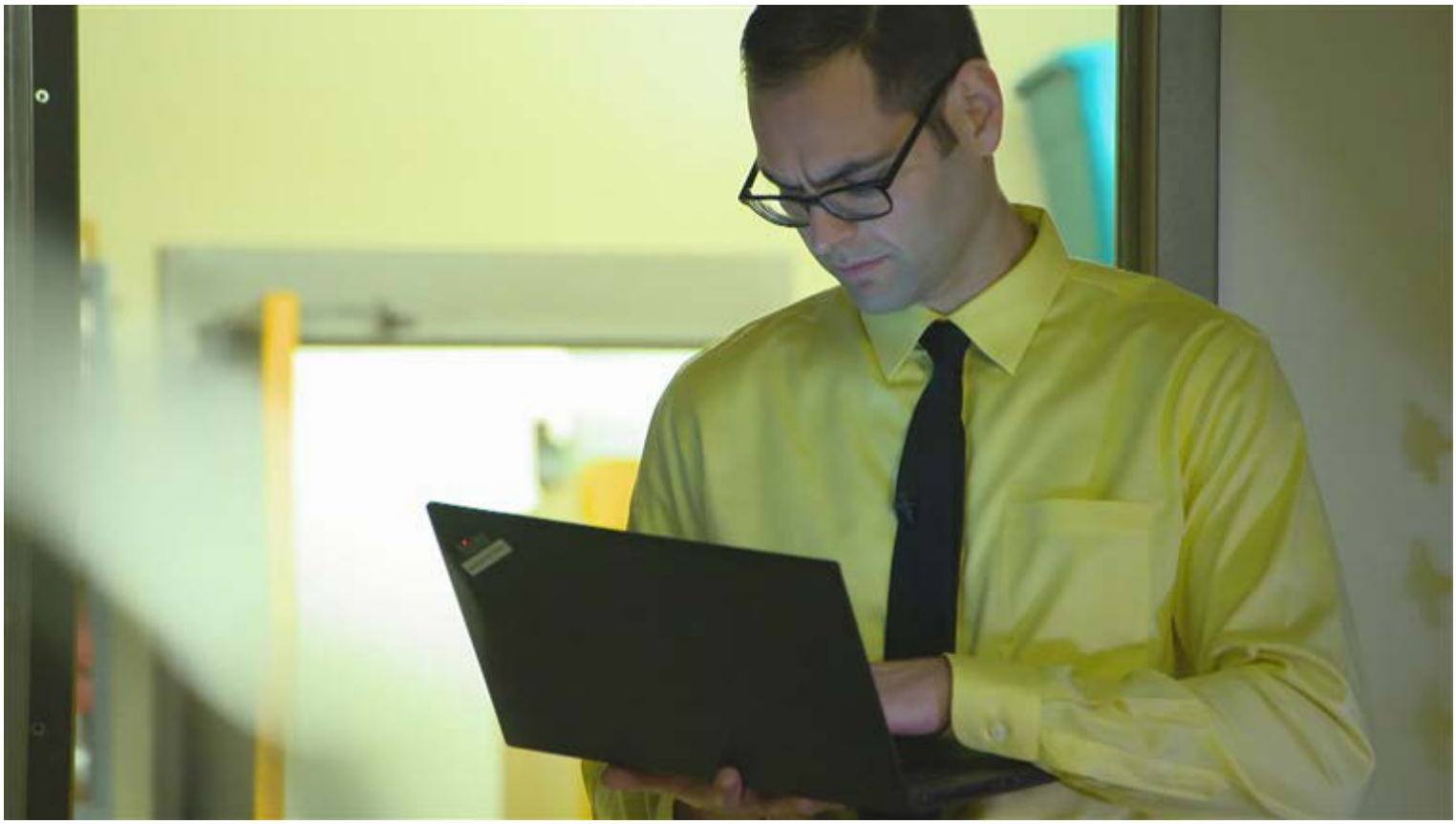

Massoud Motamed worked for the FDA for nearly three years as an inspector for drug plants overseas. During his time, Motamed sounded the alarm on at least two facilities, one in China and another in India, that would become part of the ongoing valsartan, losartan and irbesartan recalls. NBC News

May 10, 2019, 1:01 PM EDT

By Didi Martinez, Brenda Breslauer and Stephanie Gosk

The notice arrived at the home of Denise Schreck, a New Jersey woman who suffers from high blood pressure, last July.

"URGENT PRODUCT RECALL," blared the words at the top of the letter from her pharmacy.

The blood pressure medication used by Schreck and millions of other Americans was tainted. The culprit? A chemical with the potential to cause cancer.

Schreck went online to learn more and discovered that the generic drug, valsartan, was in fact found to contain a contaminant formerly used in the production of rocket fuel, according to a government fact sheet.

"I was just really blown away," Schreck, 51, told NBC News. "It's shocking to know that you've been taking a probable carcinogen for four years."

For more information, tune in to NBC Nightly News with Lester Holt tonight at 6:30pm ET/5:30pm CT

Denise Schreck is one of millions of Americans who have been prescribed the blood pressure medication, valsartan.
NBC News

The valsartan recall came as little surprise to Massoud Motamed, a former inspector with the U.S. Food and Drug Administration (FDA). More than a year before the notices went out, Motamed had tried to sound the alarm on what he flagged as potential systemic problems at two facilities in China and India that produce the active ingredients in generic valsartan and other blood pressure medications.

Speaking out publicly for the first time, Motamed told NBC News that the FDA ultimately overruled his recommendation to crack down on one of the plants. Perhaps more alarming, he says the issues at the two overseas drug production facilities are hardly unique.

"This is only the tip of the iceberg," Motamed said in an exclusive interview.

The valsartan case underscores a new reality in the pharmaceutical industry — a growing reliance on foreign manufacturers to provide the raw ingredients for drugs sold in the U.S. According to FDA data, roughly 85 percent of the facilities manufacturing the ingredients in American drugs are located overseas, many from China and India where production costs are low and experts say local government oversight is less stringent.

The shift has contributed to a flood of recent recalls and fueled escalating concerns about the safety of medicines consumed in the U.S.

Since last summer, drug companies have announced a total of 45 recalls of generic lifesaving blood pressure medications. They include certain versions of valsartan and two other blood pressure drugs, losartan and irbesartan, as well as other blood pressure medications that contain the recalled drugs in their formulations. The raw ingredients were all traced to overseas manufacturing sites where drugs can be processed at a lower cost than at U.S. facilities.

"Growing up, we had this saying, 'You get what you pay for,'" Motamed said. "We have that belief for everything except pharmaceuticals. If we want to drive competition and drive the price down, it comes at the cost of quality."

Massoud Motamed NBC News

For Motamed, the recalls tell only part of the story. He says a more systemic issue has largely gone unreported: FDA inspectors struggling to keep up with foreign drug manufacturers that may bury or hide problems in their production.

Last year, the FDA inspected only one in five registered human drug manufacturing facilities abroad, according to agency data.

With U.S. inspectors scrambling to review a sprawling network of overseas drug production plants, the FDA is often left to rely on the word of the facility managers, Motamed said.

"I believe it would surprise Americans how much we rely on the manufacturer and whatever they tell us to say that a drug is good or bad," the former inspector told NBC News.

The FDA also inspected only about one in five domestic drug manufacturing facilities last year, according to agency data. But unlike inspections at U.S. plants, where investigators can show up without warning and ask for more time to examine conditions if they identify potential issues, Motamed said the foreign site reviews are often hobbled by language barriers and time constraints.

"Say I'm at a domestic facility and I tell my supervisors that I'm finding all these problems and I need more time to inspect. That happens — no issue," Motamed said.

"The same is not true of a foreign facility. I've had inspections where I really could have benefited from the extra time and I knew there were problems to be uncovered, but I had to leave the country."

Motamed spent three years as an FDA investigator, working mainly overseas to inspect foreign manufacturing facilities. A Texas native with a Ph.D. in biochemistry, Motamed, 34, joined the agency driven by a desire to contribute to the field of public health.

He had been in the role for more than two years when he went to inspect the Zhejiang Huahai Pharmaceutical plant in Linhai, China — the company that produced the tainted ingredients in Schreck's recalled medication — in May 2017.

Motamed's four-day inspection turned up a series of alarming issues that he later outlined in official reports. Facilities and equipment not maintained. Anomalies in testing not investigated. And "unknown

impurities" dismissed as laboratory error.

After his visit, and as first reported by Bloomberg, Motamed recommended that a warning letter be sent to the firm — an official action that bars the company from gaining the approvals to produce new U.S. drugs at the facility, until it resolves the issues.

But three months later, he was overruled by FDA management. The FDA decided to allow Zhejiang Huahai to voluntarily fix the problems on its own, the agency wrote in an official document obtained by NBC News, citing the firm's compliance history and mostly "adequate responses" to impurities in their testing.

"There are many factors that inform the FDA's decisions at a given time regarding what action to take following an inspection," the FDA said in a statement to NBC News. "We make those decisions in the interest of patient safety based on all information available to us, including evidence collected during an FDA inspection and a manufacturer's proposed corrective actions."

After facing criticism over its handling of the case, the FDA said it would have been "unlikely" to catch the impurities at the source of the recall during a routine inspection.

"Nonetheless, our inspections did reveal systemic problems of supervision that could have created the conditions for quality issues to arise," reads a January 2019 FDA press release.

In a statement to NBC News, Zhejiang Huahai said it's "working closely with regulators here and abroad to evaluate the source of the impurities that resulted in the recall" and is determining if "any modifications to its manufacturing processes are necessary."

Denise Schreck got the notice from her pharmacy in July that her blood pressure medication was being recalled due an "unexpected impurity" in her medication in the form of a probable human carcinogen. NBC News

The problems were not confined to the facility in China. While investigating a drug production factory in India, Hetero Labs Limited, in December 2016, Motamed discovered what appeared to be a brazen attempt to cover up issues at the plant.

"I was going to the bathroom and I kept seeing that people were going into an archival room. And that's not generally typical," Motamed said.

He decided to review the firm's closed circuit TV footage. What the inspector saw next shocked him.

NEWS
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POLITICS
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Motamed watched footage of individuals shredding company documents four days before his arrival, the inspection report says.

"They were staying up all night shredding extensive amounts of documents right before our audit," Motamed said. "...It means there are systemic issues."

"It's one of the more concerning findings I've had over the years," the former inspector added.

The FDA eventually sent a warning letter to Hetero in August 2017, citing "significant violations of current good manufacturing practice." Some 19 months after Motamed first flagged suspicious activity at the plant, Hetero was found to be one of the sources of the contaminated drug ingredients for sale in the U.S.

Hetero did not respond to several requests for comment by NBC News.

In the case of valsartan products, the FDA said last August that more than half of all the medication sold in the U.S. was being pulled from store shelves.

While it's unknown exactly how many people have been impacted by the recalls, the sheer demand for the drugs suggest it could reach into the millions. In 2016, 1.6 million people purchased valsartan and 9.2 million bought losartan, according to data provided by the U.S. Department of Health and Human Services.

The recalls create a vexing challenge for consumers like Don Grybb, who said he struggled to find a suitable alternative after finding out that his valsartan medication was being pulled from store shelves.

"Almost from prescription to prescription, I would find significant changes in my blood pressure," said Grybb, 68, of Michigan.

Don Grybb said he was made aware of the recent valsartan recall when he got a call from his pharmacy telling him that they couldn't refill his medication. Courtesy of Don Grybb

The FDA and outside healthcare professionals have warned consumers against suddenly stopping their medication due to the recall, saying that the short-term risks outweigh the potential impact of consuming the recalled medication.

The uncertainties surrounding the medications also pose challenges to doctors.

"It's hard to know what to prescribe patients," said Dr. Randall Zusman, a cardiologist at Massachusetts

General Hospital Heart Center in Boston. "You want to assume it's safe and effective. You don't want to feel like you are prescribing something that causes harm."

The FDA says the overall risk posed by the impurities is small. For valsartan, FDA testing found the pills contained somewhere between three and 210 times the agency's acceptable level for NDMA, the probable carcinogen at the center of the recall. If 8,000 people took the highest dose of the contaminated drug daily for four years, the FDA estimates, there may be one additional case of cancer over the lifetimes of those people.

"This is troubling to us and we know it's troubling to the public," the FDA said in a statement. "The concern is appropriate."

Experts said the contaminants are still powerful at low levels. "This is well beyond the risk that government agencies typically deem acceptable," said Lisa Lefferts, senior scientist at the Center for Science in the Public Interest. "While most people won't get cancer from the contaminants in these pills, it's an unacceptable risk, and avoidable."

The FDA has issued a list of medications free of the probable carcinogens and says it has been working to mitigate and prevent shortages.

"Our first action was to immediately undertake a major operation to investigate and to identify the root causes of the presence of these impurities and to work with companies to address the risks that the impurities posed to patients," Dr. Janet Woodcock, the FDA director for the Center for Drug Evaluation and Research, said in a statement to NBC News.

Dozens of consumers have now gathered to sue nearly every company involved in the recall through a consolidated multidistrict litigation case in New Jersey.

"There are a lot of things that could have been done to prevent something like this," Daniel Nigh, an attorney for the plaintiffs, told NBC News.

The Association for Accessible Medicines, the trade group for generic drug manufacturers, said its "member companies with affected products voluntarily recalled their medicines containing valsartan and have worked closely" with the FDA.

"Patients in the United States can be confident that the medicines they take are safe and effective," the group added. "Manufacturers of generic medicines and the Food and Drug Administration work to ensure

that prescription drugs meet the same high-quality standards regardless of where they're manufactured."

Motamed left the FDA in 2017, disillusioned over his experience trying to police a sprawling industry in what he described as a "cat and mouse" game where companies do what they can to conceal problems from the FDA. He believes the agency needs to hire more qualified investigators and needs to conduct more inspections of the overseas facilities producing drug ingredients.

Now working for the private pharmaceutical sector in India, Motamed said he's speaking out to raise awareness about the risk of tainted drugs.

"I think there's a significant portion which, if we test it here in the U.S., would not pass," Motamed said.

As for Schreck, the anxiety brought on by the valsartan recalls has prompted her to stash her bottle of pills in a small brown cabinet above her kitchen sink.

Why? She sees it as evidence that could be used in a court of law in the event that cancer were to infect her body one day.

"I hate to think that because of this I run an extra risk of developing cancer," Schreck said. "But it is my proof."

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