June 22, 2015

The Honorable Orrin Hatch
Chairman
Senate Committee on Finance
219 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Senate Committee on Finance
219 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Johnny Isakson
131 Senate Russell Office Building
Washington, DC 20510

The Honorable Mark Warner
475 Senate Russell Office Building
Washington, DC 20510

Dear Chairman Hatch, Ranking Member Wyden, Senator Isakson and Senator Warner:

On behalf of VIVUS Inc. (VIVUS), I am pleased to have this opportunity to submit comments on your May 22 letter to stakeholders regarding chronic care, as it relates to the Medicare population. VIVUS is a biopharmaceutical company developing innovative, next-generation therapies to address unmet needs in areas such as obesity, diabetes, and sleep apnea. We applaud your efforts in forming the bipartisan full Finance Committee chronic care working group and for accepting comments that would enhance the care of Medicare beneficiaries with chronic conditions. We believe that treating and preventing obesity is essential to preventing the onset of other costly chronic conditions.

Innovative medicines contribute enormous health, economic, and social welfare benefits to individuals. A healthy population is also more productive and less costly to public health programs. At VIVUS, we developed the weight management medication, Qsymia® (phentermine and topiramate extended-release) capsules CIV. Qsymia was approved by the Food and Drug Administration (FDA) in 2012 and is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial BMI of 30 or greater (obese), or 27 or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes, or dyslipidemia.

In response to your eight issue areas that were listed in your letter, we wish to mainly focus on the following two:

4. The effective use, coordination, and cost of prescription drugs; and

7. Options for empowering Medicare patients to play a greater role in managing their health and meaningfully engaging with their health care providers

The Effective Use, Coordination and Cost of Prescription Drugs

Current weight-loss treatment options in Medicare include behavioral counseling and surgery. There is no lower-cost, middle ground for patients with moderate needs. Access to a full array of options, in conjunction with education, diet, and exercise is needed to tackle obesity and reduce chronic conditions associated with the disease. To build on Medicare's counseling program, drug therapy will add to the beneficiary's success. Labels include important, responsible protections against overutilization. In Qsymia's case, if patients do not achieve 3% weight loss after 12 weeks, they either discontinue or escalate to top dose. If patients on Qsymia do not achieve 5% weight loss on top dose after 12 weeks on it, they must discontinue treatment.

In the pivotal trials of Qsymia, patients who received treatment for 1 year lost an average of ~10% of their initial body weight on the recommended dose of Qsymia and ~12% - 14% of their initial body weight on the top dose of Qsymia. Weight losses were accompanied by significant improvements in systolic blood pressure, lipids (increased HDL and reduced triglycerides), glycemic parameters (reduced fasting insulin, fasting glucose, and HbA1c), and other important cardiovascular risk markers. The clinical significance of these effects is highlighted by the fact that these improvements were observed despite significant reductions in the use of antihypertensive medications, lipid lowering agents, and treatments to manage type 2 diabetes.

Options for Empowering Medicare Patients to Play a Greater Role in Managing Their Health and Meaningfully Engaging with Their Health Care Providers

Obesity is a major public health issue in our country. Around 36 percent of adults in the United States are obese, while many others are overweight and may soon be contending with obesity. Unfortunately, anyone who is overweight or obese can face health consequences. Obesity is linked to heart disease, stroke, cancer, type 2 diabetes, dyslipidemia, joint issues, obstructive sleep apnea, and many other chronic conditions. Beyond the health risks, obesity carries significant stigma. Weight prejudice can have profound consequences in social acceptance, employment and even medical care. Tragically, these societal biases ignore an important fact: obesity is a medical condition as declared by the American Medical Association in 2013.

Given obesity's many consequences, people have a strong incentive to lose weight. While diet and exercise may succeed in the short-term, many have trouble maintaining their weight loss. The inability to maintain weight loss is not a function of will, but rather of biology. Obesity restructures how the body responds to food, and thus, measures beyond basic diet and exercise are sometimes required. Bariatric surgery has helped many people achieve significant weight loss. More recently, pharmaceutical companies have developed a new generation of weight loss drugs. There are currently four FDA-approved medications for chronic weight management and more are in the pipeline.

Even with these advances, barriers to these medications for patients remain. Though many private health insurance policies cover anti-obesity and weight management drugs, Medicare does not cover them under Part D as there were no FDA-approved weight management drugs at the time the Part D program was created. The Social Security Act (specifically Title 19), which governs the Medicare Part D program, excludes or restricts certain drugs from basic coverage. Specifically, "agents when used for anorexia, weight loss, or weight gain," are excluded from the definition of Part D covered drugs. In a letter to Congress in January 2015, Sylvia Burwell,

Secretary of Health and Human Services (HHS) stated that expansion of Part D coverage would require a legislative change by Congress and has offered HHS staff to provide technical assistance on legislation. While coverage under Part D is not allowed, Part D plans wishing to provide coverage of chronic weight management medications may do so as a supplemental benefit as they can with other drugs that are excluded from the definition of Part D drugs.

Typically, payers and employers design drug benefit plans based on Part D guidance/requirements. Exclusion of anti-obesity and weight-management drugs from Part D creates further barriers for employers to add these therapies into their standard benefit design. Employers who want to cover anti-obesity and weight-management drugs need to buy a separate rider which is a cumbersome process creating more hurdles for patients to access these important therapies.

Along with many private health insurers, Federal government departments and agencies have recognized the adverse and costly impact of obesity and related chronic conditions to their beneficiaries and increasingly provided coverage for FDA-approved prescription drugs for obesity and weight management. In early 2014, the Office of Personnel Management announced that all insurance carriers offering coverage under the Federal Employees Health Benefits (FEHB) Program should cover prescription medications approved by the FDA for obesity. Shortly thereafter, the Department of Veterans Affairs released practice guidelines for obesity treatment which include recommendations for obesity and weight management drugs.

This disparity in coverage between Medicare and other payers puts Medicare beneficiaries at a great disadvantage as they battle with multiple chronic diseases. While they may be motivated to lose weight, they lack access to all available options. It is truly difficult to empower Medicare patients when they are forbidden to have all of the available options to battle obesity. Between the human cost, the budgetary impact and the burden on our health care system, obesity and the chronic diseases associated with obesity have become an enormous policy issue. We must develop creative solutions to meet the policy challenge and allow our Medicare population to have the same access as individuals with private or other Federal coverage to help address obesity and chronic disease.

Policy Recommendation

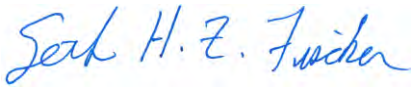
Earlier this month, Senators Carper and Murkowski introduced S. 1509, the Treat and Reduce Obesity Act of 2015. In addition, Representatives Erik Paulsen and Ron Kind, introduced the House companion bill with the same title, H.R. 2404 on May 18. The bills would authorize the Secretary to cover medication for treatment of obesity or for weight loss management for an overweight individual with one or more comorbidities under Medicare Part D. The bi-partisan piece of legislation had 4 original cosponsors (Sens. Heinrich, Cassidy, Coons and Grassley) in the Senate and 36 original cosponsors in the House. In addition, the bills have over 40 patient groups, health care providers and biomedical manufacturers supporting the measure.

If the FDA approves medication to treat or cure a disease, all Americans should have access to it – not just some. We need to make sure that the Centers for Medicare and Medicaid Services has the legal authority to do so.

Conclusion

We are pleased to see that so much work and dedication have been performed thus far and we are willing to make ourselves available as a resource to you and your staffs at any time. We encourage the Finance Committee and the bipartisan chronic care working group to work with those who are battling obesity and over-weight management issues, as it truly is a major health issue that needs to be addressed and allowing those individuals to have access to all the right tools will only help our country's health care system by preventing chronic diseases. If you have any questions or comments on this letter, please contact Sunil Karnawat at 510-566-7644 or karnawat@vivus.com.

Sincerely,



Seth H.Z. Fischer
Chief Executive Officer
VIVUS, Inc.