# Top Cancer Researcher Fails to Disclose Corporate Financial Ties in Major Research Journals

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Dr. José Baselga, the chief medical officer at Memorial Sloan Kettering Cancer Center, in 2015. Cindy Ord/Getty Images

#### By Charles Ornstein and Katie Thomas

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One of the world's top breast cancer doctors failed to disclose millions of dollars in payments from drug and health care companies in recent years, omitting his financial ties from dozens of research articles in prestigious publications like The New England Journal of Medicine and The Lancet.

The researcher, Dr. José Baselga, a towering figure in the cancer world, is the chief medical officer at Memorial Sloan Kettering Cancer Center in New York. He has held board memberships or advisory roles with Roche and Bristol-Myers Squibb, among other corporations, has had a stake in start-ups testing cancer therapies, and played a key role in the development of breakthrough drugs that have revolutionized treatments for breast cancer.

According to an analysis by The New York Times and ProPublica, Dr. Baselga did not follow financial disclosure rules set by the American Association for Cancer Research when he was president of the group. He also left out payments he received from companies connected to cancer research in his articles published in the group's journal, Cancer Discovery. At the same time, he has been one of the journal's two editors in chief. A decade ago, <u>a series of scandals involving the secret influence</u> of the pharmaceutical industry on drug research prompted the medical community to beef up its conflict-of-interest disclosure requirements. Ethicists worry that outside entanglements can shape the way studies are designed and medications are prescribed to patients, allowing bias to influence medical practice. Disclosing those connections allows the public, other scientists and doctors to evaluate the research and weigh potential conflicts.

"If leaders don't follow the rules, then we don't really have rules," said Dr. Walid Gellad, director of the Center for Pharmaceutical Policy and Prescribing at the University of Pittsburgh. "It says that the rules don't matter."

The penalties for such ethical lapses are not severe. The cancer research group, the A.A.C.R., <u>warns authors who fill out disclosure forms</u> for its journals that they face a three-year ban on publishing if they are found to have financial relationships that they did not disclose. But the <u>ban is not included</u> in the conflict-of-interest policy posted on its website, and the group said no author had ever been barred.

Many journals and professional societies do not check conflicts and simply require authors to correct the record.

Officials at the A.A.C.R., the American Society of Clinical Oncology and The New England Journal of Medicine said they were looking into Dr. Baselga's omissions after inquiries from The New York Times and ProPublica. The Lancet declined to say whether it would look into the matter.

Christine Hickey, a spokeswoman for Memorial Sloan Kettering, said that Dr. Baselga had properly informed the hospital of his outside industry work and that it was Dr. Baselga's responsibility to disclose such relationships to entities like medical journals. The cancer center, she said, "has a rigorous and comprehensive compliance program in place to promote honesty and objectivity in scientific research." Asked if he planned to correct his disclosures, Dr. Baselga asked reporters what they would recommend. In a statement several days later, he said he would correct his conflict-of-interest reporting for 17 articles, including in The New England Journal of Medicine, The Lancet and the publication he edits, Cancer Discovery. He said that he did not believe disclosure was required for dozens of other articles detailing early stages of research. "I have spent my career caring for cancer patients and bringing new therapies to the clinic with the goal of extending and saving lives," Dr. Baselga said in the statement. "While I have been inconsistent with disclosures and acknowledge that fact, that is a far cry from compromising my responsibilities as a physician, as a scientist and as a clinical leader."

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## The corporate imprint on cancer research

Dr. Baselga, 59, supervises clinical operations at Memorial Sloan Kettering, one of the nation's top cancer centers, and wields influence over the lives of patients and companies wishing to conduct trials there. He was paid more than \$1.5 million in compensation by the cancer center in 2016, according to the hospital's <u>latest available tax disclosures</u>, but that does not include his consulting or board fees from outside companies.

Many top medical researchers have ties to the for-profit health care industry, and some overlap is seen as a good thing — after all, these are the companies charged with developing the drugs, medical devices and diagnostic tests of the future.

Dr. Baselga's relationship to industry is extensive. In addition to sitting on the board of Bristol-Myers Squibb, he is a director of Varian Medical Systems, which sells radiation equipment and for whom Memorial Sloan Kettering is a client.

In all, Dr. Baselga has served on the boards of at least six companies since 2013, positions that have required him to assume a fiduciary responsibility to protect the interests of those companies, even as he oversees the cancer center's medical operations.

The hospital and Dr. Baselga said steps had been taken to prevent him from having a say in any business between the cancer center and the companies on whose boards he sits. The chief executive of Memorial Sloan Kettering, <u>Dr. Craig B.</u> <u>Thompson</u>, settled lawsuits several years ago that were filed by the University of Pennsylvania and an affiliated research center. They contended that he hid research conducted while he was at Penn to start a new company, Agios Pharmaceuticals, and did not share the earnings. Dr. Thompson disputed the allegations. He now sits on the board of Merck, which manufactures Keytruda, a blockbuster cancer therapy.

Ms. Hickey said the cancer center cannot fulfill its charitable mission without working with industry. "We encourage collaboration and are proud that our work has led to the approval of novel, lifesaving cancer treatments for patients around the world," she said.

### Some disclosures are required; others aren't

After the <u>scandals</u> a decade ago over lack of disclosure, the federal government began requiring drug and device manufacturers <u>to</u> <u>publicly disclose payments</u> to doctors in 2013.

From August 2013 through 2017, Dr. Baselga received nearly \$3.5 million from nine companies, according to the federal Open Payments database, which compiles disclosures filed by drug and device companies.

Dr. Baselga has disclosed in other forums investments and advisory roles in biotech start-ups, but he declined to provide a tally of financial interests in those firms. Companies that have not received approval from the Food and Drug Administration for their products — projects still in the testing phases — do not have to report payments they make to doctors.

Serving on boards can be lucrative. In 2017, he received \$260,000 in cash and stock awards to sit on Varian's board of directors, according to the <u>company's corporate filings</u>.

ProPublica and The Times analyzed Dr. Baselga's publications in medical journals since 2013, the year he joined Memorial Sloan Kettering. He failed to disclose any industry relationships in more than 100, or about 60 percent of the time, a figure that has increased with each passing year. Last year, he did not list any potential conflicts in 87 percent of the articles that he wrote or cowrote. Dr. Baselga compiled a color-coded list of his articles and offered a different interpretation. Sixty-two of the papers for which he did not disclose any potential conflict represented "conceptual, basic laboratory or translational work," and did not require one, he said. Questions could be raised about others, he said, but he added that most "had no clinical nor financial implications." That left the 17 papers he plans to correct.

Early-stage research often carries financial weight because it helps companies decide whether to move ahead with a product. In about two-thirds of Dr. Balsega's articles that lacked details of his industry ties, one or more of his co-authors listed theirs.

In 2015, Dr. Baselga published an article in the New England Journal about a Roche-sponsored trial of one of the company's drugs, Zelboraf. Despite his financial ties to Roche, he declared that he had "nothing to disclose." Fourteen of his co-authors reported ties to Roche.

Dr. Baselga defended the articles, saying that "these are highquality manuscripts reporting on important clinical trials that led to a better understanding of cancer treatments."

### Industry Connections

Some of Dr. José Baselga's known relationships with health care companies. He has failed to disclose any industry ties in dozens of research articles since 2013.

Board of Directors Aura Biosciences\* (cancer startup) Bristol-Myers Squibb Foghorn Therapeutics (cancer startup) Grail\* (cancer testing startup)

 Eli Lilly\*
Novartis\* Roche/Genentech\*

Scientific or Clinical Advisory Board ApoGen Biotechnologies (cancer statup) Aura Biosciences (cancer startup) Grail (cancer testing startup) Juno Therapeutics\* Grail\* (cancer testing startup)
Infinity Pharmaceuticals\* (cancer startup)
Varian Medical Systems (radiation equipment)
Pald Consultant
AstraZeneca\*
Seragon Pharmaceuticals (cancer startup)

startup)

## Founder or Co-Founder Mosaic Biomedicals Tango Therapeutics (cancer startup)

Source: Analysis by The New York Times and ProPublica. Note: Dr. Baselga worked with these companies at different times. Former relationships are marked with a \*.

The guidelines enacted by most major medical journals and professional societies ask authors and presenters to list recent financial relationships that could pose a conflict.

But much of this reporting still relies on the honor system. A study in August in the journal JAMA Oncology found that one-third of authors in a sample of cancer trials did not report all payments from the studies' sponsors.

"We don't routinely check because we don't have those kind of resources," said Dr. Rita F. Redberg, the editor of JAMA Internal Medicine, who has been <u>critical of</u> the influence of industry on medical practice. "We rely on trust and integrity. It's kind of an assumed part of the professional relationship."

Jennifer Zeis, a spokeswoman for The New England Journal of Medicine, said in an email that it had now asked Dr. Baselga to amend his disclosures. She said the journal planned to overhaul its tracking of industry relationships.

The American Association for Cancer Research said it had begun an "extensive review" of the disclosure forms submitted by Dr. Baselga.

It said that it had never barred an author from publishing, and that "such an action would be necessary only in cases of egregious, consistent violations of the rules."

Among the most prominent relationships that Dr. Baselga has often failed to disclose is with the Swiss pharmaceutical giant Roche and its United States subsidiary Genentech.

In June 2017, at the annual meeting of the American Society of Clinical Oncology in Chicago, Dr. Baselga spoke at a Rochesponsored investor event about study results that the company had been counting on to persuade oncologists to move patients from Herceptin — which was facing competition from cheaper alternatives — to a combination treatment involving Herceptin and a newer, more expensive drug, Perjeta.

The results were so underwhelming that Roche's stock fell 5 percent on the news. One analyst described <u>the results as a "lead</u> <u>balloon," and an editorial</u> in The New England Journal called it a "disappointment." Dr. Baselga, however, <u>told analysts</u> that critiques were "weird" and "strange."

This June, at the same cancer conference, Dr. Baselga struck an upbeat note about the results of a Roche trial of the drug taselisib, <u>saying in a blog post</u> published on the cancer center website that the results were "incredibly exciting" while conceding the side effects from the drug were high.

That same day, Roche announced it was scrapping plans to develop the drug. The news was another disappointment involving the class of drugs called PI3K inhibitors, which is a major focus of Dr. Baselga's current research.

In neither case did Dr. Baselga reveal that his ties to Roche and Genentech went beyond serving as a trial investigator. <u>In 2014,</u> <u>Roche acquired Seragon</u>, a cancer research company in which Dr. Baselga had an ownership stake, for \$725 million. Dr. Baselga received more than \$3 million in 2014 and 2015 for his stake in the company, <u>according to the federal Open Payments database</u>.

From 2013 to 2017, Roche also paid Dr. Baselga more than \$50,000 in consulting fees, according to the database.

These details were not included in the conflict-of-interest

statements that are required of all presenters at the American Society of Clinical Oncology conference, although he did disclose ownership interests and consulting relationships with several other companies in the prior two years.

ASCO said it would conduct an internal review of Dr. Baselga's disclosures and would refer the findings to a panel.

Dr. Baselga said that he played no role in the Seragon acquisition, and that he had cut ties with Roche since joining the board of a competitor, Bristol-Myers, in March. As for his presentations at the ASCO meetings in the last two years, he said he had also noted shortcomings in the studies.

The combination of Perjeta with Herceptin <u>was later approved</u> by the F.D.A. for certain high-risk patients. As for taselisib, Dr. Baselga stands by his belief that the PI3K class of drugs will be an important target for fighting cancer.

Charles Ornstein is a senior editor at ProPublica.