STAT

NIH rejected a study of alcohol advertising while pursuing industry funding for other research

By Sharon Begley @sxbegle

April 2, 2018



Ian West/PA Wire via AP

It's rare for officials at the National Institutes of Health to summon university scientists from hundreds of miles away. So when Dr. Michael Siegel of Boston University and a colleague got the call to meet with the director of NIH's Institute on Alcohol Abuse and Alcoholism, he said, "I knew we were in trouble."

He never imagined, however, that at the 2015 meeting the director, George Koob, would leap out of his seat and scream at the scientists after their PowerPoint presentation on research the agency had eagerly funded on the association between alcohol marketing and underage drinking. "I don't f***ing care!" Koob yelled, referring to alcohol advertising, according to the scientists.

Koob also made clear that NIAAA would pull back from such research, recalled Siegel and his colleague, David Jernigan of Johns Hopkins University, who described the previously undisclosed meeting in Bethesda, Md., in separate interviews with STAT. Shocked by the encounter, they retreated to an NIH cafeteria, asking each other what had just happened — and why.

It would take them three years to figure it out: In 2014 and 2015, Koob's agency was quietly wooing the alcoholic beverage industry to contribute tens of millions of dollars for a study on whether drinking

"moderate" amounts of alcohol was good for the heart. Those efforts were brought to light by recent reports in <u>Wired</u>¹ and the <u>New York Times.</u>²

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Now STAT has found that the ties between Koob, his agency, and the alcohol industry were deeper than previously known — and that he told an industry official he would quash "this kind of work," to which the industry objected. Doing so would be a radical departure from the NIH <u>mission</u>⁴, in which decisions about what research to fund are supposed to be based on scientific merit and public need.

Koob, in a previously undisclosed email sent six months before the contentious 2015 meeting and provided to STAT, had assured the alcohol industry's leading trade group that research like Jernigan's and Siegel's on alcohol advertising, which was published in respected journals, would never again be funded.

"Sam: For the record. This will NOT happen again," Koob wrote in a 2014 email to Samir Zakhari, senior vice president for science at the Distilled Spirits Council of the United States, the lobbying group for alcoholic beverage producers.

In a written response to STAT, Koob said the email "was to convey that I had no intention of supporting research that was not of the highest scientific quality. NIAAA funds a vast amount of research on underage drinking, which is among the Institute's top research priorities." An NIAAA spokesman said Koob, 70, and other officials were not available for interviews, and NIAAA officials said they could not speak to a reporter without clearance by NIH's communications office.

At the time of the 2015 meeting, no outsider was aware of NIAAA's efforts to get industry funding for the very costly study of moderate drinking. With those revelations, Siegel said, "things finally made sense. If they're soliciting money from industry, they wouldn't want to do anything that would affect their chance of getting that money. Of course that will bias them toward intimidating researchers who study things [the industry doesn't] like."

In fact, Koob was true to his word. Jernigan applied for another NIAAA grant later in 2015, and received a high rating from a review panel comprised of other scientists. But an NIAAA Advisory Council that Koob leads has the ultimate authority on whether to fund studies, and it rejected the proposal.



George Koob, director of the National Institute on Alcohol Abuse and Alcoholism Dave Kotinsky/Getty Images for HBO

The saga involving Siegel and Jernigan began in 2011, when they and colleagues launched a study of whether alcohol marketing is associated with underage drinking. The research came in response to a "request for applications" from NIAAA. Such requests reflect the institute's priorities; when it identifies an important public health or scientific question, it wants to ensure researchers study it. In this case, research had shown that cigarette ads make teenagers more likely to smoke, and to smoke specific brands; might beer and liquor ads have the same effect?

The scientists were awarded an NIAAA grant, receiving roughly \$600,000 per year from 2011 to 2014 to fund data collection, analysis, and the work of their graduate students and postdoctoral fellows. Their "ABRAND" study — "Alcohol Brand Research Among Underage Drinkers" — eventually yielded 27 papers published in respected journals, including one in 2014 that found a strong link between what alcohol brands teenagers saw advertised on television in the previous 30 days and what brands they drank.

"That had never been reported before," Siegel said.

Dr. Susanne Tanski of Dartmouth's Geisel School of Medicine, who studies underage drinking, said Siegel's and Jernigan's paper became a key piece of evidence in the growing recognition that marketing by alcohol producers increases brand awareness among future customers.

The study did not sit well with the alcohol industry, nor with Koob, a neurobiologist who <u>became</u>

NIAAA's director⁸ in January 2014 after <u>three decades</u>⁹ at Scripps Research Institute in California. When a staffer at the free-market Competitive Enterprise Institute penned an <u>op-ed</u>¹⁰ slamming Jernigan for having a "neo-prohibitionist agenda" funded with taxpayer dollars, Koob rushed to reassure the industry.

On July 30, 2014, he emailed Zakhari, who had joined the Distilled Spirits Council in 2012 two months after retiring from NIAAA, where he had worked for more than 20 years. The industry group had hosted discussions about funding for the moderate drinking study.

In the 6:11 p.m. email, after assuring Zakhari that "this will NOT happen again," Koob continued, "It was funded over 3 years ago under a PA [project announcement] that does not exist anymore," according to a copy of the email Siegel obtained through a public records request and shared with STAT. Koob ended with a promise: "I will NOT be funding this kind of work under my tenure. Best wishes george."

Zakhari, who in his industry role <u>criticizes</u>¹¹ studies showing that drinking alcohol is associated with some cancers and <u>disputes</u>¹² that alcohol abuse is rising, replied less than two hours later: "Thanks, George. I am 100% sure that you will spend research money on real science. You have several people in the division of epidemiology who push to fund this kind of research out of shear [sic] ignorance or because they are sympathetic. This kind of research not only wastes precious research dollars but also damages NIAAA's stature within the NIH community. Best regards, Sam"

Samir Zakhari From: Wednesday, July 30, 2014 8:01 PM Sent: Koob, George (NIH/NIAAA) [E] To: Subject: Re: Commentary in Baltimore Sun about an NIAAA grantee, David Jernigan Thanks, George I am 100% sure that you will spend research money on real science. You have several people in the division of epidemiology who push to fund this kind of research out of shear ignorance or because they are sympathetic. This kind of research not only wastes precious research dollars but also damages NIAAA's stature within the NIH community. Best regards, Sam > On Jul 30, 2014, at 6:11 PM, "Koob, George (NIH/NIAAA) [E]" <george.koob@nih.gov> wrote: > > Sam: For the record. This will NOT happen again. It was funded over 3 > years ago under a PA that does not exist anymore. I will NOT be > funding this kind of work under my tenure. Best wishes george

Email exchange between Koob and and Samir Zakhari of the Distilled Spirits Council of the United States. STAT

A spokesman for the Distilled Spirits Council, Frank Coleman, did not respond to questions about Zakhari's communications with NIAAA but said his concern about Jernigan's work "echoes the many questions that have been raised about his advocacy methodologies and conclusions."

In his written response to STAT, Koob said the email exchange was triggered by "critical evaluation" of one of Jernigan's studies "in the media and the scientific community." In early 2015, he continued, "I informed Dr. Jernigan that I would be pleased to receive proposals on intervention-related research in the advertising domain, when a hypothesis was being tested that could assist the goal of preventing underage drinking."

A few months after the email exchange, Koob summoned Jernigan and Siegel to NIAAA's offices. The meeting took place in January 2015, and Koob's deputy and two other NIAAA officials also attended, said Siegel and Jernigan, whose recollections of the meeting were consistent.

Siegel summarized his and Jernigan's ABRAND study, showed the NIAAA officials published papers describing their findings, and tried to convince them that studying advertising was important as part of a larger effort to reduce underage drinking, much as had been done for cigarette smoking.

"I have a clear memory of this because it was not something you could forget," Siegel said. "Dr. Koob kept trying to downplay the importance of this research, insisting it was not advertising that made teenagers drink but peer pressure and parents. He was giving us the industry line."

He and Jernigan agree that their study did not make an open-and-shut case that ads caused teens to drink the advertised brands, or to drink, period. It's possible that kids who already drink, or drink certain brands, or who are inclined to, gravitate toward certain TV shows, and that those shows just happen to carry ads for those brands.

"That's a perfectly legitimate scientific criticism of our work," Jernigan said. "But that's not the discussion we had."

Instead, Koob responded to Siegel's presentation with his profane declaration. He invoked his collegeage son and his friends, saying underage drinking has nothing to do with what ads teenagers see.

Finally, Koob reiterated the pledge he had made to the alcohol industry group: No matter how high a score a grant proposal from the two scientists received from the reviewers who evaluate NIAAA funding requests, Siegel recalled Koob telling them, "I'll never fund it." Jernigan's recollection is slightly different: He believes Koob left the door open to funding one more study.

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Siegel and Jernigan remained puzzled about the meeting until the recent media revelations that NIAAA and academic scientists had, in 2014, pitched industry on a proposed study described as likely to provide enough evidence of the health benefits of moderate drinking for alcohol "to be recommended as part of a healthy diet." NIAAA received \$67 million for the study from industry, funneled through an NIH foundation, later in 2015.

It didn't take three years for the scientists to conclude that Koob wasn't bluffing about not funding "this kind of work."

Jernigan had submitted a proposal for a small pilot study, to be funded at about \$200,000 in each of two years, to analyze the Facebook pages and Twitter accounts of alcohol brands to see whether they were marketing their products in ways that could promote underage drinking.

In a June 2015 evaluation of the grant application, called a pink sheet, NIAAA reviewers said "the proposed research is significant and innovative." The reviewers, according to the evaluation shared by Siegel, showed "an extremely high level of enthusiasm for this application" and scored it "in the exceptional range."

The proposal then moved to the second layer of review, called the <u>Advisory Council</u>, ¹⁴ which Koob chairs. Lower-scoring proposals can be funded and higher-scoring proposals denied. Jernigan's social media study was denied funding by the council; he said he never received any explanation. The chairperson of the first review committee, Elizabeth D'Amico of RAND, declined through a spokesperson to discuss that denial.

Siegel has moved on from research on alcohol to studies of firearms. Jernigan continues to study alcohol and its marketing, with funds from the Centers for Disease Control and Prevention. But because of NIAAA's waning interest in the topic, he said, he has struggled to find adequate funding to support the young scientists he trains.

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