

# NEWS DIGEST

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- UK: First drug approved under NICE's fast-track approval pilot process
- US: Bills to address lack of competition in pharma are advanced
- DTx: First FDA approved video game for ADHD expands its features
- UK: Issues another fine for unfair pricing practices



# UK: FIRST DRUG APPROVED UNDER NICE'S FAST-TRACK APPROVAL PILOT PROCESS

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## THE NEWS

This summer, NICE (UK HTA) is piloting a new cost comparison fast track appraisal process for the review of selected low risk appraisals. On Monday, August 2nd, the body published draft guidance for the first drug to ever undergo this process: Bimekizumab by UCB Pharma.

Bimekizumab has shown to be more effective in treating severe plaque psoriasis than its three comparators, all previously approved by NICE.

## HOW IT WORKS

The pilot program operates by using a subset of the appraisal committee to make a recommendation without the need for a full committee meeting. The selected committee members assess low-risk treatments, comparing them to similar therapies which have already been approved by NICE.

Once initial guidance has been prepared it is then considered by the entire committee prior to its release. If any concerns arise, a full committee meeting can then be scheduled.

source: <https://bit.ly/3fuaWnj>



# US: BILLS TO ADDRESS LACK OF COMPETITION IN PHARMA ARE ADVANCED

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## THE NEWS

On July 29th the Senate Judiciary Committee unanimously voted to advance four pieces of bipartisan legislation in response to a recent push against high drug prices driven by lobbying groups, the Senate Finance Chairman's pricing reform blueprint and Joe Biden's executive order.

Senator, Richard Blumenthal, comments:

"Abuses in the patent systems and the exploitation of loopholes in current law have kept generics off the market and stifled innovation. Our bill makes the patent system stronger by validating new products, spurring innovation, and protecting generics."

## THE LEGISLATION

The advanced legislations includes the following acts:

- Stop Significant and Time-wasting Abuse Limiting Legitimate Innovation of New Generics (Stop STALLING) Act (S. 1425)
- Preserve Access to Affordable Generics and Biosimilars Act (S. 1428),
- Prescription Pricing for the People Act of 2021 (S. 1388) and
- Affordable Prescriptions for Patients Act of 2021 (S. 1435)

source: <https://bit.ly/3rRoiPs>



# DTX: FIRST FDA APPROVED VIDEO GAME FOR ADHD EXPANDS ITS FEATURES

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## THE NEWS

Akili Interactive Labs have announced the expansion of their video game treatment EndeavorRx. The game was the first digital therapy to be approved by the FDA for the treatment of ADHD in June last year. Its 5 clinical trials have been described as central to gaining the approval.

A year on, the company has announced the introduction of new features as part of its patient-responsive approach. The features include additional quests and personalisation options to further increase engagement. Akili Interactive Labs highlights the need for rapid product iteration in delivering effective results for patients through DTx.

## HOW IT WORKS

The game helps children develop their ability to manage competing cognitive tasks and ignore distractions by presenting them with simultaneous sensory and motor stimuli.

Through adaptive algorithms patients receive personalised treatments that encourage them to continuously improve their performance and allow their progress to be tracked in real time.

source: <https://bit.ly/2TMUWVB>



# UK: ISSUES ANOTHER FINE FOR UNFAIR PRICING PRACTICES

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## THE NEWS

Less than two months after fining £260m to Auden Mckenzie and Actavis UK, now known as Accord-U, for "inflating NHS prices" the UK issues another pricing fine.

This time the fine equates to over £100m. It comes as a result of an investigation conducted by the Competition and Markets Authority (CMA) which unveiled Advanz's 1,110% price increase for thyroid tablet packs between 2009 and 2017.

## THE IMPACT

As increasing numbers of excessive price inflations are uncovered we observe stricter pricing rules and reformations being introduced across the globe. These in turn impact the future and pricing freedom of the entire pharmaceutical industry.

One of the most recent examples of strictening pricing rules and regulations includes the newly advanced pharmaceutical pricing acts from the previous article. In addition, we anticipate numerous further changes on the horizon for the US in particular as Biden's executive order comes into play.

source: <https://bit.ly/3xilw5E>



# GET IN TOUCH

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*"We always welcome your thoughts and opinions on the topics raised here.*

*If you'd like to share anything or hear how we can support you in getting your product to market email Paul and Graham, managing directors, today at:*

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