

## NIH ends alcohol study, citing funding, credibility problems

June 15 2018, by Lauran Neergaard

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In this June 7, 2008 file photo, a woman evaluates the aroma of a wine in California. On Friday, June 15, 2018, National Institutes of Health Director Dr. Francis Collins announced the NIH is shutting down a study that was supposed to show if a single drink a day could prevent heart attacks, citing ethical problems that would undermine the credibility of its findings. (AP Photo/Eric Risberg, File)

The U.S. government is shutting down a study that was supposed to show

if a single drink a day could prevent heart attacks, saying ethical problems with how the research was planned and funded undermine its credibility.

The National Institutes of Health used money from the alcohol industry to help pay for a study that ultimately was expected to cost \$100 million. It's legal for NIH to use industry money in addition to taxpayer dollars for research as long as certain rules are followed. The problem: An NIH investigation concluded Friday that a small number of its employees had close contact with industry officials that crossed those lines.

Some of those interactions "appear to intentionally bias" the study so that it would have a better chance of showing a benefit from moderate alcohol consumption, said NIH Deputy Director Lawrence Tabak.

Those employees, from the NIH's National Institute on Alcohol Abuse and Alcoholism, then kept their interactions with industry secret, he said, even after the NIH started the normal process for asking companies or other outside groups to help fund a research project.

Those actions cast "doubt that the scientific knowledge gained from the study would be actionable or believable," Tabak told a meeting of the NIH director's advisers.

Another concern: Some outside experts who had reviewed the study plans raised concerns that it was too small and too short to address the potential problems of a daily drink—such as an increased risk of cancer or heart failure—and not just potential benefits such as a lowered risk of a heart attack.

"Purely on scientific grounds, I never really quite understood why this trial was being done," Dr. M. Roy Wilson of Wayne State University told NIH Director Francis Collins after hearing the investigation's

conclusions. People who have a glass or two of wine—himself included, he said—"don't do it for health reasons."

The research was supposed to track 7,800 people who were assigned to take either a drink a day, or totally abstain, for several years. Only 105 people had enrolled by last month, when Collins temporarily suspended the study after a New York Times article first raised questions about the funding policy violations.



In this Sept. 18, 2017 file photo, National Institutes of Health Director Dr. Francis Collins speak during a news conference in Trenton, N.J. On Friday, June 15, 2018, Collins announced the NIH is shutting down a study that was supposed to show if a single drink a day could prevent heart attacks, citing ethical problems that would undermine the credibility of its findings. (AP Photo/Matt Rourke)

On Friday, Collins announced he was completely shutting down the research. "This is a matter of the greatest seriousness," he said.

The study was being led by Beth Israel Deaconess Medical Center in Boston, which said in a statement that it was "deeply committed to ensuring the scientific and ethical integrity of any research study involving our investigators" and would review NIH's findings.

In a statement late Friday, the lead researcher, Beth Israel's Dr. Kenneth Mukamal, said he and rest of the research team were "deeply disappointed" in NIH's decision.

"We stand fully and forcefully behind the scientific integrity" of the study, Mukamal said. He added that "every design consideration was carefully and deliberately vetted with no input or direction whatsoever from private sponsors, who have had no contact" with study staff since the trial began.

Aside from how alcohol can impair behavior and judgment, scientists have long debated if drinking various amounts can truly translate into a specific health benefit. What the NIH's alcohol research agency calls "low-risk" drinking is no more than seven drinks a week for women and no more than 14 drinks a week for men.

Asked if it would be possible for NIH to try to answer some of those health questions after the financial controversy, Tabak responded, "It would not be an easy study to conduct."

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Citation: NIH ends alcohol study, citing funding, credibility problems (2018, June 15) retrieved 19 April 2024 from <https://medicalxpress.com/news/2018-06-nih-industry-funded-alcohol-benefits.html>

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