FDA Invention Fights Counterfeit Malaria Drugs

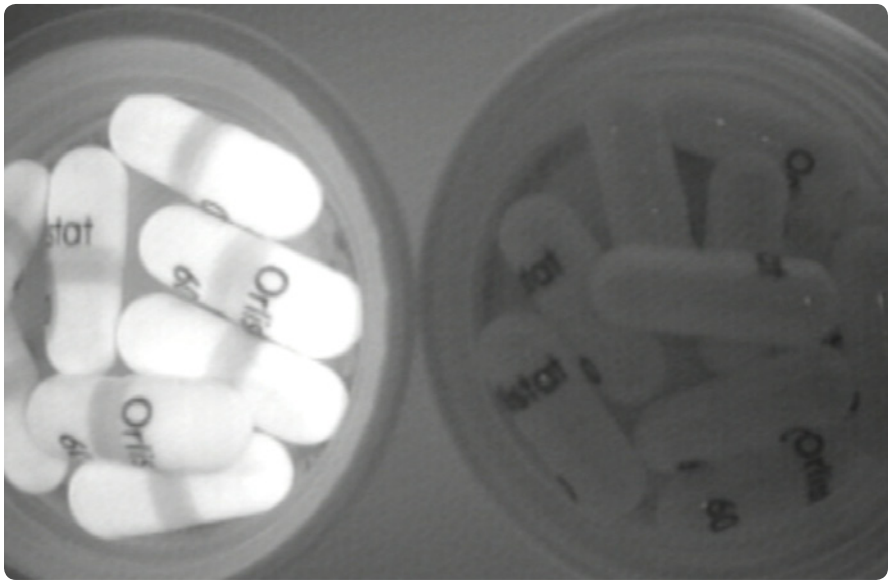
As nations and non-profits diligently work together to treat malaria patients and prevent the disease's spread, they also are forced to deal with a flood of counterfeit or substandard anti-malarial drugs.

Tragically, more than a third of anti-malaria drugs available in Sub-Saharan Africa and Southeast Asia are counterfeit or substandard. These drugs "not only deprive people of life-saving treatment, but can also lead to parasites resistant to authentic medications," says FDA Commissioner Margaret A. Hamburg, M.D.

Now, armed with an innovative, portable tool invented by Food and Drug Administration (FDA) scientists, FDA officials have launched a public-private partnership to combat counterfeit or substandard malaria medicine. The tool allows workers in the field, even in remote locations, to quickly, easily and cheaply identify suspect medicine.

The tool, simply named the Counterfeit Detector Device, Version 3, or CD-3, will be deployed and tested in Ghana this year and next. A second testing program is planned in a location yet to be determined. Malaria strikes more than 200 million people a year, mostly in Asia and Africa. The disease kills more than 660,000 people globally each year, mostly children.

"CD-3 illustrates the spirit of innovation and the commitment to public



The CD-3 (top), a small portable device invented by FDA scientists, is being deployed to screen for counterfeit and sub-standard malaria drugs. Using wavelengths of light, CD-3 reveals differences between authentic (bottom right) and counterfeit (bottom left) drugs that look the same to the naked eye.

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health that our scientists have," says Melinda K. Plaisier, FDA's acting Associate Commissioner for Regulatory Affairs. "They saw a need and invented a technology to address it. It started off solving an immediate problem in FDA labs, and now is being leveraged to impact global health."

The Invention

Work on the counterfeit detection tool started in 2005, when Nicola Ranieri, a scientist in FDA's Forensic Chemistry Center (FCC) in the Office of Regulatory Affairs, looked into the use of ultraviolet (UV) light sources, including those used in crime scene investigations, for detecting counterfeit drugs.

Approaches already being used at the FCC to identify counterfeit or substandard pharmaceuticals required sophisticated lab instrumentation and highly trained scientists. Ranieri envisioned a hand-held tool that was cheap, portable and easy to use.

Initially laboring at his kitchen table for hours after work, Ranieri taught himself electronics and collected components he needed to create a rudimentary tool. He and Mark Witkowski, a vibrational spectroscopist at the FCC, worked together to develop and refine ideas that were incorporated into a prototype which became the CD-1.

Lessons learned from the first tool led to the development of the CD-2 and eventually CD-3, which incorporated additional wavelengths, including infrared, to illuminate the product being examined, along with a monitor, cameras and data storage capabilities.

Looked at through this tool, the counterfeit drugs and their packaging appear markedly different—even to laymen—from authentic products placed next to them. CD-3 can be used at remote locations and costs a fraction of the price of existing laboratory-based and field-deployable technologies.

Since 2010, the tools have been used in some U.S. ports and mail centers, where drugs entering the county after being bought over the Internet represent a major problem.

In order to gear up for a global deployment strategy, FDA recently signed a letter of intent with New York-based Corning, Inc. to refine and improve the tool for eventual manufacture on a broader scale.

The Mission

The counter-counterfeit program employing the CD-3 will leverage an existing network of organizations engaged in this work. FDA is partnering with the U.S. Agency for International Development (USAID) (*http://www.usaid.gov/*) and the Presidential Malaria Initiative, which funds overseas drug surveillance systems carried out by the non-profit United States Pharmacopeia (USP) (*http://www.usp.org*).

The initial deployment of the CD-3 in Ghana will take place at five surveillance sites in provincial towns, with funding provided by the Skoll Global Threats Fund (*http://www.skollfoundation.org/*).

FDA is providing the tools and the necessary training; technical help will be provided by the Centers for Disease Control and Prevention and the National Institutes of Health.

Samples of drugs to be tested will be obtained from hospitals, clinics and both public and private pharmacies. Suspect products will be retested at a quality control laboratory and provided to Ghanaian authorities for enforcement action.

Ghana was chosen as the initial deployment site because of location—more than 90 percent of malaria deaths occur in Africa—and because it offers a stable government and is a pharmaceutical manufacturing center in sub-Saharan Africa.

Additionally, partners USAID, PMI and USP are already established there and have existing relationships with national regulatory authorities.

"By combining the resources of governments, non-profits and private enterprise, this project serves as a model for attacking huge problems with severe consequences," says Hamburg. "FDA is honored to be a part of it."

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