GENERICS MANUFACTURING AND CHANGING EQUIPMENT NEEDS

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The global market for generic drugs is poised for ongoing rapid growth, owing to a range of drivers, including market forces, looming patent cliffs and regulatory guidance promoting generics as a workable solution to the growing costs of healthcare. The development of new generic products redistributes the manufacture of a given drug from a single to multiple companies, with corresponding shifts in the deployment of relevant equipment assets.

MARKET GROWTH IN GENERICS

The global generics market is predicted to grow continuously and rapidly over the next several years. According to a report by Zion Market Research, the generics drug market is expected to balloon into the next decade, growing at a compound annual growth rate (CAGR) of approximately 10.8% from 2016 to 2021. The report predicts that the generics market will reach $380.60 billion by 2021, which is nearly double the approximate worth of the segment in 2015, which was $200.20 billion.[1]

This push toward generics is being driven by a host of factors. As drug prices rise and the overall spending on healthcare increases, both the government and private sector insurance companies are seeking ways to level out costs without jeopardizing access to life-saving medicines for populations that are most in need. In addition, the demand for drugs has increased in both the United States and emerging markets, with a global geriatric population steadily growing. As a cheaper way to access the same medicines, generic drugs have become increasingly important as a more accessible option for those who are in need of care and are unable to afford branded drug products.

FDA ENCOURAGEMENT AND APPROVAL OF GENERICS

Generic drugs are in a unique position in the industry, largely because of the promise they hold for reducing costs and extending access. This promise has been recognized and championed by the U.S. Food and Drug Administration (FDA) under Commissioner Scott Gottlieb. Dr. Gottlieb has pushed for the development of generics by releasing a series of guidances to the industry on how to "genericize" even drugs with the greatest manufacturing complexity.

In a statement released in October 2018, Dr. Gottlieb emphasized the agency's encouragement of efforts taken to replicate complex drugs in generic form, noting that this furthers the wider mission of medicine by broadening the use of existing therapies.

"These draft guidances are aimed at ensuring that we provide as much scientific and regulatory clarity as possible with respect to complex generic drugs. This focus is critical because, first and foremost, these drug products provide important therapies to patients. We believe they're also becoming increasingly significant to the economic health of the generic drug industry. Being able to 'genericize' a complex drug can be a high-value opportunity for a generic drug developer," read the statement. "Addressing these challenges – and promoting more generic competition to complex medicines – is a key part of our Drug Competition Action Plan, and our efforts to promote patient access and more affordable medicines," Dr. Gottlieb concluded.[2]

FOR CDMOs LOOKING TO BEGIN MANUFACTURING GENERICS OR LOOKING TO EXPAND THEIR PORTFOLIO TO INCLUDE A NEW GENERIC DRUG, **PROCURING MACHINERY FROM A TRUSTED USED EQUIPMENT DEALER SERVES AS A WAY TO GUARANTEE RELIABLE EQUIPMENT FROM LEADING OEMs AT A REDUCED PRICE AND LEAD TIME.**

In addition to releasing a number of generic guidances, Commissioner Gottlieb has made it clear just how interested the agency is in driving generics to market by approving them in droves. The FDA set a record for approving the highest number of generic drugs in one month, with 126 total approvals (96 full and 30 tentative) in July 2018.[3] While that month was a standout, it was an extension of a larger trend.

In late January 2019, Gottlieb issued a statement outlining the agency's intention to advance additional policies to promote generic competition for complex drugs, which are typically more difficult to copy owing to their formulation, delivery systems or the complexity of their active ingredients but nonetheless present the potential for generic drug developers and, more importantly, benefits to patients.[4] He further discussed how the FDA's increase in inspections of generic drug plants – particularly the increasing ratio of pre-approval versus surveillance inspections – reflects a move to a more risk-based inspection model that will help achieve more generic approvals.[5]

The trend of rapidly and frequently approving generics has given them a special significance, especially in the current American climate. As the national dialogue over drug pricing comes to a head, there is momentum behind generics. Generics are perceived as a possible remediation to what many consider to be a drug-pricing crisis, and this positioning has been greatly bolstered by action taken by the FDA.

THE GENERIC OPPORTUNITY

The high demand for generics from a host of players – including the FDA, the government, insurance companies and patients globally – indicates that there is a tremendous opportunity for drug manufacturers that begin to produce generic medicines.

In order for a generic company to demonstrate that their drug is the same as the branded version, the drug must meet the following specifications, according to the FDA:[6]

+ The active ingredient in the generic medicine is the same as in the brand-name drug/innovator drug.
+ The generic medicine has the same strength, use indications, form (such as a tablet or an injectable) and route of administration (such as oral or topical).
+ The inactive ingredients of the generic medicine are acceptable.
+ The generic medicine is manufactured under the same strict standards as the brand-name medicine.
+ The container in which the medicine will be shipped and sold is appropriate, and the label is the same as the brand-name medicine's label.

CDMOs AND ORIGINATOR COMPANIES IN GENERICS PRODUCTION

Contract development and manufacturing organizations (CDMOs) occupy a key position in the supply chain in regard to

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generics. A drug often passes from an originator company (this company can range from virtual pharma to big pharma) and on to a CDMO, which is the company with the expertise and the resources to actually make the drug. A CDMO that has produced product for an originator company is in a unique position to be able to manufacture product for a generics company as well, given that they are able to use the same machinery and achieve a conforming product.

THE PATENT CLIFF

As a number of blockbuster drugs edge closer to (or completely fall off) the patent cliff, many companies are eyeing the opportunity to manufacture these drugs for the first time as generics. This shift in manufacturing from one company to another has led to an interesting situation with regard to equipment assets. There can be a simultaneous demand for – and surplus of – relevant machinery following a drug's clearance for generic production. While generics-producing firms seek the necessary equipment to make their product available to the market, originator companies are often faced with a surplus of machinery as the market share of their blockbuster product declines.

NAVIGATING ASSET SURPLUS AND PROCUREMENT

As a trusted equipment resource with a long history in the pharmaceutical industry, Federal Equipment Company has years of relevant experience both acquiring surplus machinery from facilities that are no longer in need of it and selling used equipment to those that do. Beyond the cost savings and short lead times associated with purchasing dependable used equipment, our business model provides a particular benefit in the context of generics manufacturing. Since FDA regulations mandate that manufacturing of generic drugs match the manufacturing of the originator products, the indirect acquisition by a generics manufacturer of equipment formerly used for the originator product would constitute an ideal scenario. Divesting themselves of surplus equipment also benefits the originator company by freeing up room on their facility floor and creating a return on investment on machinery that is no longer viable for them.

This win–win situation can be facilitated from start to finish by a used equipment dealer such as Federal Equipment Company. We are equally equipped to provide solutions to companies that are in need of machinery as those who are dealing with a surplus of equipment on a global scale. For example, there is an increasing demand for manufacturing equipment in Eastern Europe, with a corresponding equipment surplus in Western Europe. Following the recent establishment of a European office in the Netherlands, we are well positioned to partner with European companies looking to divest or acquire equipment assets.

Our turnaround time – taking a machine from our warehouse straight to the factory floor of the company where it is needed – can happen in days or weeks, rather than months as is typical with new equipment. Our fast delivery increases speed to market; gaining time with a machine and having it in use immediately can produce tangible benefits for a company's bottom line.

For CDMOs looking to begin manufacturing generics or to expand their portfolio to include a new generic drug, procuring machinery from a trusted used equipment dealer serves as a way to guarantee reliable equipment from leading OEMs at a reduced price and lead time. As generics become a more viable option and blockbuster drugs fall off the patent cliff, the opportunity to manufacture generics has become even more attractive, especially when equipment can be acquired quickly and at a reduced cost. As the FDA continues to champion and rapidly approve generics that are manufactured identically to their branded counterparts, the sector is poised for significant growth and presents an enormous opportunity, especially for CDMOs that are already adept and experienced with manufacturing for originator companies. P

REFERENCES

1. *Global Generic Drug Market Size Share to Reach 389 Billion by 2021.* Zion Market Research. 21 Mar. 2018. Web.
2. *Statement from FDA Commissioner Scott Gottlieb, M.D., on new efforts to advance the development of generic copies of complex drugs to improve patient access to medicines.* U.S. Food & Drug Administration. 9 Oct. 2018. Web.
3. Levy, Sandra. "FDA commissioner Gottlieb touts record number of generic drug approvals in July." *Drug Store News.* 10 Aug. 2018. Web.
4. *Statement from FDA Commissioner Scott Gottlieb, M.D., on 2019 efforts to advance the development of complex generics to improve patient access to medicines.* U.S. Food and Drug Administration. 30 Jan. 2019. Web.
5. Palmer, Eric. "FDA moving to 'risk-based' inspections even as valsartan scare adds new wrinkle to oversight." *Fierce Pharma.* 30 Jan. 2019. Web.
6. "Generic Drug Facts." U.S. Food & Drug Administration. 4 Jun. 2018. Web.

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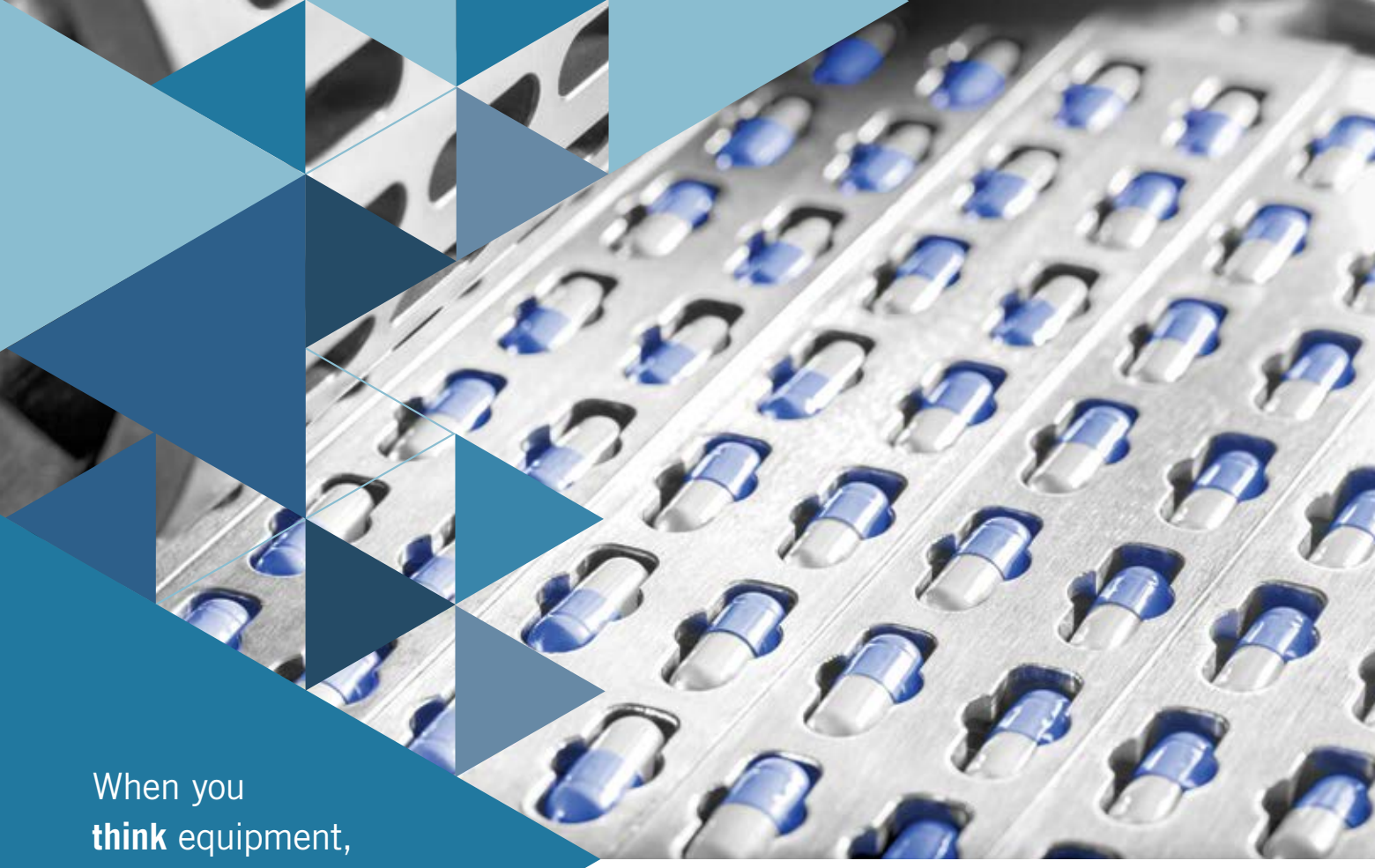

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