Georgia Tech researchers were part of a three-continent, multi-organization effort known as “Operation Jupiter” that successfully identified and shut down manufacturers who were flooding Southeast Asia with counterfeit – and ineffective – anti-malarial drugs.

With 11 different organizations, including the Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO), the Wellcome Trust – and ultimately the international law enforcement agency INTERPOL – the effort provided Chinese officials with enough information to shut down the drugmakers.

Beyond the human health cost of failing to effectively treat hundreds of thousands of malaria cases, the fake drugs could be fueling development of malarial strains that may become resistant to the most sophisticated drug now available to treat the disease: artesunate. That’s because counterfeiters sometimes include small quantities of the real drug in their fakes, possibly to fool simple quality tests. By not killing the malaria parasites, the small artesunate doses could facilitate development of resistance.

As their part of the investigation, Georgia Tech researchers used mass spectrometry techniques to analyze nearly 400 drug samples provided by public health authorities. They also developed methods to speed up analysis, including an ionization process that reduced the time required to test a drug sample from 30 minutes to just a few seconds.

Activities aimed at addressing the widespread problem of counterfeit anti-malarial drugs were reported February 12 in the journal *PLoS Medicine*. Georgia Tech’s efforts to develop faster analytical techniques were sponsored by the National Science Foundation, while the sample analysis was supported by a small grant from WHO.

Malaria kills more than a million people each year worldwide, and is a risk for about 40 percent of the world’s population. Most victims would survive – if they had access to the proper drugs.

“About 50 percent of the samples obtained from the field in Southeast Asia were fakes,” says Facundo Fernandez, an assistant professor in Georgia Tech’s School of Chemistry and Biochemistry. “They look very real, even down to the hologram in the packaging. It’s very difficult to tell which ones are the fakes and which ones are real.”

When Fernandez began analysis of the drug samples, he assumed that they would not include real active ingredients. But his graduate students Christina Hampton and Leonard Nyadong soon discovered that the counterfeiters were making their fake anti-malarials with a broad range of mostly expired pharmaceuticals.

“We found old and ineffective anti-malarials like chloroquine,” he adds. “We found antibiotics like erythromycin. We found all sorts of drugs that basically have no effect on resistant malaria parasites.”

Mass spectrometry provides a very effective means of identifying samples by accurately determining their molecular weight. But the conventional analysis can be time-consuming – especially in the preparation of samples.

Fernandez and his Georgia Tech group developed a faster method that allows them to analyze hundreds of samples in a single day.
Their goal was to make mass spectrometry analyses responsive to time constraints required by law enforcement agencies involved in anti-counterfeiting.

“These are methods that let you analyze a solid sample without any significant preparation,” he explains. “You can take a tablet, put it in front of the instrument with an ionization source, and you get a quick snapshot of what’s in the sample. It provides a very high throughput pipeline to identify samples quickly.”

The Operation Jupiter team ultimately provided enough information that Chinese authorities were able to shut down the manufacturers, which were sophisticated operations able to accurately mimic the packaging and holographic seals of legitimate pharmaceutical companies.

Fernandez and his students remain involved in anti-counterfeiting activities and hope to obtain additional funding to continue supporting the efforts. They are now investigating fake anti-malarials sold in Africa, analyzing assortments of drugs sold in markets there and studying other faked drugs, such as tamiflu.

Large pharmaceutical companies can afford to pursue counterfeiting themselves, Fernandez noted, but in many cases, drugs sold in developing nations come from small companies that cannot afford private investigators and law firms to go after the counterfeitors.

“The problem is not over,” he cautions. “There are more fakes and more fake producers. But at least this is a beginning. Having an opportunity to do some good in this area is very satisfying.”

Graduate student Leonard Nyadong demonstrates an ionization technique that speeds up the testing of samples.