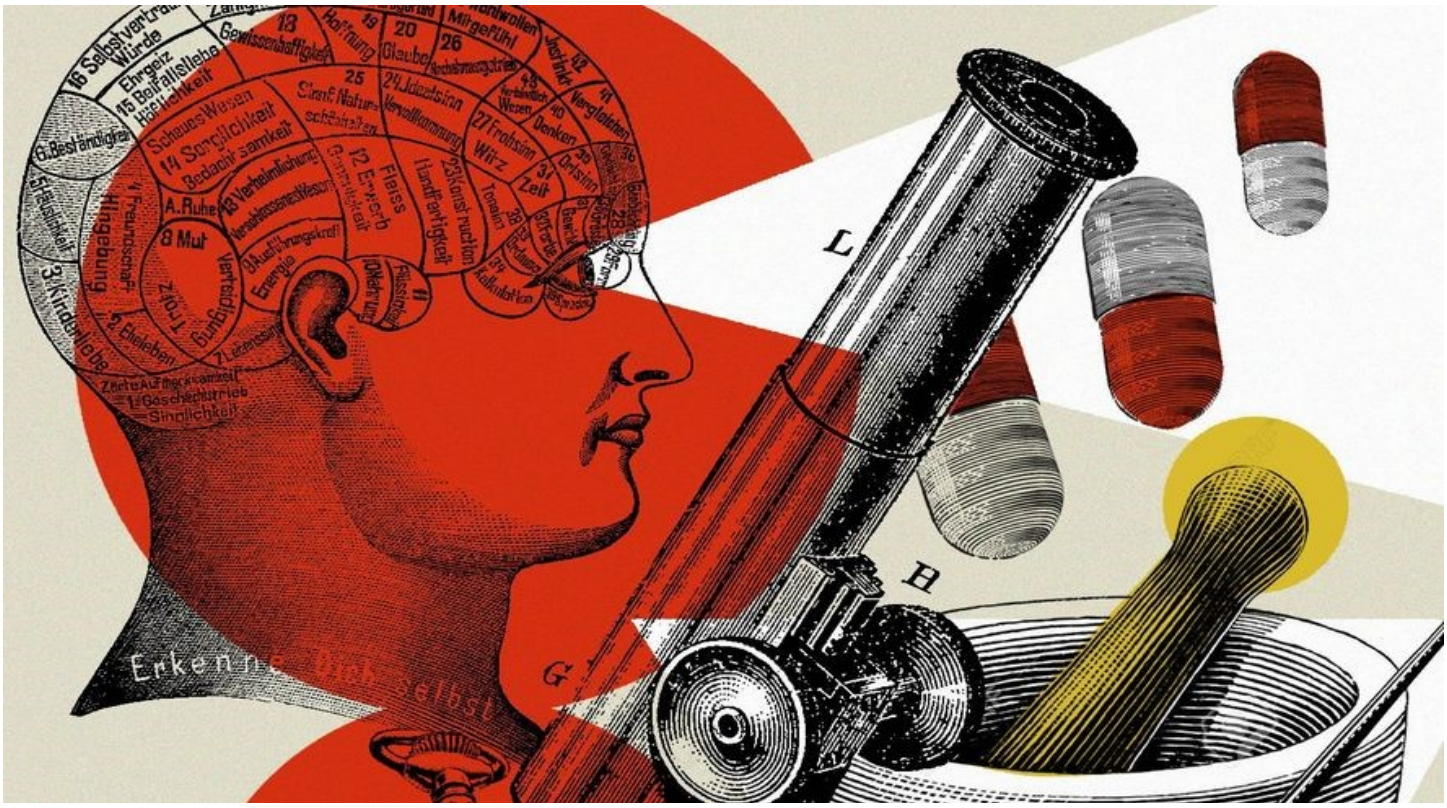
Bring back Natpara: FDA must help hypoparathyroidism sufferers

Agency must show the same urgency for these Americans that it shows for treatment of COVID-19



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By Bob Sanders - - *Wednesday, December 23, 2020*

ANALYSIS/OPINION:

When I was just 18 years old, I was diagnosed with hypoparathyroidism, a rare disease that causes seizures, extreme fatigue and other life-altering complications. The only other people I knew with this debilitating condition were family members. It felt like we were alone in the world.

But we weren't alone. About 80,000 Americans live with hypoparathyroidism. And right now, they're suffering even more than usual.

That's because the FDA pressured the manufacturer of the only FDA approved hormone treatment for hypoparathyroidism and pulled it off the market in September 2019 due to safety concerns with the drug's delivery device. Ever since, patients have seen their symptoms dramatically worsen.

This suffering can't continue. It's time for FDA officials to realize how profoundly debilitating this condition is, stop dragging their feet, and give patients additional and better treatment options.

Hypoparathyroidism occurs when the parathyroid glands — located on the thyroid glands in people's necks — are either removed, injured or can't produce the parathyroid hormone for genetic reasons. Most people develop the disease after surgery. Patients with this condition often experience unstable and fluctuating calcium levels.

When blood calcium levels drop too low, patients can experience "calcium crashes," a dangerous complication that causes people to have seizures or act delirious. Sadly, these calcium crashes are all too common — almost 70% of hypoparathyroidism patients have experienced a calcium crash in the past year. Over 40% suffered calcium crashes as often as weekly.

One patient I know experienced such a severe crash, police actually arrested her at the hospital — she was behaving so erratically, officers thought she was high on drugs. My own daughter, who also has hypoparathyroidism, has been rushed multiple times to the ER due to calcium crashes. Since the disease is so rare, her symptoms were not properly treated by the ER doctors. They knew her calcium levels were critically low but were focused on treating her symptoms. I had to plead with them to give her calcium while watching her condition deteriorate for six hours.

Hypoparathyroidism is mentally taxing as well and can cause significant "brain fog." In a recent survey, 100% of respondents reported the condition harms their mental health and interferes with their daily lives. Many patients can't hold down normal jobs.

For decades, the only treatment option was a combination of calcium and active vitamin-D supplements. Finding the right balance is extremely difficult. Too little can lead to calcium crashes, but too much can cause organ calcification. And long-term use of calcium supplements increases the risk of kidney disease.

Then, in 2015, everything changed. The FDA approved the first parathyroid hormone therapy — called Natpara — as an adjunct therapy for hypoparathyroidism to be used with supplements.

For a few brief years, our lives changed. Patients felt their conditions were better controlled for the first time ever. But last year, the FDA raised concerns about the possible danger of small rubber particles from the delivery device contaminating the drug, leading the manufacturer to take the treatment off the market through a voluntary recall.

Gaining — and then losing — an effective treatment has been gut-wrenching for people with hypoparathyroidism. One woman I know describes it as a catch-22. Either she avoids supplements and suffers from low calcium, or she risks her kidneys by taking supplements.

Frustratingly, it's unclear when the manufacturer will be allowed to reintroduce Natpara to the broader market. The FDA did create its first-ever Special Use Program, enabling some Americans to continue accessing Natpara after jumping through numerous bureaucratic hoops to obtain the necessary approvals. The program's mere existence shows that the FDA recognizes the debilitating consequences of hypoparathyroidism.

But only about 400 people have qualified for the program. For the foreseeable future, the overwhelming majority of patients are stuck with supplements as a standard of care treatment. We're the last patient group without an effective, widely available treatment for an endocrine deficiency disease.

The FDA has done an amazing job of granting rapid preliminary approvals and authorizations of treatments for COVID-19.

It's time for the agency to show that same urgency for Americans suffering from hypoparathyroidism — by bringing Natpara back to market and giving all patients access to new and promising medicines that have been proven safe in clinical trials. There's no reason for these patients to suffer any longer.

* Bob Sanders is chairman of the Hypoparathyroidism Association.