In a press release, Christof Sohn (right) promoted a questionable breast cancer blood test as "revolutionary."

Heidelberg University

German university finds 'severe' misconduct by researcher who promoted questionable cancer blood test

By Hinnerk Feldwisch-DrentrupOct. 25, 2019, 11:05 AM

A university commission announced this week it had found evidence of "extensive and severe scientific misconduct" by Christof Sohn, director of the women's clinic at Heidelberg University Hospital in Germany and the lead researcher behind a highly publicized but questionable blood test designed to detect breast cancer.

The hospital has been rocked for months by the scandal, which has led to ongoing criminal proceedings. The hospital intended to release the results of an external investigation into the scandal at a press conference on 22 October, the same day that Heidelberg University released the report from its commission for good scientific practice. But that day, after a petition from Sohn, a local court ordered the cancelation of the press conference to protect the rights of and presumption of innocence for Sohn, who reportedly has been suspended from teaching and research for 3 months and faces a university disciplinary inquiry. Following the court's decision, the university also removed its commission's report from its website. Prosecutors in Mannheim, Germany, declined to name suspects in their ongoing inquiries concerning economic crimes.

The affair began in February, when Sohn promoted the blood-based liquid biopsy test as a "new, revolutionary option" in a **press release** that appeared on the websites of both the hospital and HeiScreen GmbH, a spin-off company. The institutions claimed the test, which looks for 15 biomarkers that reflect cancer-related genetic processes, has a sensitivity of 80% to 90% for some groups of women with breast cancer. (Sensitivity reflects the proportion of women with cancer that is correctly identified.)

The press release said the test, based on a study of more than 900 women, was to be launched commercially this year. A story in *Bild*, Germany's biggest tabloid newspaper, **called the test** a "world sensation." In an interview with *Bild*, Sohn said the test wouldn't replace mammograms, but said it could be an early detection system that avoids the radiation of mammogram x-rays. He added that the test has only "half as many false positive results" as mammograms—which, depending on age, typically have false positive rates of about 5% to 10%.

That claim was contradicted by results Sohn presented in a talk at a scientific meeting in February in Düsseldorf, Germany. His talk slides showed that the test had a specificity of 45% to 73%, according to the German online magazine *MedWatch*. That's equivalent to an enormously high false positive rate of up to 55%, where about every second woman without breast cancer would receive a positive result—an unusable test. Nonetheless, at a press conference at the meeting, Sohn, his project colleague Sarah Schott, and HeiScreen CEO Dirk Hessel praised the test. Sohn talked up the test's sensitivity, but avoided discussing its false positive rate, even when asked by a journalist.

The promotion of the test "is totally unacceptable," says Gerd Gigerenzer, director of the Harding Center for Risk Literacy at the Max Planck Institute for Human Development in Berlin, who has followed the case. "Trying to market such a test ... is close to a crime."

When asked for an explanation in May, Sohn said his statements in *Bild* referred only, and hypothetically, to young women, for whom mammograms offer little diagnostic help. The hospital argued that Sohn was responsible for communicating the test's false positive rate, although a hospital spokesperson confirmed that other top hospital officials read the press release in advance. "It is not the responsibility of the directorate and corporate communication to compare scientific slides with statements from scientists," hospital spokesperson Doris Rübsam-Brodkorb said in May.

In July, an external panel established by the hospital board presented the results of a preliminary investigation, criticizing the press releases as premature and "yellow press instead of serious science communication." According to the panel's preliminary report, the scientists responsible for the project and all involved directors had sufficient knowledge to "see and assess" the problems.

Simone Schwanitz, head of the external panel and a department head at the science ministry in Germany's Baden-Württemberg state, said in an accompanying statement to the report that the scandal has caused "reputational damage to the medical hub in Heidelberg." In July, the dean of the medical faculty of the university and both the hospital's chairperson and its financial officer resigned from their positions.

Before it was taken down, the new report from the university commission pointed to Sohn as the main culprit, although it said that others also acted improperly. Scientific errors and shortcomings can be found "from the beginning of the research on the blood test, and since then continuously," the report said.

For the moment, Sohn has prevented publicity of the investigation by the hospital's external panel. He requested that the administrative court in Karlsruhe, Germany, ban further dissemination of comments already included in the panel's preliminary report until ongoing disciplinary procedures against him concluded.

In the interim order, obtained by *Science*Insider, the court said that presenting Sohn as guilty of misconduct had violated his constitutional rights, and that previous statements eroded the presumption of innocence. "We will make every effort to be able to present the commission's results at a later date," Schwanitz said in a statement. The court confirmed to *Science*Insider that the hospital on 23 October lodged a complaint against the order. A higher administrative court in Mannheim will now rule on the matter.

HeiScreen's website is still up, along with promotional material for the test. A company statement from May said the blood test "functions" under laboratory conditions, and that further studies on ovarian and breast cancer would be conducted. Sohn declined to comment for this story, saying that because of his civil servant status he could not answer questions.

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Hinnerk Feldwisch-Drentrup