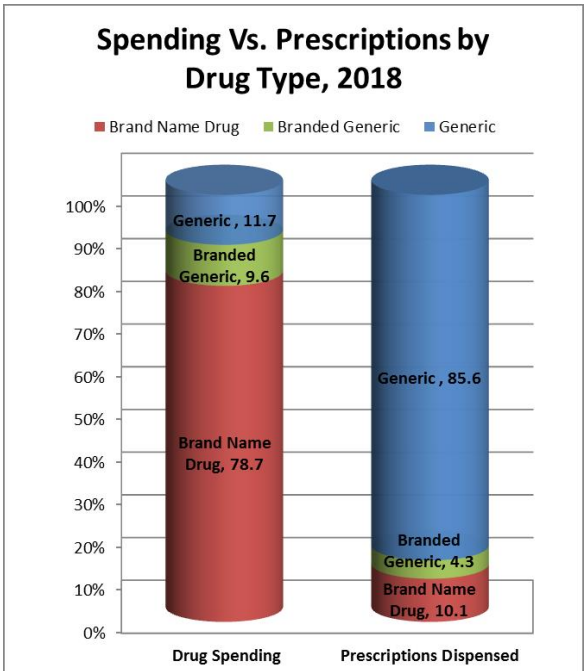
Feature Article: Comparing Three Kinds of Generic Drugs

In the United States, 9 out of 10 prescriptions are for generic drugs. The number of generics continues to grow as more brand name drugs are coming off patent, opening the door for non-brand name drugs that are therapeutically equivalent. In 2019, several well-known brand name drugs became available as generics, including Lyrica (for fibromyalgia), Narcan (emergency treatment for opioid overdose), Eliquis (stroke prevention), Gilenya (multiple sclerosis), and Viibryd (major depression).

This chart shows how generics (in blue) account for a relatively small portion of total spending on drugs (about 11%), but account for more than 85% of the drugs sold:



For United States. Chart by AskaPatient.com June 2020. Data Source: HDA Research Foundation 2019 Fact Book . Note: Breakdown of Authorized Generics not available. Based on 2018 CMS practice, this spending may be included within Brand Name Drug Spending.

While most people think of a generic as a cheaper version of a brand name drug, there are actually three distinct kinds of generic drugs. Arguably, the definitions can be hazy for two of them (authorized and branded generics), leading to confusion among consumers. The confusion even carries over to the health care system, because of the way behind-the-scenes rebates by manufacturers and pharmacy benefit managers (PBMs) have been "strategically" calculated in order to increase profits. (See Resources section at the end for link to recent news on the topic of rebates.) Here is an overview of the three kinds of generic drugs:

Unbranded Generics

This category has the most number of drugs, and includes what we think of as traditional generic drugs.

- When it can be sold: These generics can be sold after the branded drug's patent expires, and are manufactured by a company that has had a generic drug application (called an **Abbreviated New Drug Application** or ANDA) approved by the FDA.

- Ingredients and Manufacturing: The generic drug must have the same active ingredient, same strength, conditions of use, and dosage form as the brand name version, but may use different inactive ingredients and production methods. The drug may look different than the brand, but is considered to be "therapeutically

equivalent." More than 80% of generic drug active pharmaceutical ingredients are made overseas, and lately questions about manufacturing quality have been a topic of concern by lawmakers and others.

- **Availability and Number of Suppliers:** Widely available, often from many suppliers. However, not every brand name drug that is eligible to be developed as a generic has a generic equivalent. In fact, the FDA publishes a list of drugs that are "available" to be developed as generics.
- **Examples:** The osteoporosis drug **Actonel** 35mg. has six companies with ANDA approvals. Antidepressant Zoloft (sertraline hydrochloride) has ten generic versions of its 50mg tablets. More examples can be found on the FDA web site. To find out if there are generics available for a particular drug, search the Drugs@FDA database for a brand name drug, then scroll down to "therapeutic equivalents" tab to view all of the approved generics for the drug.
- **Advertising:** Generic drugs may not be advertised to consumers; they are known by their **chemical ingredient name**.
- **Price:** This is the **least expensive** kind of generic drug. It is not uncommon for consumers to notice that a bottle of generic pills may be less expensive than an over-the-counter medication.

Authorized Generics

Sometimes, shortly before a branded drug goes off-patent or even sometimes years afterwards, a maker of a brand name drug will create its own version of a generic, which is called an "authorized generic." This is a growing category of drugs, and the FDA now has more than **1,200 brand formulations** on its quarterly list of authorized generics, representing **563 unique product names**.

The reason for the growth in the number of authorized generics, according to one expert, is that "Of all the ways drug companies try to protect sales as patents expire — changing doses, adding ingredients, seeking approval to treat new diseases — authorized generics are by far the most profitable, returning $50 for every dollar invested, research firm Cutting Edge Information calculated in 2015." *U.S. News* reported that by 2014, more than one-third of brand drugs had a matching authorized generic.

- **When it can be sold:** May be sold before and after the drug patent expiration. The company does NOT have to file the Abbreviated New Drug Application with the FDA, because it is making the product based on the original drug's **New Drug Application** (NDA). May be sold concurrently with the brand name drug; may be sold after the brand name has been discontinued.
- **Ingredients and Manufacturing:** Authorized generics are made in exactly the same way as the brand name drug, using the same active and inactive ingredients. It might be made by the original manufacturer, a generic company that is owned by the brand name company, or a contracted company. The FDA requires that the pharmaceutical company notify the FDA if it markets an authorized generic, but the information is **not** included in the FDA database of approved drugs. The NDA holder may market both the authorized generic and the brand-name product at the same time.
- **Availability**: Can be more difficult to find if unbranded or branded generics also exist for the product. Some consumers go out of their way to request an authorized generic or pay extra for it because they find it is more effective.
- **Examples:** Actonel, Lyrica, Geodon, Plaquenil, Lipitor, Straterra, and many more. Companies that make them include Greenstone, Prasco, Patriot, Sandoz, Par, and others.
- **Advertising:** Authorized generic drugs may not be advertised to consumers; they are known by their **chemical ingredient name**.
- **Price:** This is the **most expensive** kind of generic, but it is generally less expensive than the brand name drug.

Branded Generics

A generic that is labeled with a brand name instead of the ingredient name is considered to be a branded generic.

- When it can be sold: Branded generics can be sold after the original branded drug's patent expires. The branded generic must go through the same approval process as an unbranded generic: they are manufactured by a company that has had an **Abbreviated New Drug Application** (ANDA) approved by the FDA.

- Ingredients and Manufacturing: The branded generic drug must have the same active ingredient, strength, conditions of use, and dosage form as the original brand name version, but may use different inactive ingredients and production methods. The drug may look different than the original brand, but is considered to be "therapeutically equivalent."

- Availability and Number of Suppliers: Branded generics are losing market share in the U.S., but are growing in popularity in low and middle-income countries. In 2003, 11% of all prescriptions in the U.S. were for branded generics, but by 2018, that number dropped to 4% (see chart above).

- Examples: Oral contraceptive Chryselle (norgestrel and ethinyl estradiol) progesterone drugs Prometrium and Endometrin, antibiotic Trimox (amoxicillin), Digitek (digoxin), Nifedical (nifedipine), Levoxyl, Levothroid, Unithroid (levothyroxine)

- Advertising: Branded generic drugs may not be advertised to consumers. However, the products benefit from brand-name recognition, with names that are easier to pronounce than the chemical ingredients and so more likely to be a product that patients and doctors ask for by name.

- Price: More expensive than unbranded generics, but less expensive than authorized generics. As of 2018, branded generic products were 13 times more expensive than unbranded generics, and made up 21% of all generic products worldwide.

Sources and More Reading:

- Is an Authorized Generic Drug the Same Thing as a Generic Drug?
FDA questions and answers about the topic, as well as downloadable list.
https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs

- "The FDA Generics and Differentiating Authorized from Branded Types" by pharmacist Karen Berger
https://www.pharmacytimes.com/contributor/karen-berger/2018/05/the-fda-generics-and-differentiating-authorized-from-branded-types-

- The Value of Authorized Generics
https://health.usnews.com/health-news/patient-advice/articles/2016-05-19/the-value-of-authorized-generics

- Branded Generics: What They Are and Why They're Profitable
https://www.drugpatentwatch.com/blog/branded-generics-what-they-are-and-why-theyre-profitable/

- Drugmakers Master Rolling Out Their Own Generics To Stifle Competition
https://khn.org/news/drugmakers-now-masters-at-rolling-out-their-own-generics-to-stifle-competition/

- The bipartisan *Fair and Accurate Medicaid Pricing (AMP) Act of 2019* closed a loophole that had allowed pharmaceutical companies to compute "average manufacturer price" by averaging the price of an authorized generic with the brand name drug, thus greatly reducing rebates paid to Medicaid.
https://www.advisory.com/daily-briefing/2019/10/08/medicaid-rebate
In May, 2020, guidance was issued to industry: https://www.medicaid.gov/prescription-drugs/downloads/mfr-rel-112.pdf

This week we did not include news highlights because of the feature article. For the latest **COVID-19**, **FDA**, and other **health care news**, check the news feed section of our web site:

Pharmaceutical/COVID-19
FDA News and New Drug Announcements
Seniors Health

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Ask a Patient Weekly Healthcare Newsletter: June 21, 2020