

New drugs with high abuse potential more likely to be approved, go to market to treat pain

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"Despite the prevalence and societal costs of pain in the United States, investment in pain medication development is low, due in part to poor understanding of the probability of successful development of such

medications," said the authors of a study published online first in *Anesthesiology*.

"The opioid crisis has highlighted the need for new therapeutics with low abuse potential to treat chronic pain," they said. "While pharmaceutical companies recognize this need, because of the subjective nature of pain ... the conduct of clinical trials for new drug approval is a lengthy and costly proposition." According to the authors, a better understanding of the probability of the successful development of new pain medications would reduce some of the investment risks.

In the retrospective study, Dermot P. Maher, M.D., M.S., M.H.S., assistant professor, John Hopkins University School of Medicine, Baltimore, and financial engineering colleagues at the MIT School of Management analyzed 469 pain pharmaceutical development programs involving 399 unique active pharmaceutical ingredients between 2000 and 2020. They used publicly available clinical trial metadata from databases provided by Informa Pharma Intelligence to determine the probabilities of success, duration, and survivorship of the pain medication development programs.

The study found that 27.8% of drugs with high abuse potential made it all the way through the development process, compared to only 4.7% of new drugs with low abuse potential. Although the number of drugs with high abuse potential being developed has decreased since the peak of the opioid epidemic in 2010, they are more likely to successfully complete the development process and receive regulatory approval than medications with lower abuse potential.

"The higher probability of successful development could represent a more thorough biological understanding of pain signaling pathways targeted by medications with high abuse potential compared to the novel mechanisms offered by alternative medications with lower abuse

potential," they said.

"The opioid crisis was a wake-up call for medicine as a whole," said Dr. Maher. "On the one hand, we had patients who were simply asking for their pain to be addressed. On the other hand, physicians had very little in their pharmaceutical toolbox that was either remarkably effective, non-addictive or lacked major side effects."

It's important to recognize that it is possible to successfully develop pain medications, he noted. "We can increase our understanding of pain mechanisms and target the development of new pain treatments to address this unmet medical need," said Dr. Maher.

In an accompanying editorial, Michael S. Sinha, M.D., J.D., M.P.H., and Kelly K. Dineen Gillespie, R.N., J.D., Ph.D., echo Dr. Maher's support for more development of pain medications with better safety profiles. Federally funded research must be conducted to learn more about the biology and mechanisms of pain, they said.

"The National Institutes of Health (NIH) and other research sponsors must allocate funding toward the development of safer analgesics and nonpharmacologic pain management strategies," they state. "Expanding support for the NIH Helping to End Addiction Long-term (HEAL) Initiative is one way to achieve this goal."

Changes are also warranted, they assert, "in public and private financing models to encourage and reward interdisciplinary, multimodal, and time-intensive pain treatment programs—programs that are highly effective in enhancing well-being and function but currently scarce in a system that continues to reward fragmented and intervention heavy care. Investment in cross training for providers in pain medicine, substance use disorder treatment, is needed as well as trauma informed care. Innovative, noninvasive biotechnology also holds promise."

To change the trajectory of pain management research, they conclude, "concerted action by key private and public stakeholders across multimodal treatment domains is the best path forward."

More information: Dermot P. Maher et al, Estimates of Probabilities of Successful Development of Pain Medications: An Analysis of Pharmaceutical Clinical Development Programs from 2000 to 2020, *Anesthesiology* (2022). [DOI: 10.1097/ALN.0000000000004265](https://doi.org/10.1097/ALN.0000000000004265)

Michael S. Sinha et al, Realigning Incentives for Novel Pain Therapeutics, *Anesthesiology* (2022). DOI: 10.1097/ALN.0000000000004287

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