Valisure Oral Testimony – 5min

Chairman Grassley, Ranking Member Wyden, and Members of the Committee, thank you for the honor of being able to speak before you today. I am the founder and CEO of Valisure, where our mission is to help ensure the safety, quality, and transparency of medications, and we do this with a very simple but novel approach: we check.

Valisure is the only pharmacy that checks the chemistry of every batch of every medication at no additional cost to patients. This is particularly important given our country's heavy reliance on overseas manufacturing and COVID-19 putting additional strain on an already stressed system. Valisure currently rejects over 10% of the medication batches we test due to a variety of product defects.

The pharmaceutical supply chain is extremely complex and heavily reliant on the self-regulation of overseas manufacturers. When you buy a bottle of medication, it's like buying a used car. Those pills are often already a year or two old, have traveled thousands of miles, and touched dozens of hands. No one buying a used car is satisfied to know that the original manufacturer said, "it's good." You want a Carfax report; you want to see a 100-point inspection on that car. None of that transparency is available for medications. While the FDA cannot do everything or be everywhere, we strongly believe that more can – and must – be done.

The idea of independently checking drugs may be new to industry, but not to the academic world. However, warnings from academics have unfortunately been largely ignored. A grim example of this is the drug Zantac. In 1977, Senators sat in this very building and listened to testimony that certain drugs are unstable and form the extremely potent carcinogen NDMA. Similar concerns were raised a year later at a summit held by the World Health Organization and the United Nations. Zantac has the exact chemical structure to form NDMA that the scientific community warned about, and yet the drug was approved only a few years later.

In the following decades, dozens of studies implicated Zantac as chemically unstable and easily prone to forming NDMA, but these papers had practically zero impact. By the 1990s, Zantac had become the top-selling drug globally and among the most commonly prescribed to treat acid reflux in pregnant women and infants.

It was not until 2019, 36 years after the drug's approval, that Valisure performed the simple action of independently checking generic Zantac syrup prescribed to our co-founder's infant daughter. The results were so dramatic we immediately took the drug off our formulary. But we were not satisfied by simply publishing our findings in a journal. We petitioned the FDA

directly; we spoke to press; and we did not back down from the crystal-clear science that Zantac is fundamentally unstable and should be taken off the market. Two months ago, after dozens of countries had already banned this dangerous drug, the FDA finally granted our petition, and Zantac was officially taken off the U.S. market. Without independent testing and the drive to make it broadly transparent, Zantac could have remained on the market for many more decades to come.

The immense value of independent testing does not have to be limited just to Valisure's pharmacy. I believe there are two clear paths to applying independent analysis throughout the U.S.

First is a data-driven approach: drug quality scores. Results from independent chemical analysis can be combined with broad regulatory data and boiled down into quality scores that can be as simple as a red/yellow/green rating that provide transparency to any drug purchaser. Buyers can use this guidance to buy green, occasionally yellow, and avoid red. A landmark paper by leaders from eight prominent health care institutions was just published on this approach last week.

Additionally, for a handful of important drugs that are particularly vulnerable to quality issues, there is a more definitive solution: what we call certified drugs. By employing independent batch-testing of drugs up to the manufacturer level, we can weed out poor quality batches and bring certified medications to millions of Americans regardless of which pharmacy they go to. This is entirely reasonable to do for critical drugs, such as metformin.

Metformin is the top diabetes drug and the 4th most prescribed medication in the U.S. with over 80 million prescriptions a year. Valisure has published two studies showing that approximately 40% of metformin products are contaminated with the carcinogen NDMA above FDA acceptable limits. This means millions of Americans are taking a drug every day that contains a carcinogen that absolutely should not be there.

In summary, we have very serious problems in the drug supply chain that are caused by a very complex set of factors, all of which made worse by COVID-19. It is imperative that we act quickly to better protect the American public. Above all, independent, scientific analysis cannot continue to be ignored and must be part of a new, transparent path forward. Thank you very much, and I look forward to your questions.