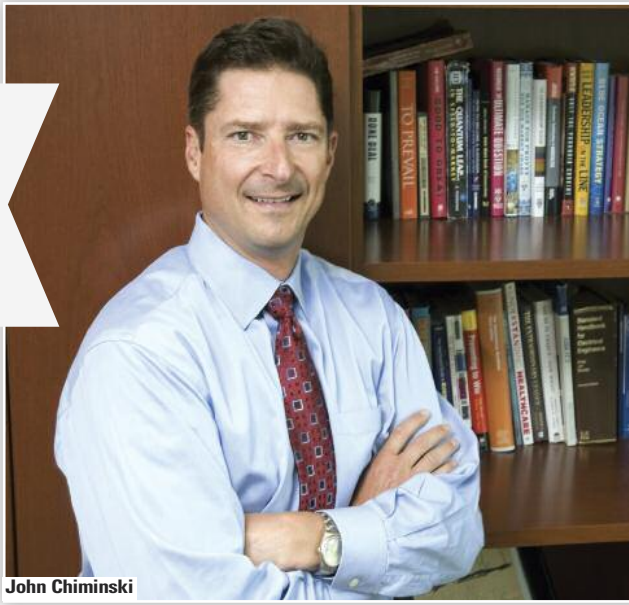
The New Business Model:

Developing Payer-Friendly Drugs Through Partner Innovation

JOHN CHIMINSKI, President and CEO of Catalent Pharma Solutions, discusses why a business model that uses technologies and new ways of working with providers to bring to market innovative products is critical to the industry's future success.


John Chiminski

PV: *Why do you think a strategic partnership model is needed?*

CHIMINSKI: Most life-sciences thought leaders agree that the traditional R&D model fails to meet current challenges. Many have described the emergence of Pharma 3.0 as a new business model that invites collaboration with traditional and non-traditional partners, embraces greater transparency, and encourages shared risks and rewards. Despite this, plans to change the innovation process over the next three years are a leading priority at only 54% of companies, according to a recent Economist Intelligence Unit survey.

A new business model implementing strategic alliances with network partners and providers aims to break down the barriers to innovation at biopharmaceutical companies, allowing new ideas to flow more freely. One such innovation is optimizing products through technology while they are still in development. This new model offers biopharmaceutical companies the chance to learn how to rescue existing drug candidates, increase R&D productivity, and strengthen product performance. Setting up alliance teams that are fully engaged and empowered to drive collaborations ensures success for true strategic partnerships.

In a strategic partnership with a technology solutions provider, visibility to the innovator company's existing development compound challenges and priorities is a first, important step to help the company bring these compounds through the pipeline. Structured innovation sessions oriented to achieving the compound's target therapeutic profile are one way to chip away at some of these challenges. The more transparency an innovator offers in terms of its real challenges, needs, and priorities, the more a strategic partner can contribute through innovative ideas as well as consistent delivery and performance.

PV: *How can a new model lead to innovation in drug optimization?*

CHIMINSKI: There are many ways that drug manufacturers can improve their products, but we believe two important areas for optimization address major unmet needs: the need to reduce administration costs by shifting compounds from medical professional-administered to self-administered, and the need for patient adherence improvement.

A technology solutions provider can offer value early on in the development process to address these unmet needs; the products that result could lower drug costs in Western markets and increase access to vital drug therapies in developing countries. Just one example of this kind of optimization is developing an immunotherapy or vaccine that can be administered orally.

Our research and long history in oral drug delivery shows that every design choice made in early development, while setting target profiles and choosing dose forms, can impact patient adherence. Better solubility, permeation, and absorption of drugs can be achieved through use of technologies that change the place of absorption or time of release, thus helping molecules to work better in patients.

At the same time, the same technologies can also favorably impact some of the behavioral drivers of patient non-adherence by helping patients to use their products properly.

The quest to improve patient adherence is driving greater reimbursement pressures today. Taking these reimbursement considerations into account from the start saves time and money. Current reimbursement pressures are a direct result of private insurers' and the Centers for Medicare & Medicaid Services' (CMS) increased focus on comparative effectiveness research. Understanding early on how to design payer-friendly drugs pays off.

PV: *Why should the industry reach out to payers as strategic partners?*

CHIMINSKI: Historically, innovator companies have had limited access to payers' formulary decision-makers until very late in a product's development or even at launch. Lack of communication between drug manufacturers and payers during the earlier parts of the drug development process leads to costly gaps between subject adherence rates during clinical trials and patient adherence rates in the real world. It benefits both payers and drug manufacturers to sit down together early on in the drug development process to discuss the kinds of improvements products need to demonstrate.

Knowing the questions payers want answered while a drug is in early-stage development will increasingly become an integral part of the drug development process. It isn't easy to find the answers to these questions, but innovators and payers can together find ways to do so.

PV: *What are the benefits of working more effectively with partners?*

CHIMINSKI: The benefits of becoming more integrated with partners who can provide novel solutions to meet the new challenges of the drug development landscape are clear. In this new business model, companies should expect strategic delivery technology partners to solve real problems through formulation and dose form optimization, combined with packaging and other innovations to create payer-friendly drugs. Acting as one, both parties can take ownership of real challenges and new ideas, as well as co-invest in improved products. When both companies truly operate as real partners, they create more value for all involved — innovators, providers, payers, and patients. PV

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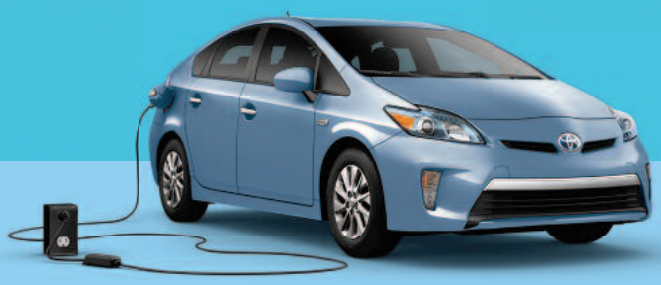

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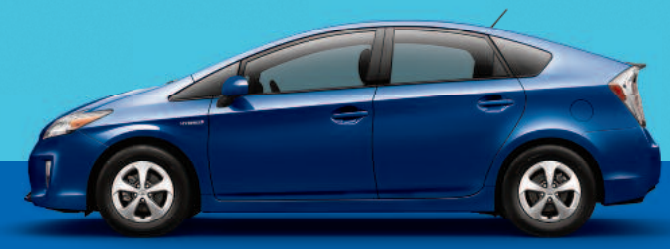

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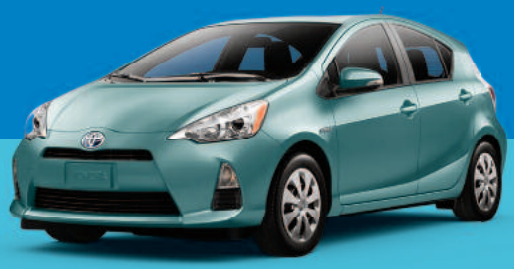

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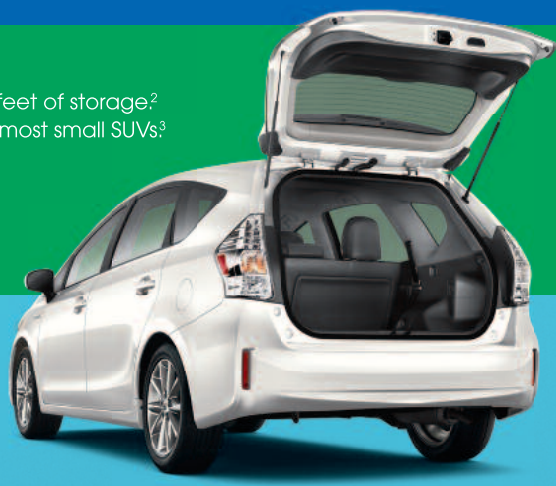

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