Physician survey shows lack of understanding of the FDA's approval process

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Many physicians are unfamiliar with how the Food and Drug Administration's (FDA) regulates new drugs and medical devices, and they may be under the impression that the data supporting these approvals are more rigorous than they are, according to a national survey of physicians conducted by researchers at UC San Francisco (UCSF).

Physicians said they wanted to see more rigorous pre-market evidence as well as regulatory action against drugs and devices that do not demonstrate safety and effectiveness after they have been approved for use. The study was published January 8, 2024, in *Health Affairs*.

"Many of the physicians we queried felt that the FDA has become more lenient overtime," said first author Sanket Dhruva, MD, MHS, a UCSF cardiologist, assistant professor of medicine and member of the Philip R. Lee Institute for Health Policy Studies. "Physicians need—and want—to know if a drug or device was rigorously studied before they can make recommendations to their patients."

Physicians' knowledge of FDA's approval processes is important in informing clinical decisions and patient discussions. In recent years, several aspects of the FDA review process have changed, including the nature of the evidence required for approval. One of the most prominent modifications is the increasing use of expedited pathways to make potentially promising drugs and devices available to patients on the basis of earlier-stage data.

The researchers conducted a national survey of 509 randomly selected internists, oncologists, and cardiologists. They developed survey questions about drugs and high-risk medical devices that covered four

domains: physicians' perception of FDA approval, characteristics that physicians think are important among studies supporting FDA approval, views about expedited FDA development or review and views about moderate-risk device approvals.

Among those participating in the survey, 41% reported moderate or better understanding of the FDA's drug approval process, and 17% reported moderate or better understanding of the FDA's medical device approval process. Among physicians, 59% thought that the FDA's current bar for approval of new drugs was about right, with 66% feeling similarly for new devices. Yet, more than a quarter of the respondents thought that the FDA was too flexible in the data accepted for new approvals for both drugs and devices.

Nearly all physicians thought that randomized, blinded trials that met primary endpoints should be very important factors required to secure regulatory approval, with majorities saying that the FDA should require two or more randomized controlled trials of most new drugs (57%) and for most new devices (60%). Nearly all physicians thought the FDA should revoke approval for drugs in the accelerated approval program (95%) or breakthrough devices (89%) that did not show benefit in post approval studies.

"It was not surprising to find that physicians overwhelmingly felt that randomization, blinding, and meeting primary endpoint thresholds were important characteristics of trials used to support regulatory approval," said Dhruva. "Despite these preferences, the proportion of studies leading to FDA approval that feature these characteristics has fallen in recent years."

While 93% of respondents thought that the FDA's Breakthrough Devices Program was a good idea, 30% thought that high-risk medical devices should be supported by more rigorous clinical trial evidence compared

with drugs. For accelerated-approval drugs in which a confirmatory trial was not conducted within agreed-on timelines, 60% of respondents thought that the FDA should withdraw approval, and 93% thought that the FDA should prohibit advertisements or other promotion for accelerated approval indications.

The authors note that the prevalence of physicians reporting lack of understanding of drug and medical device approval reflects the limited coverage of these topics during medical education. They also suggest that the FDA could explain clearly and concisely how and why a drug was authorized, including the key rationale in its risk-benefit assessment and what knowledge gaps remain.

More information: Sanket S. Dhruva et al, Physicians' Perspectives On FDA Regulation Of Drugs And Medical Devices: A National Survey, *Health Affairs* (2024). DOI: 10.1377/hlthaff.2023.00466

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