



**Dr. Ponni Subbiah, MD, MPH**

**Chief Medical Officer, Indivior PLC**

**Statement to the House Energy and Commerce Subcommittee on Health**

**Hearing on**

***Combating the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety***

**February 28, 2018**

Good morning. Thank you, Chairman Burgess and Ranking Member Green, for the privilege to address the Subcommittee and for recognizing the importance of combatting the current opioid crisis. I am Dr. Ponni Subbiah, a neurologist and Chief Medical Officer at Indivior. Indivior is a global specialty pharmaceutical company. Our core focus is addiction medicine. We have a 20-year legacy of commitment to our vision that all patients have access to evidence-based treatment for the chronic condition and co-occurring disorders of addiction. We developed the first buprenorphine-based opioid use disorder treatment for patients in the United States. Today, we have a global portfolio of treatments for opioid addiction and a pipeline of product candidates to address unmet patient needs for this disorder and other chronic conditions, including alcohol use disorder and schizophrenia.

To address the opioid epidemic, it is important to understand the patient journey. It is complex and often misunderstood. Addiction is a brain disease and not a moral failure. However, social stigma, prejudice and misconceptions about addiction, coupled with feelings of guilt and shame, often prevent people from seeking help. Addiction is often punished and criminalized.

Even when people want to stop using illicit drugs, cravings and withdrawal symptoms can be so intense that generally there is only a small window of time when a person is emotionally and physically able to pursue treatment. The healthcare system, however, does not always encourage

treatment during that window due to structural barriers to care. This is one of many reasons that the majority of those who need help go untreated. For this reason, Indivior believes that any patient in need of approved treatments for opioid use disorder should have access to the medically-assisted treatment (MAT) prescribed by their health care professional. Several government agencies have noted that MAT has recognized track records of success.

Indivior's core guiding principle - focus on patient needs to drive decisions - inspired our research and development team to develop SUBLOCADE™ which received FDA approval on November 30, 2017. SUBLOCADE is the first once-monthly Schedule III buprenorphine extended-release injection for subcutaneous use. In the face of the growing addiction crisis, FDA granted the product Fast Track approval and Priority Review designation. It is indicated for the treatment of moderate to severe opioid use disorder in patients as part of a complete treatment plan that includes counselling and psychosocial support. SUBLOCADE uses the ATRIGEL® delivery system which allows for once-monthly dosing and is intended to be administered only by healthcare providers.

SUBLOCADE will be distributed through a restricted distribution system, which is part of a Risk Evaluation and Mitigation Strategy (REMS) program. The goal of the REMS is to mitigate serious harm or death that could result from intravenous self-administration by the patient. All healthcare settings and pharmacies that order and dispense SUBLOCADE must be certified and establish processes and procedures to verify that the medication is dispensed directly to a healthcare provider for administration by a healthcare provider only.

As every patient's journey towards recovery is different, access to additional treatment options is critical. SUBLOCADE represents one such option that we believe will be essential to addressing the needs of patients, families and communities battling the opioid epidemic.

New innovations are expanding medication-assisted treatment options. Government policies impacting these treatments must adapt to ensure patients have access to all evidence-based treatment options.

Historically, buprenorphine treatments have been daily, oral medications and the Controlled Substances Act allows for dispensing of these medications directly to patients. However, as stated earlier, SUBLOCADE, as required by our risk management program, can only be administered directly by the healthcare provider and cannot be dispensed directly to the patient.

In recent years, the distribution of injectable products has evolved from a traditional buy-and-bill system, where physician practices purchase drugs directly from a distributor, to one that allows specialty pharmacies to ship a patient's prescription directly to the administering provider. For example, current long-acting injectable treatments used for schizophrenia utilize both these distribution methods to ensure optimal patient access to these medications.

Based on this, we agree with Representatives Costello and Nolan, the sponsors of the *Ensuring Patient Access to Substance Use Disorder Treatments Act of 2018*, that the law needs to be clarified so that these next generation buprenorphine products can also be accessed directly by healthcare providers through a specialty pharmacy restricted delivery system as well as a traditional buy and bill system.

We agree with the Committee that there is a role for Congress, and the Administration, to update laws to allow for new medical technologies. We support the proposed legislation to remove any ambiguity in the current law to ensure that patients with opioid use disorder and their providers have the same level of access to these innovative treatments as they do to other injectable products. We believe this technical clarification will ensure the safest distribution channels for these new treatments.

Thank you again for the opportunity to address the Committee.

All of us together can transform addiction from a human crisis to a recognized and highly treated disease. We stand ready to support the Committee's work however we can. I would be happy to answer any of your questions. Thank you for your leadership and consideration.

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