

Baby formula shortage hits hard with imports limited

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The <u>baby formula shortage</u> has cast a spotlight on the heavily concentrated industry that manufactures the product, sparking a debate over whether import restrictions, "<u>big bottle</u>" or both set the stage for this crisis.

• Four companies — Abbott Laboratories, Mead Johnson, Perrigo and Nestle — account for more than 87% of the market, according to IBISWorld.

Why it matters: With parents <u>scrambling</u> to track down formula following the collision of supply chain issues and a <u>massive recall</u>, they want answers on how this could happen with such a life-critical product.

- Republicans have criticized the FDA for cracking down too hard on Abbott, while Democrats have blasted the industry for lacking competition.
- The FDA says it's moving quickly to lift restrictions on imports to help parents who are struggling to find adequate replacements for their babies.

Be smart: A combination of manufacturing complexity, distribution challenges, low profit margins, tariffs and regulatory restrictions got us here.

- The product is expensive to make because it's medically sensitive and it's tightly regulated by the FDA, whose temporary shutdown of the Abbott Nutrition plant in Sturgis, Michigan, after a foodborne pathogen was discovered there has exacerbated the shortage.
- "The difficulty of shipping dairy-based products overseas" has historically limited imports, according to an IBISWorld report.
- Plus, European Union imports are largely prohibited since it's harder to oversee those factories. Such imports still occur on the black market, and free-market advocates say they can be imported safely, according to the Cato Institute, a libertarian think tank.

The big picture: There's no easy switch to flip right now.

• "You don't want to bring in substandard baby formula," Peter Pitts, president of the Center for Medicine in the Public Interest and a former associate commissioner of the FDA, tells Axios. "It's very hard to make, it's very complicated chemistry. It's almost medical food in a sense."

Worth noting: While there are a variety of smalltime makers of baby formula, the industry is largely dominated by big companies because it's a low-margin business, Pitts says. Hence why it's not easy to quickly set up new production sites.

• "These are not little factories on the corner. These are whole campuses," he says.

What's next: Abbott said late Monday afternoon that it had reached a consent decree with the FDA that would allow it to reopen its plant within two weeks after it takes certain initial steps to ensure it can safely operate the site.

• It estimates 8–10 weeks in total from that point before products could hit shelves.