceutical industry? Total business processes (drug development, manufacturing process development, commercial manufacturing methods, and supply chain) will be impacted. Again, the potential savings could account for 25 percent of the global revenue. Such savings would lower overall healthcare costs. Now, that would be something to cheer about.