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How Did Carcinogenic Generic Pill Get Past the FDA?

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STORY AT-A-GLANCE -

- Since 2018, the carcinogenic compound NDMA has been found in several different drugs, including three blood pressure medications (valsartan, losartan and irbesartan), two heartburn medications (Zantac and Axid) and the diabetes drug metformin
- In the case of valsartan, three companies whose drugs were recalled in 2018 had all purchased the active ingredient from a Chinese manufacturer called Zhejiang Huahai Pharmaceutical Co.
- The U.S. Food and Drug Administration checks less than 1% of imported drugs for impurities or potency, and in five years sent warning letters to only 25% of companies suspected of faking quality data
- While generics are a boon to patients in that they're far less expensive while still providing the same benefits, there's more room for error as they also receive far less scrutiny by regulators, and manufacturers are trusted to regulate themselves
- An estimated 80% of all active drug ingredients are manufactured in China and India, and overseas plants are rarely inspected by U.S. authorities

This article was previously published September 30, 2020, and has been updated with new information.

Previously, I reported that carcinogenic N-nitrosodimethylamine (NDMA) had been found in certain blood pressure, heartburn and diabetes medications. As of February 2020, drugs recalled due to contamination with this poison included:[1]

- Valsartan, losartan and irbesartan (high blood pressure medications)
- Zantac[2] and Axid (heartburn medications)
- Metformin (diabetes medication)

In the case of valsartan, the three companies whose drugs were recalled in 2018 had all purchased the active ingredient from a Chinese company called Zhejiang Huahai Pharmaceutical Co. It's one of China's largest manufacturers of generics.[3]

Since 2018, the recall has been expanded dozens of times to also include losartan and irbesartan, made by more than 10 different companies with distribution in some 30 countries.[4]

As reported[5] by Bloomberg in December 2019, the U.S. Food and Drug Administration checks less than 1% of imported drugs for impurities (or potency for that matter). Clearly, the regulatory system, which is meant to safeguard patients, is broken, and trust in drug manufacturers is often misplaced.

Disturbingly, Bloomberg's report[6] suggests the NDMA contamination at Huahai may have been intentional, at least in the sense that profitability was prioritized over thorough quality testing and perfecting of novel manufacturing methods.

What Is NDMA?

NDMA is a water-soluble chemical known to cause cancer in animals. In humans, it's classified[7] as a probable carcinogen and causes serious liver damage and liver failure.[8]

According to the Environmental Protection Agency's technical fact sheet,[9] NDMA, which can form in both industrial and natural chemical processes, is a member of N-nitrosamines, a family of potent carcinogens.

"Potential industrial sources include byproducts from tanneries, pesticide manufacturing plants, rubber and tire manufacturers, alkylamine manufacture and use sites, fish processing facilities, foundries and dye manufacturers," the EPA notes.

However, we now know the chemical can also be produced during the manufacturing of drugs.

Historically, there are several cases[10] in which NDMA was used as a poison. In 1978, a German teacher's wife died after he put NDMA in her jam and a Nebraska man was sentenced to death that same year for spiking lemonade with it, killing two people.

In 2013, a Chinese medical student died as a result of an April Fool's prank when NDMA was put into the water cooler, and in 2018, a Canadian graduate student poisoned a post-doctoral fellow by injecting it into an apple pie. Meanwhile, hundreds of millions of patients around the world have been taking drugs contaminated with this poison, oftentimes daily, for years on end.

Can FDA Ensure Drug Safety?

Bloomberg's report[11] reviews the history of how carcinogens like NDMA have crept into the generic drug supply, and raises serious questions about the FDA's ability to ensure drug safety.

The article features the story of Karen Brackman, who after taking generic valsartan for two years suddenly found herself with a diagnosis of a rare and aggressive liver cancer, despite having no family history of cancer, and no specific risk factors for it.

As reported by Bloomberg,[12] some of the contaminated valsartan pills contained as much as 17 micrograms of NDMA per pill, an amount estimated by European health regulators to give 1 in 3,390 people cancer. Brackman suspects she's one of the unlucky ones.

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Most Active Ingredients Are Manufactured in China and India

An estimated 80% of all active drug ingredients are manufactured in China and India, and overseas plants are rarely inspected by U.S. authorities. At present, the U.S. has just one FDA inspector's office in China. In the case of valsartan, even when a plant is inspected and found wanting, it can take years before problems are addressed — if ever.

> *"Huahai, the first manufacturer found to have NDMA in its valsartan, is also the one whose product had the highest concentration*," Bloomberg reports.[13]
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> *"When an FDA inspector visited in May 2017, he was alarmed by what he saw: aging, rusty machinery; customer complaints dismissed without reason; testing anomalies that were never looked into.*
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> *He reported that the company was ignoring signs its products were contaminated. Senior FDA officials didn't reprimand Huahai; they expected the company to resolve the problem on its own. Huahai didn't …*
>
> *It wasn't until a year later that another company … found an impurity in Huahai's valsartan and identified it as NDMA. That was when the FDA demanded drugmakers begin looking for NDMA in their valsartan. They found it again and again."*

As David Gortler, a drug safety consultant and former FDA medical officer, told Bloomberg, "Valsartan is just the one we caught. Who knows how many more [tainted drugs] are out there?" Well, we now know the NDMA contamination affects many other drugs as well, including metformin, used by more than 78.6 million Americans as of 2017.[14]

Huahai's Mistake

Bloomberg goes on to recount some of the historical details of Huahei, from its inception in 1989 to its current status as one of the largest generics companies in China, and the first Chinese company to gain FDA approval to export finished drugs to the U.S. — a generic HIV medication.

When Novartis' patent on Diovan (the brand name for its valsartan drug) expired in 2011, Huahai became one of the companies to manufacture valsartan for generic drug companies. Valsartan, being a simple compound to make and used daily by millions, looked like it could be just what Huahai needed to grow and improve its bottom line.

Now, as explained by Bloomberg, if a company like Huahai wants to create its own version of a generic drug and then export it to the U.S., they must first get FDA approval. However, if they're just manufacturing and supplying the active ingredient to a U.S. company that then produces the finished product, then FDA approval is not required. All they have to do is inform the FDA if there are any changes to the manufacturing process.

In the case of Huahai's valsartan, the company did make a change to its manufacturing process, but downplayed its significance. In November 2011, Huahai stopped using the solvent used by Novartis in the manufacturing of the brand name drug, and started using another called dimethylformamide (DMF).

This turns out to have been a massive mistake, as side reactions ended up producing NDMA, which could not be removed from the drug. "The chemists at Huahai either didn't realize that or didn't consider it a potential hazard," Bloomberg writes, adding that, in 2018, after the recall began, vice chairman of Huahai, Jun Du, told an FDA inspector that "The purpose of the change was to save money," thus increasing their profits.

The cost-savings were so substantial, it allowed Huahai to dominate the global market share for valsartan. Making matters worse, since Huahai's patent was public, other generic companies copied the new, toxic, process. According to Bloomberg,[15] this is "one reason so much of the world's valsartan supply is now contaminated."

Incompetence or Intentional Poisoning?

It's hard to justify a defense of ignorance, though, seeing how the 2017 FDA inspector's report noted multiple problems at the plant, including suspicious contaminants showing up in quality tests.

Du claimed the tests showed "ghost peaks … from time to time for undetermined reasons." In another instance, he referred to the residual spike showing in testing as "noise." Huahai never investigated to determine what the contaminants might be, or how they got there. Instead, they simply omitted the incriminating tests from official reports.

The FDA inspector recommended the agency issue a warning letter, which would have meant Huahai would have to pass another inspection before continuing its manufacturing. But the FDA didn't send a warning letter. Instead, they urged Huahai to resolve the issues on their own — which they didn't.

Disturbingly, a lax FDA approach to inspections that reveal faked quality testing is not unusual. Bloomberg spoke to Michael de la Torre, who runs a database of FDA inspections. According to Torre, in the five years up to 2019, the FDA issued warning letters in response to faked data just 25% of the time.

> **“The only element who cares in this whole global supply chain is patients. ~ David Light, CEO Valisure LLC”**

Bloomberg also recounts a number of quality problems discovered at Indian drug manufacturing plants. Clearly, FDA is failing in its mission to regulate the generics industry overseas.

The industry is expected to regulate itself, and profit wins over quality concerns most of the time when no one is around to hold the companies accountable. A company is only as ethical and conscientious as the people running it.

Quality problems are really not uncommon. The New Haven, Connecticut-based online pharmacy Valisure LLC tests every drug it orders, and reports rejecting more than 10% of all batches it receives — in some cases due to inaccurate amounts of active ingredient, in others due to contaminants or other inconsistencies in quality.[16]

Kevin Schug, analytical chemistry professor at the University of Texas, told Bloomberg[17] Huahai "certainly should have caught" the NMDA contamination, and "should have modified the procedure to correct it." Former FDA medical officer Gortler agreed, saying, "Any well-trained analytical chemist would know to check. If it's not intentional, it's incompetence. At some point, those are the same."

Valisure CEO David Light told Bloomberg that while people in the industry are well aware of the problems, the overwhelming consensus is that it's not "their" problem. "There's no liability at any one point," he said. "The only element who cares in this whole global supply chain is patients."

The FDA didn't send a warning letter[18] to Huahai until November 2018, stating the obvious: The company should have anticipated the possibility that changing the process to use DMF solvent might cause problems, and when testing revealed anomalies, they should have identified the impurity.

Brackman filed a lawsuit against Huahai in April 2019. About 140 others have also sued Huahai and other drugmakers involved in the valsartan recall, and lawyers are reviewing several hundred additional cases, Bloomberg reports.

Bottom Line

This devastating and pervasive toxic exposure results largely from people's reliance on using drugs as symptomatic bandages that in no way, shape or form treat the cause of the disease. They trust their physicians to help them but sadly they have been captured by the drug industry and are nearly universally clueless on how to identify and address the underlying cause of most diseases.

That is why it is crucial to understand that YOU are responsible for your own health and need to use physicians as your consultants, and not implicitly trust them. If you provide your body with what it needs, it typically tends to self-correct and get better so you can avoid these dangerous medications which, rarely, if ever, resolve the foundational cause.

Fortunately, this COVID-19 crisis has shown us the two most important physical strategies to optimize your health: vitamin D and metabolic flexibility. The ability to eliminate insulin resistance is a strategy that addresses the majority of illnesses that you will ever encounter in your lifetime.

This is why time-restricted eating, eliminating industrially processed seed oils like soy, corn and canola oils, eating a cyclical ketogenic diet, exercising and sleeping well can improve, if not eliminate, most conditions that you would need to take medications for. As you can see, drugs can harm you just because they were made with shortcuts to increase company profits.

When you follow these health principles you will decrease, if not eliminate, your need for these dangerous medications. You will also enjoy a high degree of health and freedom from the pain, disability and suffering associated with these conditions.

Sources and References

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