

Report on Research Compliance Volume 18, Number 7. June 24, 2021 Research Integrity ‘Whistleblower’: Don’t Ignore Outsiders, Train Senior Investigators

By Theresa Defino

Elisabeth Bik will not be silenced.

While Bik, who has a doctorate in microbiology, has been active in calling out fraudulent research for several years, she gained more attention—and unpleasant backlash—when she raised questions about a March 2020 paper that proclaimed the benefits of hydroxychloroquine (in combination with azithromycin) for COVID-19.^[1]

Written by a team of French scientists, the article beget others and began a stampede that led to hydroxychloroquine being embraced by then-President Trump and an emergency use authorization being granted by the Food and Drug Administration—only to be revoked three months later amid findings that not only did the drug not work, but it had serious cardiac and other side effects.^[2] The authors’ response to Bik? As of a talk she gave in June, tweeting her address and reportedly asking a local prosecutor to investigate her for supposed harassment and extortion—allegations she strongly denies. Bik told RRC that she has not been contacted by French authorities related to these claims.

“It’s important to know that this is just trying to silence me,” Bik said. “If they attack me and my private life and dox my home address, it means that they don’t have answers to the scientific [questions] that I’m raising.”

Her life has been “ripped apart,” Bik said, adding that “without a lot of followers on Twitter”—she has 102,400—“and the support I’m receiving,^[3] I would have given up a long time ago.” Not only did she not give up, but last month she took a deeper dive into work by this same group, posting what she called part one of a series of articles on “image concerns” and other problems in 22 of their other papers.^[4]

But French researchers aren’t Bik’s only target, and she warned attendees at a recent conference that she will similarly hold U.S. investigators and institutions to account as well—and offered some thoughts on improving integrity.^[5] One tip: Just because she’s an “outsider” doesn’t mean she is a whistleblower who can be ignored.

For more than a decade, Bik was an academic “insider,” though not necessarily a whistleblower. After earning a doctorate from Utrecht University in the Netherlands, Bik spent 15 years at the Stanford University School of Medicine where she researched microbiomes of humans and marine mammals.

Interest Grew After 2016 Paper

The issue of image manipulation—and Bik’s profile—got a boost in June 2016 when she and two co-authors published a paper showing nearly 4% of images they visually screened “contained problematic figures, with at least half exhibiting features suggestive of deliberate manipulation.”^[6] The reviewed images were among 20,621 papers published in 40 scientific journals from 1995 to 2014.

Two years ago Bik became a self-employed research integrity consultant and now can say, ruefully, that she has “earned an army of trolls and enemies who are always asking me, ‘Who is paying you?’” (Answer: publishers,

universities and others; not pharmaceutical companies.) “I’m as independent as I can possibly be,” she told attendees at the annual Health Care Compliance Association Research Compliance Conference; HCCA is the publisher of *RRC*.

Bik said she is not alone in her methods but may be the only person engaged in the work full time. She and others can post comments, anonymously or with their names, on websites such as www.pubpeer.com. Her critiques appear on <https://scienceintegritydigest.com>.

Papers may contain fabrication, falsification or plagiarism as federal regulations define them, but “there could also be all kinds of errors. The work that we’re doing is not necessarily about finding science fraud. It’s about concerns or problems with papers,” Bik said.

These can include problems with the study design, misinterpretation of results, statistical or citation errors, undisclosed conflicts of interest, missing consents or approvals by institutional review boards or institutional animal care and use committees, and duplicated or altered photos or images, Bik said. Errors or intentional fabrications or falsifications may also occur in notes, bar graphs, and tables.

Based on that 2016 analysis and her expertise, Bik estimated that “the real percentage of scientific fraud might be between 5% and 10%” among published papers, which she acknowledged is a “pretty staggering number.”

Bik was joined at the session by Mary Inman, a partner with Constantine Cannon LLP who specializes in representing whistleblowers. Inman explained that Bik is the newest development in the evolution of whistleblowers—and she is rising at a time that is more ripe for fraud than ever before.

“What’s interesting is that the typical whistleblower has always been a whistleblower insider,” said Inman. Like others of her stripe, Bik “doesn’t necessarily work at the university, but is able to look at the data at the peer review [stage], journals and other things, and actually be able to detect research fraud from the outside,” Inman said.

Time of ‘Haste, Panic’

The speed with which COVID-19-related research is being funded and reported on, particularly in servers that publish papers prior to peer review, has upped the odds that misconduct and fraud will occur, Inman and Bik agreed.

Bik referred to this period as “a time of haste and panic.” As of the date of her talk, the blog *Retraction Watch* had tallied 113 COVID-19-related retractions, Bik said.

She disputed the notion that, once published, “a scientific paper is set in stone.” Papers are “still open for questions,” said Bik, whose primary focus is image manipulation and integrity issues.

Although it was not mentioned in the talk, Bik told *RRC* her work has resulted in the retraction of 498 papers. Some of that number is attributable to the shutdown of two “paper mills,” which was a joint effort with others, Bik said.

Despite this number, Bik said during the conference the “majority” of papers that she has flagged have not been corrected, “even after waiting five years. There seem to be a lot of conflicts...publishers don’t want to address these problems, institutions want to look the other way. It seems a lot of people are just sweeping these things under the rug and hoping that nobody notices these errors, but that’s not serving the reader, which is probably another scientist who tries to replicate these results.”

Bik also touched on nonpandemic reasons “scientists cheat,” noting among them the pressure to publish and the desirability of publishing positive vs. negative results.

“But, especially when you work in biology, it seems that not always your cells or your enzymes are behaving in a way that they behaved the previous day. And so you could imagine that sometimes the results do not really match up with your expectations,” Bik said. She added that she could envision a scenario where a professor might say, “I’m going to fire you if you don’t get these results.”

Such a threat “might lead [to] a post-doc or a graduate student falsifying results because they have a very strong professor, and they’re so dependent on this professor for the rest of their career. Scientific research, particularly in academia, is so hierarchical that people are focusing sometimes more on getting a letter of recommendation,” and less on “science,” said Bik.

Bik: Reduce Pressures to Publish

She added that “some countries also have a very specific focus on the output of the scientists in numbers of publications,” and investigators may receive “a monetary incentive or business class flight tickets” if they reach the publishing goal. “So, if you put really strong incentives in place, people will start to cheat just in order to get that result.”

Bik hastened to add that “most scientists are honest and hardworking” and that they “tend to believe each other when we publish our results. But as a field, science is also not immune to fraud. There is fraud in science, like there is in any other field you could think of, like banking and construction. Science has its fraud as well. And some of it is even organized.”

Institutions and others should relieve some of the “general” pressure that scientists have to publish, Bik said. While some people can handle this, others may be faced with “strong financial incentives or impossible requirements where a person needs to publish a paper, even though they are not on a research track—for example, a clinical doctor who just wants to help patients and who is forced to publish a paper. I think that’s a situation where people will do misconduct.”

“I’m not quite sure how we can ever get out of focusing in academia so much on publication,” Bik said, but added that investigators should be encouraged to publish negative results from trials.

Bik and others like her need to be on the compliance officer’s radar and, for example, be incorporated in employee training, Inman said.

Actions by Bik signal to “organizations that they need to not only be considering compliance issues and training their folks...to be dealing with transparency and ethics in research, but also that there...can be folks like Dr. Bik from the outside who can expose the issues,” Inman said.

Iman noted that if the fraudulent research was federally funded, Bik—and other outsiders—could file a qui tam action under the False Claims Act, regardless of outsider status.

Yet Bik told RRC she has more luck getting the attention of publishers than universities and other institutions.

Allegations ‘Tossed Over the Fence’

Additionally, responding to an attendee’s request for advice to compliance officers, Bik said that, “as a whistleblower who is trying to contact compliance officers at universities, for me it seems that there’s a lot of focus on trying to prevent it, but there’s almost no focus or activity...in addressing allegations once they have

been raised.”

Bik added that often she tries to “contact a research integrity officer at the institution, and I never even get an answer, or it’s impossible to find who that person is or to reach them, because they can only be reached if you’re part of the university system.”

In addition to investigating allegations, Bik said institutions should be “open to anonymous allegations” and should provide “updates to the whistleblower.”

“I have tossed a lot of allegations over the fence and never heard back, and it seems that a lot of these cases are, at least from my point of view, not being investigated,” she said. “My advice would be prevention is great but action and addressing these issues is even better.”

Bik and Inman argued that there should be legal safeguards for people like Bik, who, unlike insider whistleblowers, are not protected from retaliation. Companies and institutions often engage in “shoot-the-messenger” tactics to “scrutinize and bully the whistleblower” when confronted with claims “as a way to divert attention” from the wrongdoing, Inman said.

Inman added that the institutional culture needs to respect whistleblowers and others who speak out and listen to them, and deal appropriately with concerns rather than dismissing them.

Inman suggested that institutions and compliance officers view whistleblowers sympathetically as “good for [the] bottom line. They are forward indicators of risk. You should see them as a risk management tool, not as someone who is disloyal,” Inman said. Such a view would make a compliance officer more likely to “champion a system that supports” whistleblowers.

Compliance officers “are very much like whistleblowers,” Inman said. Both are “always delivering bad news,” for example, about activities that are not allowed because of a regulation. Compliance officers are “not a profit center.”

She said there has been a “move to raise the profile of compliance officers,” and give them more visibility and authority, which would enable them to “champion those whistleblowers” and view “them as simpatico.” This would improve the “fate of whistleblowers,” Inman said.

Often whistleblowers have gone to their employer with concerns first and then were rebuffed, prompting them to file litigation that later proves costly for the company or university. Experts say organizations would do well to ensure those concerns are taken seriously.

Inman: Outsiders Are Valuable Tipsters

In answer to a question from *RRC* about whether the institution should respond differently if the complainant is an outsider, Inman said no. “In essence, it’s the same. Because what whistleblowers are doing, whether they’re inside or outside, they’re bringing in information that hopefully will trigger an investigation by you.”

In all instances, “it’s really incumbent on you to take that tip and corroborate it,” Inman said. She added that in her experience, “the overwhelming majority of frauds are ones where there are multiple witnesses” who can support the whistleblower’s allegation.

Inman also noted that the outside whistleblower is likely to be more cooperative with an investigation because the individual has less at stake, such as employment, than an outsider.

Plea for Legal Protections

Bik added that her findings should be easier for institutions—or publishers—to accept. “The things that I am finding that might be wrong in a paper are, in a way, objective. They’re published. I can just say, ‘Figure 2A and 2B look very similar to each other,’ while the insider whistleblower may have some very specific data that only he or she might know, and that is hard to prove sometimes.”

She sees her efforts as part of the imperative to rebuild the public’s trust in science. But, as Bik noted, the work comes at a high personal cost to her.

Bik finds comfort from those “who agree with me that these scientific discussions should not be fought out in the legal arena, but that they’re purely scientific discussions. I always try my best to not insult anybody and just make it about the facts. And I always hope that the authors then reply and tell me that I was wrong by providing evidence.”

Still, she added, “I really hope that science will come up with some structure to legally protect the whistleblower who in good faith raises concerns” and is “not making any false allegations.”

1 Elisabeth Bik, “Thoughts on the Gautret et al. paper about Hydroxychloroquine and Azithromycin treatment of COVID-19 infections,” *Science Integrity Digest*, blog, March 24, 2020, <https://bit.ly/3zCRLcO>.

2 Denise M. Hinton, letter to Dr. Disbrow, June 15, 2020, <https://bit.ly/3vLTvnX>.

3 Cathleen O’Grady, “Scientists rally around misconduct consultant facing legal threat after challenging COVID-19 drug researcher,” *Science*, May 27, 2021, <https://bit.ly/35GS5Op>.

4 Elisabeth Bik, “Concerns about Marseille’s IHUMI/AMU papers – Part 1,” *Science Integrity Digest*, blog, June 2, 2021, <https://bit.ly/3vIJ1oJ>.

5 Elisabeth Bik and Mary Inman, “The Vital Role of Whistleblower Scientists in Exposing Fraudulent Research During the Pandemic,” Research Compliance Conference, Health Care Compliance Association, June 16, 2021, <https://bit.ly/3gDFx2B>.

6 Elisabeth M. Bik, Arturo Casadevall, and Ferric C. Fang, “The Prevalence of Inappropriate Image Duplication in Biomedical Research Publications,” *mBio* 7, no. 3 (June 7, 2016), <https://bit.ly/3wOjITs>.

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