Precedent needed for FDA approval decisions when evidence lacking

September 21 2021

(HealthDay)—For U.S. Food and Drug Administration applications that

went through multiple review cycles because the evidence for clinical efficacy was initially deemed insufficient, there is no mechanism for finding or tradition of citing similar cases when weighing evidence for approvals, according to a study published online Sept. 21 in the *Annals of Internal Medicine*.

Noting that the FDA has flexibility in its approval criteria in the context of life-threatening disease and unmet therapeutic need, Perrine Janiaud, Ph.D., from the Stanford University School of Medicine in California, and colleagues reviewed New Drug Applications and Biologics License Applications submitted between 2013 and 2018 that went through multiple review cycles because the evidence for clinical efficacy was initially deemed insufficient.

Overall, 117 of the 912 applications reviewed went through multiple review cycles; of these, only 22 faced additional review, mainly because of issues related to clinical efficacy. The researchers found that common bases for initial rejection included concerns about the end point, the clinical meaningfulness of the observed effect, and inconsistent results. The approval did not require new evidence but rather new interpretations of the original evidence in seven of the 22 cases. None of the FDA decisions cited reasoning that had been used in previous decisions.

"The bespoke logic and procedures the FDA follows to accommodate such situations are not formally built on prior decisions, impairing efficiency and consistency," the authors write. "The FDA needs a database of its own decisions that enables the rapid retrieval of cases with similar evidential characteristics and context and an expectation that FDA officials cite previous decisions in their decisional memos."

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