NIAAA Prostitutes Its Scientific Integrity and Helps Alcohol Industry Promote Drinking

In one of the greatest episodes of corruption of a U.S. governmental health agency during my career, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) has sold itself out to the alcohol industry by agreeing to accept \$68 million for a shoddily-designed study intended to examine the potential health benefits of moderate drinking but without similarly assessing the potential risks.

According to the New York Times: "the National Institutes of Health is starting a \$100 million clinical trial to test for the first time whether a drink a day really does prevent heart attacks. And guess who is picking up most of the tab? Five companies that are among the world's largest alcoholic beverage manufacturers — Anheuser-Busch InBev, Heineken, Diageo, Pernod Ricard and Carlsberg — have so far pledged \$67.7 million to a foundation that raises money for the National Institutes of Health, said Margaret Murray, the director of the Global Alcohol Research Program at the National Institute on Alcohol Abuse and Alcoholism, which will oversee the study."

The Rest of the Story

According to the *New York Times* article: "George F. Koob, the director of the alcohol institute, said the trial will be immune from industry influence and will be an unbiased test of whether alcohol "in moderation" protects against heart disease. "This study could completely backfire on the alcoholic beverage industry, and they're going to have to live with it," Dr. Koob said. "The money from the Foundation for the N.I.H. has no strings attached. Whoever donates to that fund has no leverage whatsoever — no contribution to the study, no input to the study, no say whatsoever.""

What a bunch of crap!

The money has **huge** strings attached: namely, the money is to be used for a trial **to examine the potential benefits of drinking**!

In other words, the alcohol industry doesn't need any further leverage because they have already won. They have succeeded in getting the NIAAA to spend 20% of its entire budget on a study which is designed to identify potential benefits of drinking. The study is not examining potential negative health effects of moderate drinking: namely, increased cancer risk, and especially breast cancer risk.

Very few people understand that the greatest influence that industry can have on research is not on the way the research is conducted, but on the topic of the research in the first place. The tobacco industry also funded research with "no strings attached." The tobacco industry completely divorced itself from the decisions of many of its funded scientists. However, the industry had already won because it essentially dictated the research agenda. The industry made decisions about what to fund and what not to fund. That is the true, critical point of leverage.

So, for example, the tobacco industry funded many studies on genetic causes of lung cancer, non-tobacco-related causes of cancer, etc., while funding few, if any, studies on the severity of nicotine addiction, nicotine addiction in youth, the exposure of youth to tobacco advertising, the positive impact of anti-tobacco regulations, etc.

No strings attached? The strings have already been attached.

If the alcohol companies were willing to donate money to NIH that could be used for any purpose that an NIH researcher proposed, such as a study to examine the effects of increased alcohol taxes on reducing youth alcohol consumption, then one could say that there are no strings attached. But

this money is clearly earmarked - and beyond that, earmarked for a study that is essentially designed to show some positive health effects of moderate alcohol consumption.

Dr. Koob's contention that this trial is an "unbiased" test is also laughable. How can it be unbiased when its major funder is the industry that markets the product under study? But the bias doesn't end there. It turns out that many of the investigators running the study have individual conflicts of interest with the alcohol industry. At my institution, such researchers would not even be allowed to be involved in a clinical trial in which they have a significant conflict of interest. Our general policy is that an investigator with a significant conflict of interest cannot conduct a clinical trial on a product made by the relevant company. We do allow conflicted investigators to conduct pre-clinical studies, such as laboratory research; however, the line is drawn definitively at the level of a clinical trial.

Just how strong are the conflicts of interest of the lead researchers for the study?

According to the *New York Times* article: "Harvard, the hub of the clinical trial, has a long relationship with the alcoholic beverage industry. In 2015 the university accepted \$3.3 million from the Foundation for Advancing Alcohol Responsibility, a group founded by distillers, to establish an endowed professorship in psychiatry and behavioral science."

In addition: "One of the trial's principal investigators, Dr. Eric Rimm of the Harvard T. H. Chan School of Public Health, has acknowledged through <u>various financial disclosures</u> that he has been paid to speak at conferences sponsored by the alcohol industry and received reimbursement for travel expenses."

Moreover: "Dr. Diederick Grobbee, another principal investigator, who is based in the Netherlands and is in charge of clinical sites outside the United States, said in a telephone interview that he has received research money from the International Life Sciences Institute, an industry group that supports scientific research."

Furthermore: "In Baltimore, the trial will be run by Dr. Mariana Lazo-Elizondo of Johns Hopkins, who received research grants in 2013 and 2014 totaling \$100,000 from the Alcoholic Beverage Medical Research Foundation. She declined to be interviewed."

And to add insult to injury: "The Barcelona study arm will be run by Dr. Ramon Estruch, who in February helped lead a "Wine & Health" conference in the wine region of La Rioja, Spain, that was supported by the wine industry. Dr. Estruch recently <u>refused to disclose</u> his financial conflicts of interest to The Journal of Studies on Alcohol and Drugs and has not responded to requests for comment."

It is clear that many of the principal investigators in the trial have personal conflicts of interest with the alcohol industry. And the lead investigator for the Barcelona study arm not only has severe personal conflicts of interest but has failed to disclose them, apparently despite numerous requests from the journal to do so. But his conflicts with Big Alcohol run deep. As I revealed in a 2016 <u>column</u>:

Dr. Ramon Estruch - is on the board of or receives money from three different research foundations, each of which is funded by alcohol companies. According to a published article: "Dr. Estruch reports serving on the board of and receiving lecture fees from the Research Foundation on Wine and Nutrition (FIVIN); serving on the boards of the Beer and Health Foundation and the European Foundation for Alcohol Research (ERAB)."

Well, it turns out that the Research Foundation on Wine and Nutrition is <u>funded by alcohol</u> companies.

And the Beer and Health Foundation is funded by the Spanish beer industry.

And the European Foundation for Alcohol Research <u>acknowledges</u> that it: "is supported by The Brewers of Europe, the voice of the brewing industry in Europe, whose members are the national brewing trade associations, representing more than 90% of European beer production."

I have also previously discussed why Harvard's objectivity regarding this research has already been severely compromised (see: <u>Harvard Medical School Teams Up with Makers of Bacardi Rum, Smirnoff</u> Vodka, Jim Beam Bourbon, and Jack Daniels Whiskey, Providing Great PR at Bargain Rates).

The study design doesn't even pass the laugh test in terms of basic epidemiology. The study is excluding nondrinkers, who are the only people who really matter because they are the ones who would potentially benefit - or be harmed - by efforts to promote moderate drinking. People who are already drinking aren't the ones who would be most affected by such a campaign.

The study is also excluding problem drinkers. People who are already drinking, but are not problem drinkers, have already demonstrated that they are capable of moderate drinking. The real issue is what happens when you successfully convince a non-drinker to start drinking every day. This trial specifically avoids (and is designed to avoid) examining that research question. But that research question is really what is at the heart of any evaluation of whether promoting moderate drinking might have public health benefit.

Even the tobacco industry, to the best of my knowledge, never succeeded in persuading the prestigious NIH to accept industry funding for a study of interest to the tobacco companies. The tobacco companies had to resort to funding their own research bodies (e.g., the Council for Tobacco Research). But here, the NIAAA is giving the alcohol industry an unprecedented gift: the acceptance of industry money to conduct a clinical trial, under the pretense of being an objective government study.

The rest of the story is that by accepting this funding from the alcohol industry to support what is supposed to be an objective NIH research agenda, the NIAAA has compromised its scientific integrity, selling out to the alcohol industry and helping the industry to promote drinking. This is not the appropriate role of the NIAAA.

This clinical trial is tainted before it has even begun. Hopefully, its participants will be informed that the study is essentially a sham - that it is funded by the alcohol industry, which has -- in a dream come true scenario -- somehow gotten the NIAAA to agree to conduct a study that is designed only to examine potential positive health effects of moderate drinking, while ignoring (and not looking for) any serious potential risks, such as cancer.

The study investigators may not reveal this critical information to the human subjects in these trials; however, there are a number of public health groups that are planning to publicize this information so that the public is aware of this scam before it does real damage to the public's health. It has already done damage to the scientific credibility of the NIAAA specifically, and of government public health research in general.

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