

Americans across the political spectrum want more transparency in drug approval decisions from FDA

Americans of all political leanings, gender, race and education levels want medical regulators to show more transparency, a new study finds.

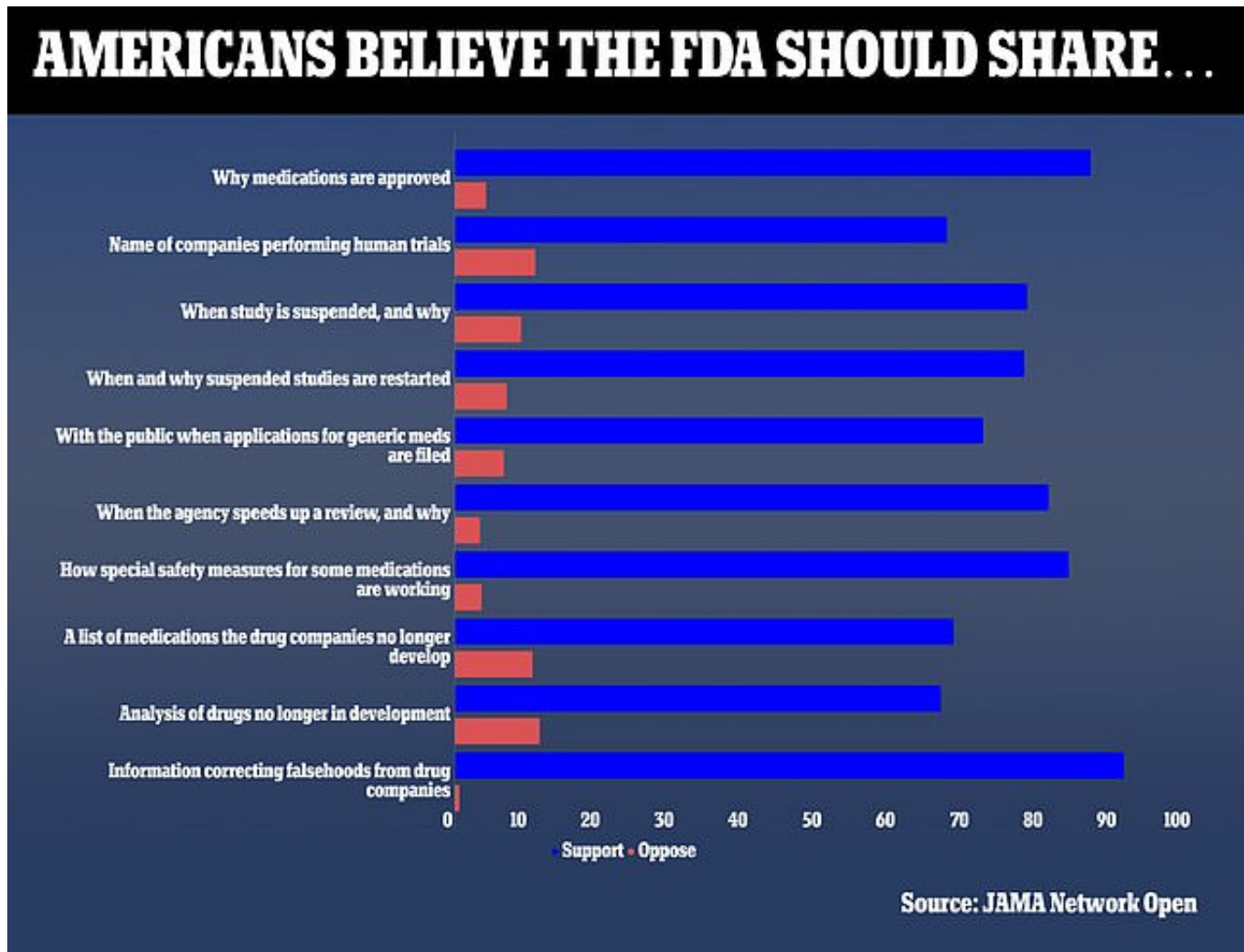
Researchers from Johns Hopkins University in Baltimore, [Maryland](#), surveyed Americans on whether they agree with certain statements about the Food and Drug Administration ([FDA](#)) and transparency in some of its decisions.

Of the ten statements presented to participants, all received support of 65 percent or higher.

Researchers also found little difference in responses from participants based on demographic factors like education or political leanings.

During a time of increased political polarization in the U.S., it is rare that Americans agree with each other from across the aisle.

It seems like the need for more transparency from the FDA is universally agreed upon, though.



'The idea behind the project was that in a time where the FDA's public profile has probably been higher than [any other time] in the living memory of everyone is there a reason that the that the agency should be communicating more clearly, and are there opportunities for do so,' Dr Tej Azad, a resident in neurosurgery at Johns Hopkins and lead author of the study told DailyMail.com.

Azad and the team, who published their findings last week in [JAMA Network Open](#), gathered data from 4,002 participants for the study.

The study population was surveyed on ten statements about FDA transparency and evaluated each on a five point scale from 'strongly agree' to 'strongly disagree'.

Questions include whether the FDA should provide more information on drug decisions, when drug trials are halted or suspended, and more explanations for actions and decisions made by federal regulators.

All ten of the statements had significantly higher levels of approval than disapproval from participants.

The most approved statement was: 'If drug companies provide false or misleading information about the development of medications to the public, the FDA should share the correct information with the public', with 90 percent of participants being in support, with only 0.6 percent showing opposition.

Only one statement had more than 11 percent opposition, 'The FDA should share with the public the agency's analyses of medications that drug companies have stopped developing.'

There was at least a 50 point margin between support and opposition for every single one of the ten statements.

Researchers also split the data across race, education level, household income, geographic region, political party identification and even who a person voted for in the 2020 presidential election.

Across the board, Americans wanted transparency from regulators. Azad



Dr Tej Azad (pictured), a neurological resident at Johns Hopkins University, said that the 'pendulum' of decision making between experts and average people should swing back to the middle

described this as a surprise, noting that Americans seem to not agree on much anymore.

Calls for transparency from the government are not novel ideas, though, and it is expected that citizens will want organizations funded by their taxes to answer to them.

There are potential downsides to expanded access to information, though. A lot of misinformation spread about COVID-19, for example, comes from genuine sources being misinterpreted - whether maliciously or not.



Researchers found that, across all demographics, Americans want the FDA to be more transparent. One lead researcher says that experts must properly convey information to regular people without being 'paternalistic' (file photo)

Ivermectin has become a household name in recent months for this very reason. The anti-parasite drug has risen to prominence in some

conservative-leaning and anti-vaccine circles as a potential Covid cure.

The source of these claims is a legitimate, peer-reviewed, Australian study that showed the drug could inhibit replication of the virus in a lab environment.

Doses used in the study are so concentrated that they would not be safe for human use, though, and the findings are only replicable inside of a lab and not in human subjects.

There have been multiple studies of ivermectin in treating Covid patients in the time since the drug's rise to prominence and each have shown that it has no ability to fight the virus in humans.

Azad says that the onus is on health experts to properly communicate information in a way that does not come off as 'paternalistic', and make sure to provide enough information to people to allow them to make the correct decision for themselves.

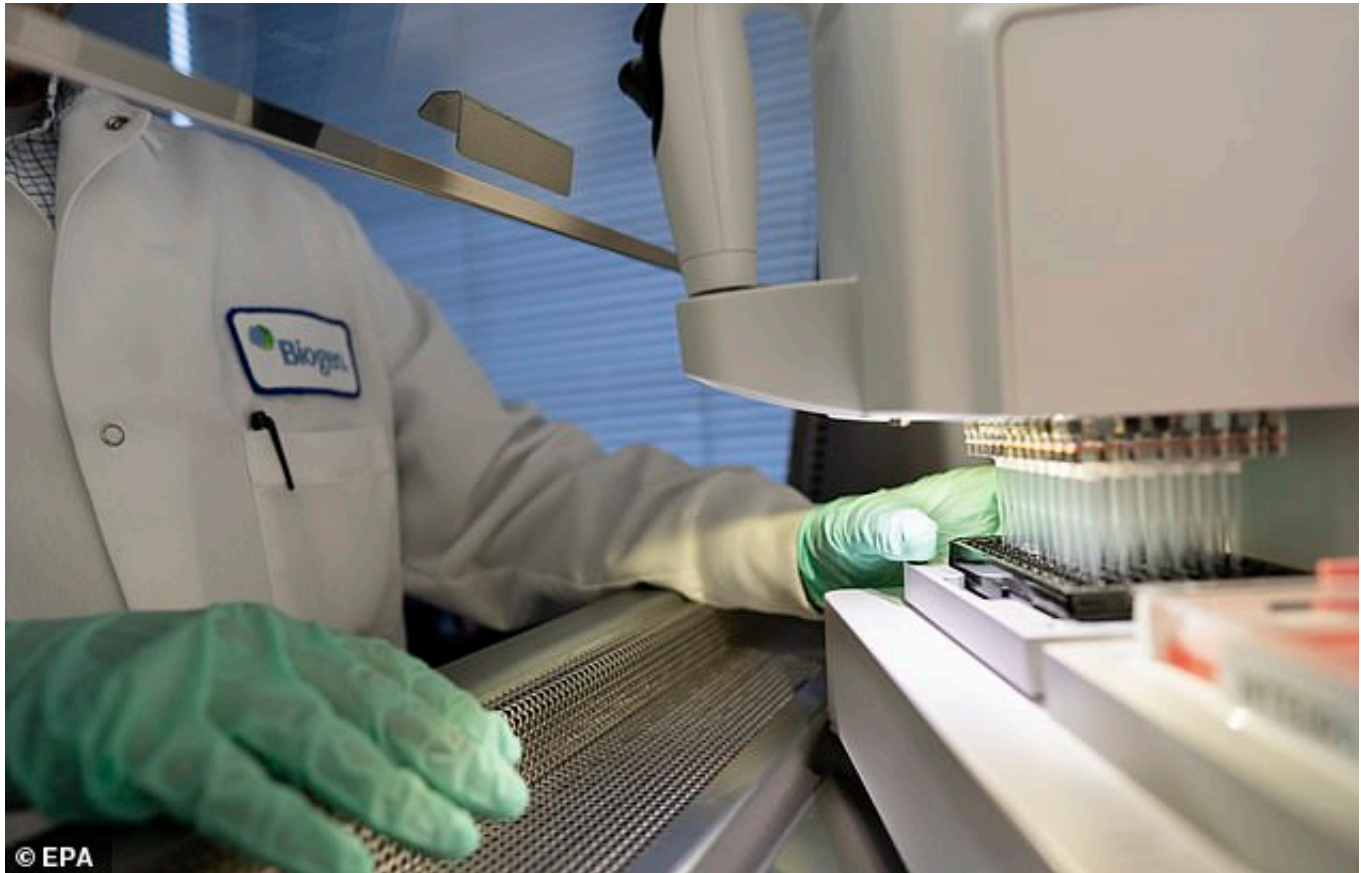
'We think about paternalism a lot,' he said.

'Where you come out in the balance between trying to get folks to adopt what you truly believe to be the right thing or the right behavior, versus truly taking a step back and [saying] "hey, here's all the information you make the call."

'I think the reality is for something like this is the the right answer lies somewhere in between.'



Americans misinterpreting an ivermectin study led to many falsely believing the anti-parasite drug could treat COVID-19 symptoms, a potential mark against greater access to information (file photo)



Biogen's Aduhelm was denied Medicare funding and the FDA was largely criticized after approving the drug despite two failed clinical trials, in what could be seen as a positive outcome of more transparency (file photo)

He describes the situation as a pendulum that is currently swinging in the direction of experts, leaving many average people feel like they are being left out of key medical decisions. The pendulum should be more towards the middle, Azad says.

An example counter to that on ivermectin is what occurred after the Alzheimer's drug Aduhelm received FDA approval last summer.

The drug still managed to receive a greenlight from the FDA despite two failed clinical trials and limited data showing it was effective.

A wave of neurological experts investigated the data for themselves, and scathed the FDA decision.

Intense backlash to the drug, fueled by these experts having access to trial data, led to the drug being rejected for reimbursement through Medicare and former FDA Acting Director Janet Woodcock even called for an investigation into her own agency for approving the drug.

In that case, transparency and easy accessibility to information may have fixed a mistake made by regulators, Azad believes.

Ten statements presented to study participants