February 6, 2020

To:
Senator Lamar Alexander, Senate HELP Committee Chair
Senator Patty Murray, Senate HELP Committee Ranking Mbr
Senator Chuck Grassley, Senate Finance Committee Chair
Senator Ron Wyden, Senate Finance Committee Ranking Mbr
Congressman Frank Pallone, House Energy & Commerce Committee Chair
Congressman Greg Walden, House Energy & Commerce Committee Ranking Mbr
Congresswoman Anna Eshoo, House Energy & Commerce, Health Subcommittee Chair
Congressman Michael Burgess, House Energy & Commerce, Health Subcommittee Ranking Mbr

From:
Martin VanTrieste
President & CEO
2912 Executive Pkwy, Ste 325
Lehi, UT 84043
martin.vantrieste@civicarx.org

RE: UNINTENDED CONSEQUENCES OF AN UNAPPROVED DRUG PROGRAM LEADING TO HIGH COSTS OF GENERIC DRUGS ORIGINALLY CLASSIFIED AS DESI (DRUG EFFICACY STUDY IMPLEMENTATION) BY THE US FDA

The purpose of this letter is to share Civica Rx's recommendation to close loopholes that lead to unreasonable price increases for decades-old drugs as a result of periods of exclusivity granted by the FDA for former Drug Efficacy Study Implementation (DESI) drugs.

Civica is a nonprofit, non-stock corporation committed to making quality generic medicines available and affordable. Civica was founded in 2018 by leading US hospital systems concerned about shortages of essential generic drugs and philanthropic organizations passionate about improving healthcare. Today, more than 45 health systems are Civica members, representing more than 1,200 US hospitals and over 30 percent of all licensed US hospital beds.

Civica acts in the best interest of patients to eliminate uncertainty in the generic drug supply chain through long-term contracts with Health Systems as well as Civica's manufacturing partners. An advisory committee of hospital pharmacists prioritizes the drugs Civica distributes.

Drug Efficacy Study Implementation (DESI):

DESI was a program begun by the US Food and Drug Administration (FDA) in the 1960s after the Kefauver-Harris Amendment, or "Drug Efficacy Amendment," resulted in a requirement for drug manufacturers to provide proof of both the safety *and effectiveness* of their drugs before approval. The DESI program was intended to classify all pre-1962 drugs that were already on the market as either effective, ineffective, or needing further study. The Drug Efficacy Study Implementation (DESI) evaluated over 3,000 separate products and over 16,000 therapeutic claims. By 1984, final action had been completed on 3,443 products; of these, 2,225 were found to be effective, 1,051 were found not effective, and 167 were pending[1].

The little-known FDA program that's driving drug prices higher[2]:

In 2006, the FDA introduced the "Unapproved Drugs Initiative" with the aim of removing unapproved drugs from the market, including DESI drugs and new drugs that were marketed without FDA approval. The Initiative required NDA (New Drug Application) approval for DESI or "grandfathered" drugs. Once the FDA approves an NDA for a DESI drug, the existing unapproved drugs are pulled from the market, until the pharmaceutical company obtains an ANDA (Abbreviated New Drug Application) approval from the FDA. The "new" drug with an approved NDA is treated as a material advance because it underwent testing for safety and efficacy—even though the DESI version was proved safe and effective over decades of actual use.

There are numerous benefits to receiving NDA approval for DESI or "grandfathered" drugs. NDA approval demonstrates to physicians, healthcare providers and patients that a drug is safe and effective.

The Sponsor of an NDA must demonstrate how the entire end-to-end manufacturing process is reliable and reproducible, and consistently meets standards of identity, strength, quality and purity. This is particularly important for the prevention of drug shortages.

In return pharmaceutical companies can potentially receive two to seven years of market exclusivity. With this exclusivity it was expected to result in moderate price increases to cover the cost of developing and maintaining the NDA. The benefit to patients is getting quality products with greater certainty of safety and efficacy.

However, the exclusivity period has had unintended consequences of a lack of competition and high price increases by the company holding the NDA. During a period of exclusivity, all other unapproved drugs must be removed from the market until additional manufacturers obtain ANDA approval. The ANDA development and approval process takes years of work by generic drug companies to develop the data and ANDA materials plus the time for the FDA to conduct inspections and review and approve the ANDA.

Recommendation:

To avoid high price increases for former DESI drugs, the FDA or Health and Human Services (HHS) Secretary Alex Azar should have the authority to eliminate this exclusivity by allowing competition to re-enter the market with DESI drugs. These re-entries would be previous manufacturers who suspended manufacturing upon approval of the NDA.

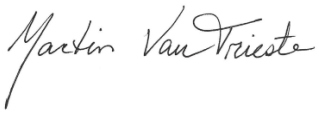
CIVICA™

Ideally, the FDA or HHS would remove this exclusivity 1) if the NDA holder enters into business practices to create an artificial monopoly, like exclusive contracts with all viable API manufacturers; 2) if the NDA holder is abusing the patent system to extend their exclusivity or; 3) if the NDA holder initiates predatory pricing, such as more than doubling the price of a drug.

In the past, the FDA has said such price increases are beyond its jurisdiction because it is not expected to take price into account when regulating a drug: "FDA does not regulate according to economic factors, nor do we have control over drug pricing," said an FDA spokesperson[2]. Civica strongly believes a legislative fix is required to close the loopholes that lead to massive price increases of decades old drugs as a result of filing 505(b)(2) NDAs for DESI drugs.

Please see attachment or click here for an addendum with examples of abuse of the DESI exclusivity.

Sincerely,



Martin VanTrieste
President and CEO
Civica Rx

1. Wikipedia: https://en.wikipedia.org/wiki/Drug_Efficacy_Study_Implementation
2. LA Times, By Michael Hiltzik, Business Columnist, SEPT. 23, 2015: https://www.latimes.com/business/hiltzik/la-fi-mh-the-little-known-fda-program-20150923-column.html