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The Sarah Cannon Research Institute, based in Nashville, received nearly \$8 million in payments from drug companies on behalf of its president for clinical operations, Dr. Howard Burris, largely for research work. Dozens of his articles published in prestigious medical journals did not include the required disclosures of those payments and relationships. (William DeShazer for The New York Times)

Prominent Doctors Aren't Disclosing Their Industry Ties in Medical Journal Studies. And Journals Are Doing Little to Enforce Their Rules

The dean of Yale's medical school, the incoming president of a prominent cancer group and the head of a Texas cancer center are among leading medical figures who have not accurately disclosed their relationships with drug companies.

by Charles Ornstein, ProPublica, and Katie Thomas, The New York Times, Dec. 8, 2018, 10 a.m. EST

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One is dean of Yale's medical school. Another is the director of a cancer center in Texas. A third is the next president of the most prominent society

of cancer doctors.

These leading medical figures are among dozens of doctors who have failed in recent years to report their financial relationships with pharmaceutical and health care companies when their studies are published in medical journals, according to a review by ProPublica and The New York Times and <u>data from other <https://jamanetwork.com/journals</u> /jamaoncology/fullarticle/2698041> recent research <https://jamanetwork.com/journals /jamasurgery/article-abstract/2696610>.

Dr. Howard A. "Skip" Burris III, the <u>president-elect of the American</u> Society of Clinical Oncology <<u>https://www.asco.org/about-asco/asco-overview</u> /<u>leadership/board-of-directors></u>, for instance, declared that he had no conflicts of interest in more than 50 journal articles in recent years, including in the prestigious New England Journal of Medicine.

However, drug companies have paid his employer nearly \$114,000 for consulting and speaking, and nearly \$8 million for his research during the period for which disclosure was required. His omissions extended to the Journal of Clinical Oncology http://ascopubs.org/doi/pdf/10.1200/JCO.2016.70.1508>, which is published by the group he will lead.

In addition to the widespread lapses by doctors, the review by ProPublica and The Times found that journals themselves often gave confusing advice and did not routinely vet disclosures by researchers, although many relationships could have been easily detected <u>on a federal database</u> <https://openpaymentsdata.cms.gov/>.

Medical journals, which are the main conduit for communicating the latest scientific discoveries to the public, often have an interdependent relationship with the researchers who publish in their pages. Reporting a study in a leading journal can heighten their profile — not to mention that of the drug or other product being tested. And journals enhance their cachet by publishing exclusive, breakthrough studies by acclaimed researchers.

In all, the reporting system still appears to have many of the same flaws that the Institute of Medicine identified nearly a decade ago when it recommended fundamental changes <<u>https://www.nap.edu/catalog/12598</u> /<u>conflict-of-interest-in-medical-research-education-and-practice></u> in how conflicts of interest are reported. Those have yet to happen.

"The system is broken," said Dr. Mehraneh Dorna Jafari, an assistant professor of surgery at the University of California, Irvine, School of Medicine. She and her colleagues <u>published a study in August</u> <<u>https://jamanetwork.com/journals/jamasurgery/article-abstract/2696610></u> that found that, of the 100 doctors who received the most compensation from device makers in 2015, conflicts were disclosed in only 37 percent of the articles published in the next year. "The journals aren't checking and the rules are different for every single thing."

Calls for transparency stem from concerns that researchers' ties to the health and drug industries increase the odds they will, consciously or not, skew results to favor the companies with whom they do business. Studies have found that industry-sponsored research tends to be more positive than research financed by other sources. And that in turn can sway which treatments become available to patients. There is no indication that the research done by Burris and the other doctors with incomplete disclosures was manipulated or falsified.

Journal editors say they are introducing changes that will better standardize disclosures and reduce errors. But some have also argued that since most researchers follow the rules, stringent new requirements would be costly and unnecessary.

The issue has gained traction since September, when Dr. José Baselga, the chief medical officer of Memorial Sloan Kettering Cancer Center in New York, resigned https://www.propublica.org/article/memorial-sloan-kettering-official-jose-baselga-resigns-after-failing-to-disclose-industry-ties after The Times and ProPublica reported ">https://www.propublica.org/article/doctor-jose-baselga-cancer-researcher-corporate-financial-ties>">https://www.propublica.org/article/doctor-jose-baselga-cancer-researcher-corporate-financial-ties>">https://www.propublica.org/article/doctor-jose-baselga-cancer-researcher-corporate-financial-ties>">https://www.propublica.org/article/doctor-jose-baselga-cancer-researcher-corporate-financial-ties>">https://www.propublica.org/article/doctor-jose-baselga-cancer-researcher-corporate-financial-ties>">https://www.propublica.org/article/doctor-jose-baselga-cancer-researcher-corporate-financial-ties>">https://www.propublica.org/article/doctor-jose-baselga-cancer-researcher-corporate-financial-ties>">https://www.propublica.org/article/doctor-jose-baselga-cancer-researcher-corporate-financial-ties>">https://www.propublica.org/article/doctor-jose-baselga-cancer-researcher-corporate-financial-ties>">https://www.propublica.org/article/doctor-jose-baselga-cancer-researcher-corporate-financial-ties>">https://www.propublica.org/article/doctor-jose-baselga-cancer-researcher-corporate-financial-ties>">https://www.propublica.org/article/doctor-jose-baselga-cancer-researcher-corporate-financial-ties>">https://www.propublica.org/article/doctor-jose-baselga-cancer-researcher-corporate-financial-ties>">https://www.propublica.org/article/doctor-jose-baselga-cancer-researcher-corporate-financial-ties>">https://www.propublica.org/article/doctor-jose-baselga-cancer-r

Burris, president of clinical operations and chief medical officer at the Sarah Cannon Research Institute <<u>https://sarahcannon.com/></u> in Nashville, referred questions to his employer. It defended him, saying the payments were made to the institution, although the New England Journal of Medicine requires disclosure <<u>https://www.nejm.org/doi/suppl/10.1056</u> /NEJMoa1609709/suppl_file/nejmoa1609709_disclosures.pdf> of all such payments.

Other prominent researchers who have submitted erroneous disclosures include Dr. Robert J. Alpern, the dean of the Yale School of Medicine, <u>who</u> failed to disclose in a 2017 journal article <<u>https://cjasn.asnjournals.org/content</u>/<u>13/1/26.long></u> about an experimental treatment developed by Tricida that he served on that <u>company's board of directors <<u>https://www.tricida.com/company/></u> and owned its stock. Tricida, which is developing therapies for chronic kidney disease, had financed the clinical trial that was the subject of the article.</u>

Alpern said in an email that he initially believed that his disclosure — that he had been a consultant for Tricida — was adequate. However, "because of concerns recently raised about disclosures," he said he notified the publication, the Clinical Journal of the American Society of Nephrology, in October that he also served on Tricida's board and had stock holdings in the company.

The journal initially told Alpern that his disclosure was sufficient. But after ProPublica and The Times contacted the publication in November, it said it would correct the article.

"The failure to disclose this information at the time of peer review is a violation of our policy," Dr. Rajnish Mehrotra, the journal's editor-in-chief, said in an email.

He later said that an additional inquiry had revealed that all 12 of the article's authors had been incomplete in their disclosures, and that the journal planned to refer the matter to the ethics committee of the American Society of Nephrology. Mehrotra also said that the journal had decided to conduct an audit of some recent articles to evaluate the broader issue.

Dr. Carlos L. Arteaga, the director of the Harold C. Simmons Comprehensive Cancer Center in Dallas, said he had "nothing to disclose" as an author of a 2016 <u>study <https://www.nejm.org/doi/full/10.1056</u> /NEJMoa1609709> published in The New England Journal of Medicine of the breast cancer drug Kisqali, made by Novartis. But Arteaga had received more than \$50,000 from drug companies in the three-year disclosure period, including more than \$14,000 from Novartis.

In an email, Arteaga described the omission as an "inexcusable oversight and error on my part," and subsequently submitted a correction.

Dr. Jeffrey R. Botkin, associate vice president for research integrity at the University of Utah, <u>recently argued in JAMA</u>, a <u>leading medical journal</u>, <u>that researchers should face <https://jamanetwork.com/journals/jama/fullarticle</u> /2712193> misconduct charges when they do not disclose their relationships with interested companies. "They really are falsifying the information that others rely on to assess that research," he said. "Money is a very powerful influencer, and people's opinions become subtly biased by that financial relationship."

But <u>Dr. Howard C. Bauchner, the editor-in-chief of JAMA, said that</u> <<u>https://jamanetwork.com/journals/jama/fullarticle/2712191></u> verifying each author's disclosures would not be worth the time or effort. "The vast majority of authors are honest and do want to fulfill their obligations to tell readers and editors what their conflicts of interest could be," he said in an interview.

As the debate continues, an influential group, the International Committee of Medical Journal Editors, is considering a policy that would refer researchers who commit major disclosure errors to their institutions for possible charges of research misconduct.

Concerns about the influence of drug companies on medical research have persisted for decades. Senator Estes Kefauver held hearings on the issue in 1959, and there was another surge of concern in the 2000s after a series of scandals in which prominent doctors https://www.nytimes.com/2008/10 /04/health/policy/04drug.html> failed to reveal their industry relationships.

Medical journals and professional societies strengthened their requirements. The drug industry restricted how it compensates doctors, prohibiting gifts like tickets to sporting events or luxury trips — although evidence of kickbacks and corruption continues to surface in criminal prosecutions. And a 2010 federal law required pharmaceutical and device makers to publicly report their payments to physicians.

Despite these changes, the system for disclosing conflicts remains fragmented and weakly enforced. Medical journals and professional societies have a variety of guidelines about what types of relationships must be reported, often leaving it up to the researcher to decide what is relevant. There are few repercussions — beyond a correction — for those who fail to follow the rules.

For example, the American Association for Cancer Research has warned authors <http://clincancerres.aacrjournals.org/content/clincanres/suppl/2017/06 /21/1078-0432.CCR-16-2267.DC1/171525_1_data_set_3728065_qg0v3w.pdf> that they face a three-year ban if they are found to have omitted a potential conflict. But the group's conflict-of-interest policy contains no mention of such a penalty <http://aacrjournals.org/content/authors/editorial-policies>, and it said no author had ever been barred. Baselga's failure to disclose his industry relationships extended to the association's journal, Cancer Discovery, for which he serves as one of two editors-in-chief. The association said it is investigating Baselga's actions.

Most authors do seem to disclose their ties to corporate interests. About two-thirds of the authors on the Kisqali study, for example, reported relationships with companies, including Novartis. But the researchers who did not included Arteaga, Burris and Denise A. Yardley, a senior investigator who works with Burris at Sarah Cannon.

The Tennessee-based research center received more than \$105,000 in fees for consulting, speaking and other services on Yardley's behalf in the three-year period in which she declared no conflicts.

The Sarah Cannon institute said it switched over a year ago to a "universal disclosure" practice promoted by ASCO, the cancer group that Burris will lead. That requires doctors to disclose all payments, including those made

to their institutions.

"We believe we adhere to the highest ethical standards in the industry by not allowing personal compensation to be paid to our leadership physicians," the center said.

ASCO said it would post corrections to Burris' disclosures in the Journal of Clinical Oncology for the past four years. The group said that in the fall of 2017 — as Burris was seeking a leadership role in the organization — it began working with him to disclose all his company relationships, including indirect payments. Burris will become president in June 2019.

"Disclosure systems and processes in medicine are not perfect yet, and neither are ASCO's," the group said in an email.

Burris, Yardley and Arteaga submitted updated disclosures to the New England Journal of Medicine, <u>which posted them on Thursday</u> <<u>https://www.nejm.org/doi/suppl/10.1056/NEJMoa1609709/suppl_file</u> /nejmoa1609709_disclosures.pdf>.

Burris' updated disclosure listed relationships with 30 companies, including that he provided expert testimony for Novartis.

Other studies recently published by the New England Journal of Medicine also omitted disclosures, including one on a 2018 study <<u>https://www.nejm.org</u> /<u>doi/10.1056/NEJMoa1715971></u> on a treatment for sickle cell disease and <u>another</u> on the recently approved cancer drug Vitravki <<u>https://www.nejm.org/doi/full</u> /<u>10.1056/NEJMoa1714448></u>, to be sold by Bayer and Loxo Oncology.

Jennifer Zeis, a spokeswoman for the journal, said it was contacting those studies' authors, and that it now asked researchers to certify that they had checked their disclosures against the federal database.

Some institutions have pushed back, arguing that the journals' inconsistent rules make it difficult for even well-meaning researchers to do the right thing.

In a letter last month to the New England Journal of Medicine, Memorial Sloan Kettering objected to the treatment of one of its top researchers, Dr. Jedd Wolchok. When he tried to correct his disclosures, the journal shifted its position, from saying its editors were satisfied with his disclosures to saying he had failed to comply with the rules, the center said in citing communications with the journal.

Wolchok, a pioneer in cancer immunotherapy, ultimately <u>corrected 13</u> articles and letters <<u>https://www.nejm.org/doi/full/10.1056/NEJMx180040></u> to the editor. To clarify reporting requirements, several publications are attempting only now to do what the Institute of Medicine recommended in 2009. The New England Journal is testing a new system in partnership <<u>https://www.nytimes.com/2018/09/30/opinion/letters/disclosure-medicine.html></u> with the Association of American Medical Colleges that would act as a central repository for reporting financial relationships.

This year, JAMA began requiring authors to confirm multiple times that they had nothing to disclose. ASCO has a centralized system for reporting conflicts to all of its journals and speaker presentations.

Dr. Bernard Lo, the chairman of the 2009 Institute of Medicine panel, said journals have only begun to confront some of the systemic flaws. "They're certainly not out in front trying to be trailblazers, let me just say it that way," he said. "The fact that it hasn't been done means that nobody has it on their priority list."

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