

September 1, 2017



The Honorable Claire McCaskill
Committee on Homeland Security and Governmental Affairs
United States Senate
Washington, D.C. 20510

Re: Insys Therapeutics, Inc.

Dear Senator McCaskill:

As you and your staff continue to review certain aspects of the commercial practices of Insys Therapeutics, Inc. (“Insys”), I would like to assure you that I stand with you and share the desire to address the serious national challenge related to the misuse and abuse of opioids that has led to addiction and unnecessary deaths and has caused so much pain to families and communities around the country.

Four months ago, I joined Insys after undergoing my own due diligence process and coming to the understanding that this company has great potential to assist patients in unmet medical needs. Like you and your staff, I was concerned about certain mistakes and unacceptable actions of former Insys employees that have been disclosed and discussed in public forums over the past several years. These mistakes and actions are not indicative of the people that are currently employed at Insys and I share your belief that the “vast majority of the employees, executives, sales representatives, scientists, and doctors involved with this industry are good people and responsible actors” including our employees. In this regard, Insys has completely transformed its employee base over the last several years. Notably, over 90% of the 250 field-based sales staff employed prior to 2014 are no longer with the organization. Even in the limited time since I joined the company, we have hired over 50 new employees and replaced key management positions including the following leaders:

- President and Chief Executive Officer
- Chief Financial Officer
- Vice President of Sales
- Regional Director of Sales
- Vice President of Marketing and Managed Care
- Senior Director of Commercial Operations
- Vice President of Medical Affairs
- Senior Director, Clinical Development Medical Affairs (a pain and addiction specialist)

Over the past several years, Insys has actively taken the appropriate steps to place ethical standards of conduct and patient interests at the heart of our business decisions. Our compliance program has been under significant scrutiny for several years from both governmental authorities but also as a result of internal reviews conducted with the assistance of external experts and counsel. During this period, we have invested significant resources in establishing an effective compliance program with protocols designed to ensure compliant and ethical behavior. We recently completed a successful gap assessment into our compliance protocols and processes by an independent, global consulting firm. This assessment was voluntarily conducted with oversight from our Compliance Committee of the Board of Directors. We

passionately believe that the company has taken necessary steps to ensure that we will not repeat the mistakes of the past.

Notwithstanding these transformative changes, as the Chief Executive Officer of Insys and a member of its board of directors, I believe that it is imperative that we take responsibility for the actions of our former employees. This belief is strongly shared by our board of directors. Insys continues to strive to do that where the facts and circumstances dictate that we do so.

I write to you today on behalf of over 400 employees, across three facilities including a research and development laboratory and a fully functional manufacturing facility who have worked tirelessly to develop and manufacture our two FDA-approved products approved for the conditions of breakthrough pain in cancer patients, nausea and vomiting associated with chemotherapy and weight loss in AIDS patients. These products fulfill a significant unmet need for patients requiring supportive or palliative care as they fight their battle with cancer or AIDS. These employees, many of whom have advanced and doctorate level degrees in the technical and health sciences are working diligently every day to develop new medicines and therapies to treat severe catastrophic diseases such as intractable pediatric epilepsy, rare genetic diseases such as Prader-Willi Syndrome, life-threatening anaphylaxis reactions, opioid overdose, opioid addiction & dependence, agitation in Alzheimer's Disease and anorexia in cancer patients. It is worth noting that since 2012, Insys has invested over \$170 million in research and development to advance our pipeline and make a positive impact in the lives of patients and caregivers.

Like so many stakeholders in healthcare and government, we hear the call to action to address the nation's opioid crisis. The opioid epidemic is a highly complex and multi-faceted issue requiring a solutions based approach. We stand ready to help address this public health crisis collaboratively through educational initiatives and drug monitoring programs centered around patients, caregivers, healthcare providers and the overall community. We feel strongly that to develop a solution we must first understand and correct the drivers of the problem.

SUBSYS® is one of six pharmaceutical products in a class called Transmucosal Immediate Release Fentanyl (TIRF). A doctor is not permitted to prescribe, a pharmacy is not permitted to dispense, and a patient is not permitted to receive any TIRF product, including SUBSYS®, unless each of them is enrolled in the Food and Drug Administration ("FDA") mandatory TIRF Risk Evaluation and Mitigation Strategy ("REMS") program. The TIRF-REMS program strives to limit the risk of abuse and misuse by restricting prescriptions to appropriate patients, preventing inappropriate conversions between medicines and educating patients, pharmacists and prescribers about potential for abuse, addiction and overdose of TIRFs, as well as the label for these products.

In 2016, there were 215 million opioid prescriptions written in the United States. SUBSYS® accounted for approximately 34,000 (less than 0.02%) of these prescriptions nationally. These 2016 prescription numbers for SUBSYS® place Insys below the top 50 manufacturers of opioids in the United States. When considering fentanyl's role in the current opioid crisis, it is important to note that in the National Heroin Threat Assessment Summary issued in June 2016, the Drug Enforcement Administration concluded that "pharmaceutical fentanyl is diverted for abuse in the United States at small levels" and recent overdose deaths from fentanyl are "largely due to clandestinely-produced fentanyl, not diverted pharmaceutical fentanyl."

From a personal perspective, we all have been touched or been affected by cancer—as a patient, caregiver, friend, family member or loved one. An aspect of cancer that can be easily overlooked and greatly underappreciated is the excruciating pain that often accompanies the disease as it progresses and is associated with surgical, radiation and chemotherapy treatment. For some patients, the breakthrough cancer pain or cancer related pain can be debilitating and devastating. We would be willing to share with you some of the experiences of patients who have benefited from SUBSYS®. Their experiences illustrate the importance of addressing and treating breakthrough cancer pain appropriately.

I sincerely welcome an opportunity to engage in a meaningful dialogue and partner with key stakeholders such as yourself, other Senators and professional consortiums to play a positive and productive role in helping our nation overcome the opioid epidemic.

Respectfully,

A handwritten signature in black ink, appearing to read 'Saeed Motahari', with a long horizontal flourish extending to the right.

Saeed Motahari
President & Chief Executive Officer
Insys Therapeutics, Inc.