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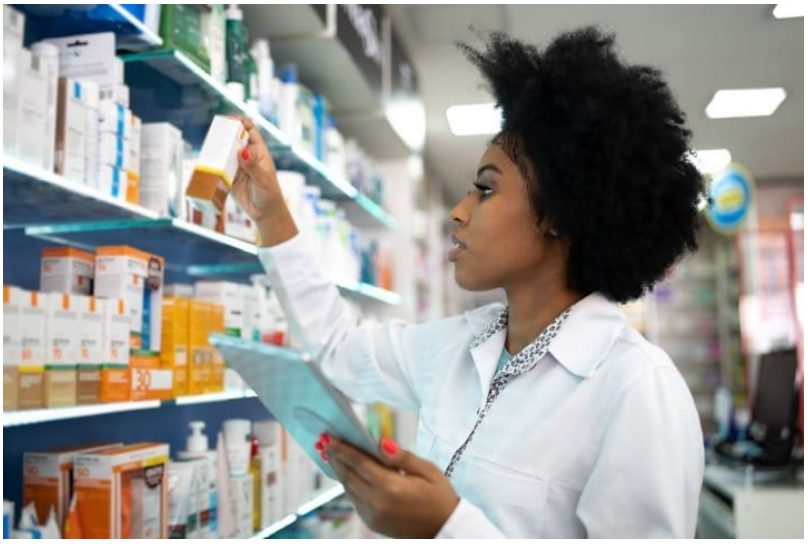
Study: Efficacy of 94 Percent of Approved Drugs Not Supported by High-quality Evidence



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The use of as many as 94 percent of recently approved drugs is not supported by high-quality evidence that demonstrates their benefits, found an international team of researchers from the United Kingdom (University of Oxford), the United States, Switzerland, and Greece. Moreover, side effects and adverse reactions to these medications are being drastically underreported across the board.

The study, titled "Most healthcare interventions tested in Cochrane Reviews are not effective according to high quality evidence: a systematic review and meta-analysis," determined that less than six percent of the medications that have been approved between January 1, 2008 and March 5, 2021 had clinical data that met the "high-quality" standard.

For reference, Cochrane Reviews is one of the largest international journals and databases combining all relevant empirical evidence about medical interventions and healthcare policies. According to its website, "Cochrane Reviews base their findings on the results of studies that meet certain quality criteria" and "apply methods which reduce the impact of bias across different parts of the review process."

According to the study design and setting description, the scientists selected a random sample of 2,428 (35 percent) of all Cochrane Reviews published in a said interval and extracted data about interventions that were compared with a placebo, or no treatment, and whose outcome quality was rated using Grading of Recommendations Assessment, Development and Evaluation (GRADE).

The results of the study were stunning:

> Of 1567 eligible interventions, 87 (5.6%) had high quality evidence on first-listed primary outcomes, positive, statistically significant results and were rated by review authors as beneficial.

Worse yet, the ineffective treatments were also found to cause an untold amount of additional damage, with over a third (36.8 percent) being formally linked to adverse reactions. Over eight percent of the approved drugs were having "significant evidence of harm."

The abstract of the study concludes,

> Most healthcare interventions studied within recent Cochrane Reviews are not supported by

> high quality evidence, and harms are under-reported.

Commenting on the findings, one of the authors, Jeremy Howick, professor and director of the Stoneygate Centre for Excellence in Empathic Healthcare, University of Leicester, wrote, "For a doctor or patient to decide whether to use a treatment, they need to know whether the benefits outweigh the harms. If the harms are inadequately measured, an 'informed choice' is not possible."

The doctor quoted a couple of examples showing that interventions dubbed "safe and effective" killed people in the past:

> For example, antiarrhythmic drugs were widely prescribed in the belief that they would reduce heart attack deaths until a clinical trial found that they actually increased the risk of death.
>
> In another example, putting infants to sleep on their stomach was recommended based on expert opinion that babies would be less likely to choke on their vomit until large studies found that stomach sleeping increased the risk of sudden infant death syndrome.

While admitting that the GRADE framework "might be too strict," Howick suggested that doctors and patients should mostly rely on treatments whose benefits and safety are confirmed by high-quality evidence.

At the same time, the doctor pointed out that research funding should be utilized to generate high-quality evidence for treatments that are already widely used but not yet supported by evidence that is considered "high-quality."

The answers to the issues raised in the study could be linked to findings of a *JAMA* study published in 2020. It found that while the number of novel biologics such as new drugs and vaccines approved increased, the review period decreased over the period between 1983 and 2018.

In particular, the study tracked how the U.S. Food and Drug Administration (FDA) had methodically relaxed its process of approving new treatments. That happened "coincidentally right around the time [Dr. Anthony] Fauci entered the picture," observed The Gateway Pundit.

The *JAMA* study found that in addition to cutting review times, "The FDA has increasingly accepted less data and more surrogate measures," which, according to the FDA, establish a correlation between the use of drug and health outcome, but may not necessarily establish a causation.

Back in 2014, Dr. Donald Light of Harvard University argued that because of the high number of adverse reactions to new drugs, people should refrain from using them "for at least five years unless patients have first tried better-established options and have the need to do so."

Dr. Light supported his recommendation by quoting data showing that new prescription drugs have a one in five chance of causing serious reactions. He continued,

> Systematic reviews of hospital charts found that even properly prescribed drugs (aside from misprescribing, overdosing, or self-prescribing) cause about 1.9 million hospitalizations a year. Another 840,000 hospitalized patients are given drugs that cause serious adverse reactions for a total of 2.74 million serious adverse drug reactions. About 128,000 people die from drugs prescribed to them.

Does the FDA not have enough resources to address the issue? It does, yet it looks as if "he who pays the piper calls the tune."

According to its website, in 2019, close to 45 percent of its entire budget came from user fees that pharmaceutical companies pay when they apply for approval of a medical device or drug.

65 percent of "Human Drugs regulatory activities" were paid by the companies whose medications the FDA is presumably regulating.