Over 2 decades, the FDA consistently approved new opioids based on studies lacking critical safety and efficacy data

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Over the past 2 decades, data submitted to the U.S. Food and Drug Administration (FDA) for new opioid approvals has lacked critical

safety and efficacy information. During this timeframe, the FDA approved opioids on the basis of pivotal trials of short or intermediate duration, often in narrowly defined pain populations, excluding patients who did not tolerate the drug. Findings from a cross-sectional analysis are published in *Annals of Internal Medicine*.

Per capita use of opioids in the U.S. remains at epidemic levels and far exceeds that of other countries. Overdose rates are at an all-time high, mainly due to heroin and fentanyl use, but most users of those illicit drugs report that their first opioid was a prescription drug. Given the role that prescription opioids have played in driving the epidemic, the regulatory activities of the FDA have been scrutinized. Little is known about the evidence required by the FDA for new approvals of opioid analgesics.

Researchers from the Johns Hopkins Bloomberg School of Public Health studied 48 new drug applications (NDAs) for opioid analgesics submitted to the FDA between 1997 and 2018 to characterize the quality of safety and efficacy data included in the submissions. The researchers focused on drugs approved for chronic pain because of the heightened safety concerns with those drugs. The data showed that since 1996, the FDA has approved 48 NDAs for prescription opioids for pain. The NDAs were based on pivotal trials, none longer than 12 weeks, often in narrowly defined pain populations. Few approvals included or referenced pooled safety analyses that incorporated systematic assessments of opioid-associated risks, such as tolerance, drug diversion, and nonmedical use. Persons who did not respond to or otherwise tolerate a product were often excluded from the trials. According to the researchers, their findings suggest several opportunities for the FDA to use its regulatory discretion to increase the safety and efficacy data generated in support of new opioid approvals.

More information: *Annals of Internal Medicine* (2020).