



The Commonwealth of Massachusetts

HOUSE OF REPRESENTATIVES
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Bills in the Third Reading

Committees:
Ways and Means
Judiciary
Economic Development and
Emerging Technologies

November 9, 2018

Food and Drug Administration
Scott Gottlieb, Commissioner
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

RE: Food and Drug Administration Approval of Dsuvia

Commissioner Gottlieb:

I write to you today in extreme disappointment of the Food and Drug Administration's approval of Dsuvia, a new opioid tablet reported to be 1,000 times more potent than morphine and 10 times stronger than fentanyl. As our country is in the midst of the opioid epidemic, I am appalled to learn Dsuvia will be available to patients in hospitals, surgery centers and emergency rooms.

We know the opioid epidemic knows no boundaries and impacts communities of all different socio-economic statuses around the country. According to the Center for Disease Control, 11.4 million people in the United States misused prescription opioids in 2016 and 2017. I imagine patients utilizing Dsuvia in health care settings will be prescribed a strong opioid upon discharge. I predict the number of people in the United States misusing prescription opioids will skyrocket with the introduction of Dsuvia.

The Center for Disease Control estimates 130 people die every day from opioid-related drug overdoses. In response to thousands of opioid-related overdoses and deaths, many states have implemented a variety of laws to attempt to combat this crisis. Over the past five years as State Representative, I have personally immersed myself in learning from providers that work to address mental health and substance use issues. These providers range from hospitals, inpatient/outpatient treatment centers, emergency

service personnel, nonprofits and volunteer groups. There is no doubt in my mind that the approval and patient use of this potent drug will open the door for potential future substance abuse.

As a State Representative representing Fall River and Freetown in Massachusetts, I have seen firsthand how devastating the opioid epidemic has impacted our Commonwealth. According to the Massachusetts Department of Public Health, in 2017 there were 1,501 confirmed opioid-related deaths across the state. The most recent data from January 2018 to June 2018 shows there were 657 confirmed opioid-related deaths across the state. According to data collected by our local opioid outreach group Project Reconnect, in 2017 there were 917 overdoses and 62 deaths in Fall River. From January 2018 to October 2018, there have been 878 overdoses and 54 deaths in Fall River. As you can see from these overwhelming statistics, we envision this epidemic will continue to grow.

I am confident that Dsuvia will take away from the positive strides our leaders in this country have made to protect our constituents from engaging in substance abuse. Please make the right decision and remove Dsuvia from the market.

Thank you for your time and consideration.

Sincerely,



Carole Fiola
State Representative
Sixth Bristol District

CC: Governor Charles Baker
Secretary Marylou Sudders
Senator Edward Markey
Senator Elizabeth Warren
Congressman Joseph Kennedy