# Do Drugs That Treat the Same Indication Compete with Each Other?

High drug prices and the rate at which they are increasing worry most Americans. A quarter of Americans report difficulties affording their medications. Recognizing the need to control spending on prescription drugs, the Federal Trade Commission (FTC) held a workshop on November 8, 2017 entitled "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics." At the workshop, Acting FTC Chairman Maureen K. Ohlhausen asserted that "competition is key to containing prescription drug costs"[1] and Commissioner of the Food and Drug Administration (FDA) Dr. Scott Gottlieb said that "one of my highest priorities as FDA Commissioner is to increase competition in the market for prescription drugs and facilitate entry of lower-cost alternatives, like generics."[2]

In his remarks at the FTC workshop, Dr. Gottlieb emphasized the common ground between the FDA and FTC: improving competition in the pharmaceutical industry to bring down prices and give patients access to transformative medications. He acknowledged the need to reward innovation, like breakthrough and transformative medications for cancer, and emphasized that patients benefit both financially and therapeutically when there are treatment choices. Dr. Gottlieb indicated that competition improves when a second drug enters a drug category and recognized the FDA's role in balancing access and innovation. In response, he introduced a new program to expedite approval of the first three generic equivalents of a medication and to reduce the length of drug approval (to 8 months for priority drugs) to help drive down costs of development and encourage new market entrants.

The shortened approval time can mean earlier access for patients. It may also encourage more drugs to enter the marketplace, resulting in increased competition between drug companies. Currently, although smaller, more agile companies may have an advantage in the innovation and early stages of drug development, they are

unable to compete with larger companies in running large Phase III clinical trials, marketing, and selling new drugs. If the costs of drug development are lower, smaller companies can fully develop and commercialize their products without having to partner with or get acquired by a larger company. As a result, more drugs could enter the marketplace to increase competition between drug companies.

**Having Treatment Options Can Lower Prices for Pharmaceuticals**

In a free market, prices are determined by the level of supply and demand of products that compete with each other. As manufacturers produce more options, patients and physicians can decide which option is better and more cost-effective. Competitive pressures in a free market force prices to reflect the relative value to patients. For example, if two treatment options are medically equivalent, patients and physicians would choose the cheaper option. If one treatment option provides better efficacy for some patients or lower side effects, patients are given the option to choose. Some patients may be willing to pay a premium for the additional benefits, but patients who don't experience the side-effects or have a disease adequately controlled by the first treatment option can choose the lower priced alternative. A free market in which patients and their doctors make decisions about treatment options based on both cost and effectiveness also encourages competition, as manufacturers try to develop better treatments for which patients are willing to pay more.

This kind of competition has proven to lower prices for Hepatitis C (HCV) drugs. In 2013, the FDA approved Sovaldi from Gilead Sciences, as the first curative treatment for Hepatitis C, and soon after combined Sovaldi with ledipasvir to make Harvoni, an even more effective treatment.[3] At $94,000 for a 12-week course of treatment, however, many patients could not afford the drug and many state Medicaid programs limited coverage. In 2014, the FDA approved Viekira Pak from AbbVie. AbbVie priced Viekira Pak at $54,000 for a course of treatment and Express Scripts dropped Harvoni coverage for people with HCV genotype 1. Since that time, more entrants into the HCV market have further brought down prices.[4]

### But… Competition *Rarely* Decreases the Price for Patent-protected Pharmaceuticals

The pharmaceutical market, however, is far from a free-market and this kind of competition seems to be an exception rather than the rule when it comes to prescription drugs. A study by the Alliance of Community Health Plans found that drug costs for widely prescribed medications *increased* substantially for many therapeutic classes including rheumatoid arthritis (RA), multiple sclerosis (MS), and diabetes, even though there were multiple treatment options for each disease. More than a dozen treatment options exist for multiple sclerosis, for example, but even the first generation of drugs to treat MS (interferon (IFN)–β-1b) that originally cost $8,000-$11,000 per year can now cost more than $60,000 per year, and there are no treatments for MS that cost less than $50,000 annually (not accounting for manufacturer's coupons).[5] A study by researchers at Oregon State University found that rather than driving down prices, manufacturers increased the price of existing drugs when a new treatment option became available for MS.[6] The authors say "the simplest explanation is that pharmaceutical companies raise prices of new and old [treatments for] MS in the United States to increase profits and our health care system puts no limits on these increases. Unlike most industrialized countries, the United States lacks a national health care system to negotiate prices directly with the pharmaceutical industry."[7] A growing body of literature suggests that in many disease areas, the release of a new drug drives prices up rather than down, as drugs do not seem to compete on price.[8]

### Factors Preventing Competition from Driving Down Prices

So why don't competitive pressures drive down prices in the pharmaceutical industry? Many factors prevent drugs in the same therapeutic class from competing on price. The most robust kind of competition is generic competition, where drugs with the same active ingredient compete with a branded drug for which the patent has expired. Generic competition reduces prices substantially. A study analyzing the top fifty selling drugs in 2014 found that after a generic competitor enters the market, the branded drug dropped to 16% of its original market share.[9] As a result

of the substantial decrease in market share, brand-name manufacturers employ a variety of techniques to reduce generic competition.[10] Given that competition with generics is an important driver of price reductions, why doesn't competition between drugs that are not chemically equivalent, but treat the same indication, also drive down prices?

- The principal-agent problem: A doctor, in consultation with the patient, chooses the treatment but does not pay for the treatment. Physicians are often unaware of treatment costs[11] and frequently don't discuss cost as part of the treatment decision-making process with patients.[12] The insurer, Medicare, Medicaid, or the patient, if he or she does not have prescription drug coverage, pays for the treatment and has little or no impact on what treatment choice is made. If a patient has good drug coverage, he or she is insulated from considering the price of a treatment. Economists refer to situations like this as a principal-agent problem, where the agent (the physician) making decisions is not the one who bears the consequences or costs of that decision (the principal).

- Lack of Price Transparency: A comprehensive report from the Commonwealth Fund states that "a lack of price transparency and availability of information about the comparative value of similar therapeutic drugs makes the drug marketplace less efficient. It also undermines the goal of robust price competition to ensure patient access to the most important drugs."[13] Without knowing the cost of a drug, specifically what the out-of-pocket costs will be for a patient, the doctor and patient cannot accurately assess whether to try a cheaper alternative treatment.

- Prescription drug formularies: Pharmacy benefit managers (PBMs) and insurers often institute a prescription formulary for beneficiaries of insurance plans. Pharmacy and therapeutics (P&T) committees ensure that formularies include enough drugs to satisfy health plan beneficiaries and give physicians a sufficient number of treatment options.[14] The

formularies, however, are often a result of negotiations with drug manufacturers and don't necessarily result in lower prices for patients. Because the negotiations about a formulary typically include all drugs made by that manufacturer as a package, the price of any one drug can be shielded from competition. In addition, drug manufacturers can negotiate terms that offer significant discounts for a particular product in exchange for keeping competitors off preferred tiers in a formulary. For example, Pfizer filed a lawsuit against Johnson & Johnson (J&J) alleging that J&J forced insurers to enter into "exclusionary contracts" that kept patients from using Inflectra, Pfizer's biosimilar drug for J&J's Remicade. Even though Inflectra cost 30% less than Remicade, less than 1% of patients used Inflectra because it was not included in most formularies.[15] In the end, formularies restrict patient choices and prevent competition between drugs that treat the same indication.

- Manufacturer Coupon Programs: Brand manufacturers can provide patients with coupons and other financial assistance to cover the cost of their prescription co-pays. Since insurers typically cover about 80% of the total price of a prescription, manufacturers can make more money by charging a higher price to insurers, even if they do not collect the 20% of the cost that the patient would pay. These incentives undo financial pressure that would otherwise steer demand to lower-priced alternatives. They prevent patients from choosing treatments with the lowest overall cost because the patient can get the expensive drug with minimal cost-sharing. Anti-kickback statues prevent Medicare and all beneficiaries of federal health care programs from using these coupons,[16] but the practice is still common for patients covered by private insurance. A study by Leemore Dafny, Christopher Ody, and Matt Schmitt estimated that coupons increased the total spending on pharmaceuticals by at least $700 million and perhaps as much as $2.7 billion between 2005 and 2010.[17]

Each of these four market inefficiencies limit competition between drugs for the same condition. As a result, the price for branded drugs could even increase when a new drug is released. If the new drug shows improvement over existing treatments, it could command a higher price than current treatments. The lack of meaningful price competition, however, allows existing treatments to raise their prices to just slightly less than the price of the newly released drug. The study cited above demonstrates how the prices for drugs that treat MS are an example of this behavior. After the Food and Drug Administration approved IFN-β-1a SC (2002), natalizumab (reintroduced 2006) and fingolimod (2010), the prices for previously existing drugs to treat MS increased and remained high.[18]

**What's the FDA to do?**

If different chemical entities do not compete with each other even when they treat the same indication, what can the FDA do to promote competition and reduce drug prices? The FDA's primary responsibility is to assess the safety and efficacy of pharmaceuticals and medical devices.[19] Commissioner Gottlieb acknowledges this role, but goes a step further to assert that the FDA has a role in promoting competition to reduce prices.[20] While the FDA should streamline the application process for new molecular entities (NMEs) and reduce any administrative barriers that increase the review time at the FDA, the FDA should not prioritize the review of NME applications as a means to increase competition.[21] The 21st Century Cures Act[22] allows the FDA to use "real-world evidence" to assess the safety and efficacy of drugs.[23] While the use of real-world evidence may shorten drug development time and allow patients earlier access to new treatments, many have argued that the 21st Century Cures Act lowers the bar for approval.[24],[25] The lower bar may give patients access to ineffective or even unsafe drugs. In a webinar on January 4, 2018, Adam Feuerstein and Damian Garde from STAT News questioned how low the approval bar could get at the FDA. They noted that the science and evidence about new drugs that manufacturers submit to the FDA are improving and the FDA is faster and more flexible than past administrations at approving new drugs. In 2017, the FDA approved a record number of new drugs, including 46 new molecular

entities (NMEs) and 10 biological therapeutics,[26] as Commissioner Gottlieb believed that additional approvals are an indirect way of increasing competition and bringing down drug prices.

The evidence suggests, however, that additional treatments for the same indication do not compete efficiently and may even result in *higher* prices for patients as companies raise the prices for existing drugs to be slightly lower than those of newly approved treatments. In addition, if the FDA keeps a high bar on safety, but lowers standards of efficacy, patients and insurers will waste money on ineffective treatments. As such, the FDA should not compromise standards of safety and efficacy in an attempt to reduce drug prices. Other agencies must work to address fundamental inefficiencies in the pharmaceutical market as identified above, such as increasing price transparency and strictly regulating co-payment assistance to patients. Only when patients and doctors *know* and *consider* the cost and effectiveness of different treatment options will branded drugs be able to compete with each other.

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[4] http://www.fiercepharma.com/pharma/abbvie-s-new-pan-genotypic-hep-c-drug-mavyret-undercuts-competition

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[15] See the Source blog post (http://sohc.modernchalk.com/pfizer-files-groundbreaking-lawsuit-against-johnson-and-johnson-alleging-anticompetitive-practices-in-the-market-for-remicade/) for more details and additional references.

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[19] https://www.fda.gov/AboutFDA/WhatWeDo/

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