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Rocket Fuel Compound Found in Diabetes Medication

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STORY AT-A-GLANCE

- N-nitrosodimethylamine (NDMA) has been found in metformin, a drug used to treat diabetes. NDMA has also been found in blood pressure medication and Zantac, an OTC drug that treats stomach issues
- Zantac contamination may have started in 2012 when the process produced NDMA as a byproduct to improve manufacturing efficiency
- Metformin prescriptions increased from 59 million in 2007 to 78.6 million in 2017, one indication of the rising number using medication to control diabetes
- Simple lifestyle changes can improve your health and reduce your dependence on drugs

Many of the decisions you make each day have a compound effect on your overall health. Making small changes in what you eat and drink, how much you exercise and the quality of your sleep can pay big dividends. The same is true of some of the small unhealthy decisions you make.

For example, lifestyle choices affect your risk for high blood pressure, Type 2 diabetes and even heartburn. If you take medications to control these conditions, you need to know that some of them have been recalled due to contamination issues.

In July 2018 the FDA[1] announced a voluntary recall of Angiotensin II receptor blocker high blood pressure medications (ARBs) that contain the active ingredient valsartan; a month later the FDA updated its list to include those containing losartan and irbesartan, among others. It has continued to update the list through the end of 2019.[2]

The initial alert was generated after some of the products tested positive for N-nitrosodimethylamine (NDMA). To give an example of how many people were affected by this, in 2017 9.2 million prescriptions were written for valsartan; 51.9 million for losartan; and 2.3 million for irbesartan.[3]

Yet, when a second nitrosamine impurity was discovered in losartan, the FDA still did not stop distribution of the drug. Instead, they suggested that patients continue their prescriptions "until their pharmacist provides a replacement or their doctor prescribes a different medication."[4]

Then, a new concern with a different drug arose, this time with an over-the-counter (OTC) medication for heartburn and other stomach issues: In September 2019 the FDA issued a warning that NDMA was also found in ranitidine (Zantac), a hystamine-2 (H2) blocker used to treat heartburn, saying:[5]

> *"Although NDMA may cause harm in large amounts, the levels the FDA is finding in ranitidine from preliminary tests barely exceed amounts you might expect to find in common foods."*

Next, test results revealed NDMA was in another heartburn drug, nizatidine[6] (brand name Axid) and just days later those medications began being recalled. As of January 2020, the FDA was continuing to announce voluntary recalls because of unacceptable levels of NDMA. To give you an idea of how many people just the Zantac recall affected, in 2017 there were 16.3 million prescriptions written for Zantac.[7]

The saga of NDMA and other nitrosamine impurities in the U.S. medication supply doesn't end there, however. Now, warnings include metformin, an oral medication for treatment of early Type 2 diabetes. In 2017 there were 78.6 million prescriptions for metformin written,[8] representing the medication with the largest number of prescriptions affected by NDMA contamination thus far.

NDMA Is Deadly in Minute Amounts

NDMA was once used in the commercial production of rocket fuel.[9] However, after animal testing demonstrated exposure to it significantly increases the risk of cancer, the chemical is now only used for research purposes. Since the compound may be absorbed from the environment, food, tobacco or medications, the FDA established an "acceptable intake" level.

The "acceptable" amount is 96 nanograms (ng). As a comparison, this is 0.000096 of 1 milligram (mg) and a grain of salt is about 1 mg.[10] Some of the generic brands of the contaminated high blood pressure medications tested at 20 times this limit.

It's important to remember these are drugs taken every day in addition to potential exposure from the environment and nitrite-preserved foods such as hot dogs, cured meat, malt beverages and salami — which, according to the University of Illinois Chicago, sometimes have "higher concentrations" of NDMA.[11]

Even worse, the World Health Organization[12] writes "there is conclusive evidence that NDMA is a potent carcinogen in experimental animals." With humans, WHO admits there is "no quantitative" measurement for the risk of NDMA causing cancer in humans, but they do say: "The results are supportive of the assumption that NDMA consumption is positively associated with either gastric or colorectal cancer."

So just how bad is NDMA? Historically, there are several case studies in which NDMA was used as a poison.[13] In 1978 a German teacher's wife died after he put NDMA in her jam. A Nebraska man was sentenced to death for spiking lemonade with it, and in 2013 a Chinese medical student died as a result of an April Fool's prank when NDMA was put into the water cooler.

FDA Ignored the Warning Signs

Novartis released valsartan (Diovan) in 1996. When the patent expired in 2012, generic drug companies began producing it, but reduced their costs by changing solvents. The change was designed to limit waste and increase the amount of drug produced, but it also produced NDMA impurities in the medication.[14]

Five years later an FDA inspection found the company had ignored their own test results demonstrating an "unidentified" impurity was present.[15] However, instead of sending a warning letter, neither the FDA nor the Chinese manufacturing firm attempted to identify the impurity. Then, in May 2018, Novartis ordered the product during their research to make a generic drug, found the impurity and identified it as NDMA.

A few months later, in August 2018, Reuters[16] reported drug recalls of NDMA-contaminated products in countries around the world, but not the U.S. — revealing dangerous holes in a medical safety net the American consumer relies on.

By this time Americans had been taking the drug for six years. Health regulators in Europe estimated 1 of every 3,390 people who were taking the contaminated pills could develop cancer. Subsequently, in the U.S., hundreds of patients with a diagnosis of cancer of the stomach, liver, colon and kidneys began filing claims with their lawyers.[17]

Metformin Use Rises With Incidence of Type 2 Diabetes

As I mentioned earlier, the newest medication to join the growing list of drugs contaminated with a component of rocket fuel is metformin. While metformin's prescription numbers have gone down from the 86.1 million prescriptions written in 2014, another measurement of prescription popularity is rank, or frequency it's prescribed compared to other drugs, and that number has vacillated from No. 6 in 2007 to remaining relatively stable at No. 4 since 2011.

As the diagnoses of prediabetes and diabetes have risen, so have the prescriptions for the oral antidiabetic medication, metformin. The drug works by limiting the amount of sugar released by your liver.[18]

Data from the CDC[19] in 2017 showed there were 30.3 million with diabetes and 84.1 who had prediabetes. The CDC also notes that new cases are increasing in young people under 20 years. Factors that increase the risk of diagnosis include smoking, being overweight and being inactive.

Despite these enormous numbers, the good news is that in some areas of the world, Type 2 diabetes appears to be trending downward in specific populations, possibly due to preventive actions that include lifestyle changes.[20]

On the downside, the American Diabetes Association believes this trend may potentially be an artifact of the data, suggesting improved screening and diagnosis have dramatically reduced the population of "susceptible individuals" and it is therefore premature to declare a victory.[21]

A Conflict With China Could Threaten Medication Supply Chain

When it comes to contamination issues, metformin generics were approved from 2004 to 2018, some of which are produced by companies distributing highly contaminated valsartan, such as Teva, Torrent and Prinston Pharmaceuticals.[22]

Currently, many generic drugs are made either in India or China.[23] The voluntary recall of valsartan, ranitidine and metformin happened to drugs that were all originally manufactured in China.

Dr. Janet Woodcock, director of the FDA Center for Drug Evaluation and Research, staunchly supports the FDA's capability of inspecting and monitoring consumer health. However, recent events have illustrated some of the challenges facing the organization's staff as they regulate a market whose production is largely outsourced to other countries.

Rosemary Gibson from the Hastings Center is a health expert and author who believes the problem is exacerbated by the two countries' differences in regulatory matters. She said, "China doesn't have anything like the consumer protection laws and product liability laws like the United States does." But Woodcock countered with her belief that the FDA uses the same standards for drugs manufactured in the U.S. or any other country.

But still, that doesn't address another challenge to the safety of the U.S. medication supply chain: the number of crucial medications manufactured in China. Mike

Osterholm from the University of Minnesota is an expert in biosecurity. He commented on the vast number of medications manufactured in China:[24]

> *"It's a major national security risk for us in two ways. We are very concerned about the quality of these drugs. Now we are caught up in an economic war in the sense of tariffs. If we were ever in an international incident with China, they would literally have their hands around our necks in terms of critical drugs. They wouldn't even have to fire a shot."*

For example, the number of metformin prescriptions pales to the combined number of statins prescribed in 2017, which totaled 216.6 million.[25] The rank for the most popular statin prescribed, Atorvastin, has steadily risen from No. 10 in 2011 to No. 2 in 2017.

Seek a Natural Cure for Type 2 Diabetes

A diagnosis of diabetes often carries with it an increased potential risk for cardiovascular disease, high blood pressure and dementia, sometimes called Type 3 diabetes.[26]

In some instances, your risk for getting diabetes goes up when you use specific medications, such as **statins**. Your risk of diabetes also rises with increasing weight, lack of activity and high carbohydrate intake that increases leptin and insulin resistance.

Many of my paternal relatives have a history of diabetes and my own experience with diabetes and review of the literature has made it clear that virtually every case is reversible and has nothing to do with drugs to control your blood sugar.

To recover from Type 2 diabetes, you must improve your body's sensitivity to insulin and leptin through diet and exercise.

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