Promoting Competition for Legacy Drugs

Rethinking exclusivity options for legacy drugs to promote competition and rein in the high cost of drugs.

What are legacy drugs and why is competition in this market needed?

Legacy drugs were marketed before the Food and Drug Administration's standards of safety and effectiveness requirements were in place. As a result, they did not go through current approval pathways, but clinical use continued based on the belief that the products were either grandfathered (e.g., marketed before 1938) or generally recognized as safe and effective (GRASE). Several legacy drugs are well-established, commonly used across the care continuum and recognized by the FDA and Vizient as essential medications. Yet, in recent years, an increasing number of these drugs have been pulled from the market following the formal approval of one competitor and the exclusion of additional competition. As a result, prices spiked and access issues ensued, among other unintended consequences.

$7.52 billion

The amount of costs to the health care system that could be avoided if access and competition to legacy drugs is maintained.

Good intentions, unintended consequences

The Unapproved Drug Initiative (UDI) encouraged manufacturers to seek formal approval for legacy drugs, a noble intent given the need to ensure safety and efficacy of prescription pharmaceuticals. Furthermore, to incentivize manufacturers to obtain "new drug" approval for these products, FDA would remove competing legacy drugs from the market creating periods of exclusivity for the newly approved products. However, manufacturers would not necessarily need to perform clinical trials given approval could be based upon data from the published clinical literature. Therefore, these new approvals largely did not generate new clinical insight regarding medication safety and efficacy, thus making the incentives of extended exclusivity disproportionate to the investment made by manufacturers.

UDI drug approval 2013-2020*

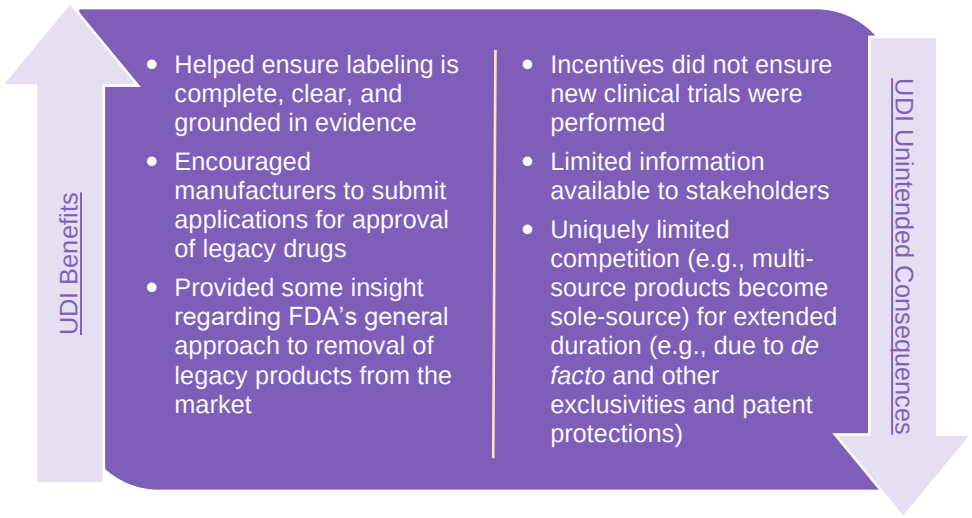
Unapproved drug	Approved drug	Exclusivity type	Exclusivity length	Percent WAC increase
Neostigmine Methylsulfate	Neostigmine Methylsulfate	de facto	Based on approval of additional products	525%; 10-ct pkg; currently 9.8% above original WAC
Vasopressin	Vasostrict	Patent protection	Through 2035	1644%; 25-ct pkg
Dehydrated Alcohol 98%	Dehydrated **Alcohol 99%**	Orphan indication	7 years	668%
Selenium 40 mcg/mL	Selenious Acid 60 mcg/mL	New Chemical Entity	5 years	1190%; 25-ct pkg
Multitrace-5	Tralement	New Chemical Entity	5 years	72%; 25-ct pkg

*These are examples of products approved from 2013-2020 and is not an exhaustive list of approvals.

Ref: Vizient report Sept 2020

Financial Consequences of Good Intentions: The unanticipated costs of the Unapproved Drugs Initiative (UDI)

In November 2020, guidance that provided the framework for the UDI was withdrawn by the Department of Health and Human Services (HHS), but manufacturers may still receive exclusivities and create access issues for providers and patients. While it is unclear whether HHS will reinstitute this framework, there is an opportunity to improve oversight of legacy drugs while addressing known consequences of the UDI.



What is needed?

Congress must close the loophole that essentially grants "de facto" exclusivity and prevent manufacturers from receiving benefits that vastly outweigh their investment when these products are approved. Vizient has also offered recommendations focused on regulatory approaches for the Department of Health and Human Services and FDA to consider to improve oversight and use of these medications.

Would it stop innovation?

NO! The manufacturers that received approvals for these legacy drugs either did not perform new clinical trials or conducted extremely small trials, and the products were, for the most part, already developed. Leaving this loophole open discourages innovation by providing manufacturers with greater exclusivity incentives for less work.

What will closing this loophole do?

It will save the US health care system hundreds of millions of dollars and encourage innovation by:

- Ensuring that manufacturers only receive market exclusivity for a drug already available as a legacy drug if they complete new and meaningful clinical studies
- Avoid drastic price increases and access challenges by preventing extra-statutory efforts to clear the market of legacy drugs based on one manufacturer obtaining approval
- Require FDA to provide clarity regarding the criteria for legacy drugs, so that manufacturers and the public understand which drugs are entitled to remain on the market absent approval
- Help control costs for the Medicare and Medicaid programs

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