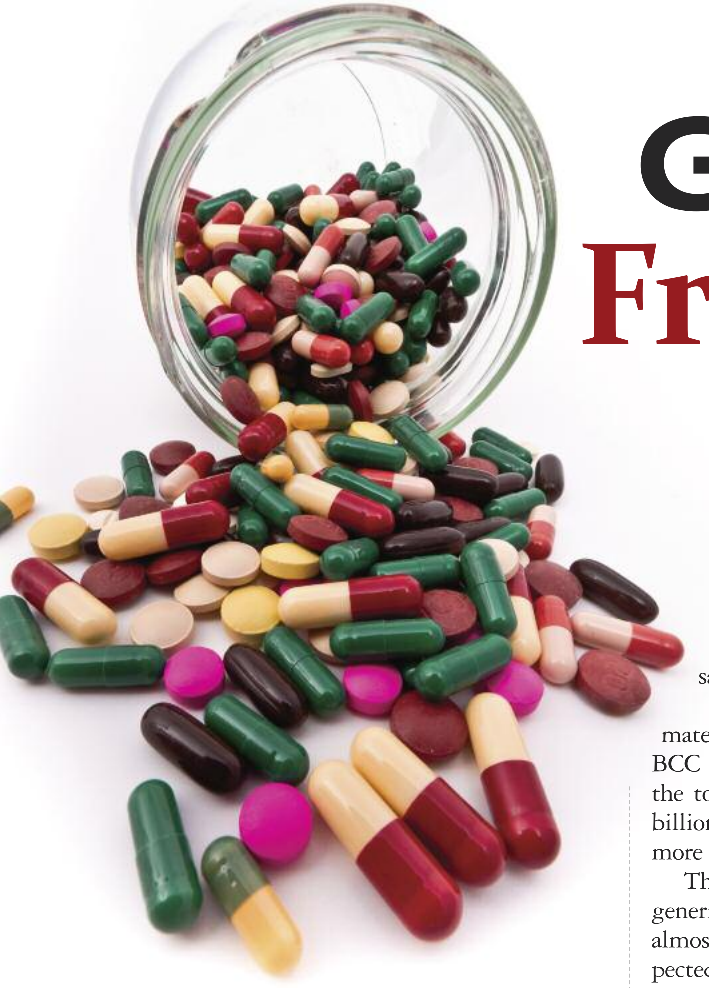


Denise Myshko

GENERICS: Front *and* Center

The generic drug era is impacting all areas of the industry as the demand for cost-effective medications increases.

As the demand for generics increases, originator companies are moving beyond the traditional end-of-cycle strategies and are deploying more aggressive tactics to not only protect their brands but to market their own generics.

David Fox, partner of the life-science practice at Hogan Lovells, says innovator companies are joining Novartis and Lilly and are branching out into the generic field, and some of the big generic players are building branded businesses.

"With the lines starting to blur, the diversity of the key players in the generic market is expanding," he says. "This is bringing about greater competition and one would hope greater growth in the both generic and the innovator markets. Some of the pure silos that we grew up with are no longer valid."

Long term, all manufacturers are going to make sure that their products can compete effectively in the marketplace, says Peyton Howell, president of AmerisourceBergen Consulting Services and senior VP of business development for AmerisourceBergen.

"This means as products mature, companies will need to have carefully planned and potentially more aggressive strategies in place in terms of pricing, payer contracting, and managed market negotiations," she says.

The global generics market was estimated at $225 billion in 2011, according to BCC Research. By 2016, it is expected that the total global generics sector will be $358 billion, a CAGR of 9.7%, and representing more than 18% of all pharmaceuticals.

The North American market is the largest generic market and was estimated to be almost $73 billion in 2011 and is expected to increase at a CAGR of 7.9% to reach $107 billion in 2016, according to BCC Research. Emerging markets represent the second-largest market category for generic drugs with a value of $57 billion in 2011 and growth of 15.1% reaching almost $115 billion in 2016.

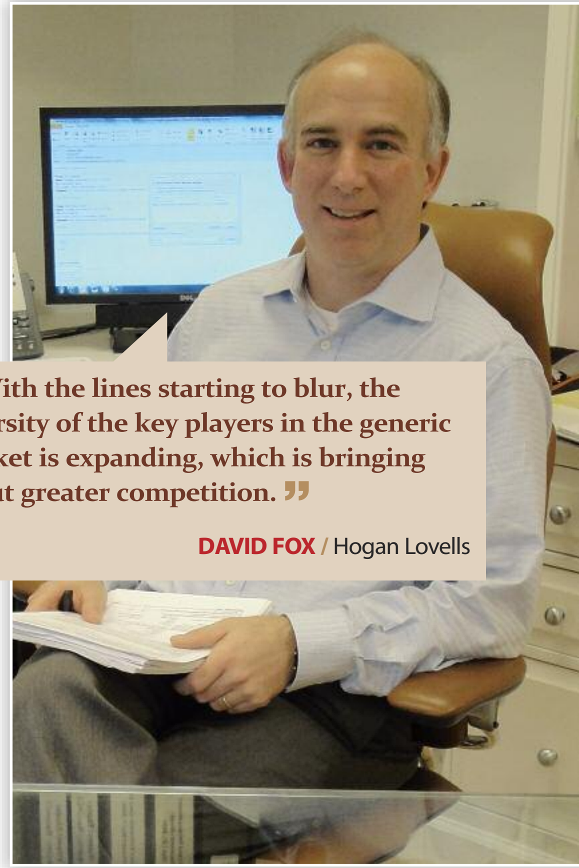
The reason the generic market is so large in the United States is that there is a huge need to reduce the cost of healthcare while providing access to consumers, says Doug Boothe, CEO of Actavis Inc.

Generics provide an opportunity because of their scale, Ms. Howell says.

"The growth of the generics market is fundamental to the cycle of the business," she says. "There is also an increased awareness of multisource products and their ability to provide the best value in the marketplace. Payers and individual providers are looking for value for their patients and they are realizing that reducing out-of-pocket costs is critical for patient adherence to treatment regimens."

The Patent Cliff

Alan Sheppard, global head of generics at IMS Health, says the main driver of generics growth will continue to be the long list of key molecules set to lose patent protection over the next couple of years.



> **"With the lines starting to blur, the diversity of the key players in the generic market is expanding, which is bringing about greater competition."**
>
> DAVID FOX / Hogan Lovells

One of the first of the blockbuster drugs to lose patent protection was Pfizer's Lipitor, which had sales of $2.63 billion in 2010. Several generic versions were released very quickly. On Nov. 29, 2010, Watson Pharmaceuticals received approval for its version, and on Nov. 30, the FDA approved Ranbaxy Laboratories' generic version of the cholesterol-lowering drug. And in December Teva Pharmaceutical Industries was granted tentative approval for its version of atorvastatin.

But Pfizer is making bold moves to hold on to Lipitor's sales. Some of the company's efforts include: offering insured patients a discount card to get Lipitor for $4 a month, far below

the $25 average copayment for a preferred brand-name drug; paying pharmacies to mail Lipitor patients offers for a $4 copay; keeping U.S. marketing spending nearly level until the last minute, versus the typical two-thirds drop in a drug's final year under patent; and negotiating unusual deals with some insurance plans and prescription benefit managers. The last move has generated some controversy.

"It would appear that Pfizer is seeking to retain volume sales of Lipitor by competing on price, thus extending the brand value beyond patent expiry," Mr. Sheppard says. "Provided there remains the potential to increase the usage of Lipitor and prices do not fall too low, then Pfizer can expect to retain volume sales in key areas.

"Strategic pricing of off-patent medicines is now a key focus as payers seek to reduce prices postpatent expiry, and one way to retain volume sales — albeit at reduced margins — is to compete with generics on price," he continues. "This may involve reducing the price of the original brand or launching a second brand or even a generic alternative, depending on regulations."

Experts say one of the biggest drivers in the generics market in terms of volume and value isn't necessarily patent expirations but Paragraph IV certification within Hatch-Waxman, which applies when patent protection has not expired but the generic drug maker claims either that the patent is invalid or that its product does not infringe the patent.

Mr. Fox says there always seems to be another cliff ahead.

"The terrain is always bumpy," he says. "There will always be those big targets whose patents are coming to their natural end. From a trends perspective, patents have a predictable cycle, which will always be present in the industry."

Mr. Sheppard says many originator companies are either already playing in the generic market — particularly in the pharmerging markets where branded generic medicines dominate and originator companies have the skills and resources to be effective players — or are considering their options.

"In many countries, there are escalating drug costs due to demographics and increasing use of innovative premium priced drugs, he says. "Because many of the new generics are of brands of gold standard therapies, there exists the potential to increase generic utilization and save costs, particularly in the current financial environment."

The Best Offense is a Good Defense

Cutting Edge Information analysts recommend branded pharma companies devise a well-rounded strategy. Defensive pricing is a widespread undertaking; 57% of surveyed companies employed some form of pricing defense in the years 2008 to 2010. Similarly, 49% plan to use defensive pricing between 2011 and 2013. The cost of this counter-generics option may help to explain its frequent use; in most cases, it is not expensive.

For brand teams, defensive pricing provides the flexibility of immediate implementation. That is, teams who choose to employ a defensive pricing plan can expect to apply that plan within weeks. In fact, 77% of responding companies begin planning a defensive pricing strategy within two years before patent expiration. The other 23% begin planning between two and four years prior to patent expiration. PV

"We and the other generic manufacturers are contributing a solution to the crisis of access to healthcare that is occurring here in the United States and around the world."

DOUG BOOTHE / Actavis

"As products mature, all manufacturers will need to carefully plan potentially more aggressive strategies in terms of pricing, payer contracting, and managed markets negotiations."

PEYTON HOWELL / AmerisourceBergen

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