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The Honorable Robert Wilkie Secretary Department of Veterans Affairs 810 Vermont Ave., NW Washington, DC 20571 robert.wilkie@va.gov

Dear Mr. Secretary:

I am writing to express my concern about the planned partnership between the VA's Office of Specialty Care Services and Virta Health Corp. ("Virta") to offer the company's diabetes management program to veterans with type 2 diabetes. The company's approach is to place patients with diabetes on a low-carb, ketogenic diet. At best, this type of diet may act as a "Band-Aid" for diabetes, yet it carries serious health risks.

Research has found that ketogenic (keto) diets such as the Virta diet do decrease hemoglobin A1C relative to both low glycemic index¹ and moderate carbohydrate (45-50 percent of calories) diets² in patients with diabetes. By eliminating nearly all sources of glucose in the diet, blood glucose plummets, and medications to lower blood sugar must be decreased. However, while a keto diet improves the key symptom of type 2 diabetes—high blood sugar—it does not necessarily fix the root cause of the disease. In fact, a keto diet may make it *worse*.

To understand how keto diets can impair glucose tolerance, it's important to recall that high blood sugar isn't the cause of type 2 diabetes—it's just the symptom. The main underlying cause appears to be fat-induced insulin resistance, or lipotoxicity.

Specifically, fat stored within muscle and liver cells is the chief offender. Insulin normally lowers blood glucose by triggering cells to take up glucose from the blood. However, fat inside cells interferes with insulin signaling. As a result, glucose builds up in the blood. More and more insulin is required to maintain normal blood glucose levels. The pancreas struggles to keep up, chronically elevated blood sugar levels result, and the patient presents with diabetes.

What does this mean for keto diets like the Virta program? Keto diets slash dietary glucose without necessarily correcting the underlying fat buildup inside muscle and liver cells, although weight loss can help. When health-promoting carbohydrates like fruit, starchy vegetables, beans, and whole grains are reintroduced, the keto dieter's blood sugar spikes.

In fact, low-carbohydrate diets high in animal protein and fat have been linked to *increased* risk of type 2 diabetes,³ and keto diets can actually *cause* diabetes-like symptoms in healthy people. A 2012 study found that healthy men did significantly worse on an oral glucose tolerance test after following a low-carb, high-fat diet for three days than after following a normal diet for three days. Specifically, they



experienced significantly higher blood glucose levels for longer. They also had lower first-phase insulin secretion—an early sign of diabetes development.⁴

However, conflicting results have been seen, perhaps due in part to varying levels of saturated fat in different keto diets. Multiple trials have shown that high-fat, high-saturated fat diets decrease insulin sensitivity. ^{5,6} Given the hazards associated with keto diets described below, regardless of the type of fat they deliver, current science suggests they are a risky choice for diabetes.

On the flip side, we know that plant-based diets are linked to a lower risk of developing type 2 diabetes, and are effective in treating it.^{7,8} Moreover, research has shown that a low-fat, high-fiber diet can help people get off insulin in as little as 16 days—without weight loss.⁹

In addition to lowering blood sugar, Virta touts its program's ability to induce weight loss. This weight loss is likely a key factor in achieving the other improvements listed on the Virta site, such as reduced hypertension and sleep apnea.

However, all five articles posted on the Virta website in support of the program appear to come from a single trial of 262 patients with type 2 diabetes (NCT 02519309). Moreover, not one of these studies followed participants for longer than one year.

Why does this matter? Research has shown that any differences in weight loss between diet styles—including low carb—effectively disappear at *two years*. Indeed, a meta-analysis of 13 different trials found that after two years, there were no significant differences in weight loss between the low-carb and "low-fat" diet styles. ¹⁰ This implies that many of the benefits promoted by Virta are unlikely to last—while potential harms could.

Ketogenic diets come with numerous short-term side effects and long-term, serious health risks:

Short-Term Side Effects

- Impaired artery function (short-term). A single high-fat meal can impair an artery's ability to widen, decreasing blood flow.¹¹
- Elevated LDL cholesterol.^{12,13} In some individuals, a keto diet can result in massive increases in LDL cholesterol, as seen in one participant whose LDL rose from 184 to a dangerous 283 mg/dL in 3 months.¹⁴
- Nutrient deficiencies. Keto diets are likely to be deficient in a wide range of vitamins, minerals, and phytochemicals found in plant foods. 15
- Constipation. Keto diets can be low in fiber, making stool hard and uncomfortable to pass.
- Nausea, fatigue, and headaches.¹⁵
- Impaired glucose tolerance.⁴

Long-Term Risks

• Increased risk of dying from all causes. Low-carbohydrate diets have been linked to an increased risk of all-cause mortality.¹⁶

- Decreased blood flow to the heart and worsened heart disease. Ironically, while keto diets can improve blood markers of cardiac risk like total cholesterol, they may increase heart attack risk. For example, one study found that an Atkins-style diet decreased blood flow to the heart.¹⁷ This is especially worrisome as people with type 2 diabetes are already at increased heart disease risk.
- Impaired artery function (long-term). An analysis of six different studies found that low-carbohydrate diets are linked to reduced artery function. In fact, excess fat can actually injure artery walls. Artery dysfunction is linked to increased risk of heart attack or stroke.
- Increased risk of colon cancer. People often eat more high-fat red and processed meats on a keto diet than they otherwise would. These products are known to increase colon cancer risk.¹⁹ Heterocyclic amines found in grilled white meat can also contribute to risk.

Moreover, the single trial publicized on Virta's website²⁰ suffers from multiple conflicts of interest. A 2017 article published in *JMIR Diabetes* describing the trial's blood glucose outcomes reveals the extent of this conflict.²¹ As the article notes, "Virta Health Corp. funded this study, and all authors have a financial relationship with the study sponsor." Study authors Jeff Volek and Stephen Phinney are also both consultants for Atkins Nutritionals, and both have received royalties for authoring low-carbohydrate diet books. Volek has also received grants from the National Dairy Council and Malaysian Palm Oil Board.

On the other hand, a plant-based diet is powerful medicine for diabetes. Not only do people following a plant-based diet have a lower risk of diabetes in the first place,²² but this style of eating can help people effectively manage and even reverse the disease.²³ Moreover, plant-based diets provide substantial benefits beyond improving diabetes: They have been shown to actively reverse heart disease²⁴—the top killer of people with diabetes—and are also linked to lower rates of cancer.²⁵

In lieu of Virta, I propose offering veterans the Physicians Committee's popular diabetes *Food for Life* program. Taught by certified instructors, this 8-week course walks people through the science behind plant-based nutrition for diabetes prevention and reversal. Instructors also provide interactive healthy cooking classes to help people master the practical skills they need to take control of their health—and prepare delicious food.

Given limited data in support of the Virta program and that any short-term benefits come with serious risks, I urge the VA to protect veterans' health and reconsider its partnership with Virta. Instead, please consider providing veterans the opportunity to manage and even reverse their diabetes using the power of plant-based nutrition.

Sincerely,

Neal Barnard, M.D., F.A.C.C.

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