The Honorable Mitch McConnell Majority Leader United States Senate Washington, DC 20510

The Honorable Lamar Alexander Chairman Senate Health, Labor and Pensions Committee United States Senate Washington, DC 20510 The Honorable Charles Schumer Minority Leader United States Senate Washington, DC 20510

The Honorable Patty Murray Ranking Member Senate Health, Labor and Pensions Committee United States Senate Washington, DC 20510

Dear Majority Leader McConnell, Minority Leader Schumer, Chairman Alexander and Ranking Member Murray:

On behalf of many organizations on the front line of our nation's prescription opioid and heroin crisis and on behalf of hundreds of thousands of American families devastated by opioid addiction, we are writing to you in opposition to the recent nomination of Dr. Scott Gottlieb to be the Commissioner of the Food and Drug Administration.

As has been well documented, our nation continues to combat an opioid addiction epidemic that is striking every community in the country. We all are numbed by the continued horrific increase in overdose deaths involving opioids which rose from 28,647 in 2014 to 33,091 in 2015. Heroin overdose deaths rose from 10,574 in 2014 to 12,990 in 2015, an increase of 23 percent. Heroin continues to flood our communities and new threats in the form of fentanyl and carfentanil are continuing to emerge virtually unstopped. When final 2016 statistics are revealed by the CDC, those deaths are expected to be even more gruesome.

Despite some progress in changing federal policies and legislation as well as the commitment of additional dollar resources in 2016, much more needs to be done.

For years, we have seen the FDA continue the approval of new opioid drugs and new uses of opioid drugs in the face of empirical evidence that directly implicates the overuse of these powerful narcotic painkillers in the explosion of opioid addiction and mortality. We are particularly troubled by the excessive influence the pharmaceutical industry has on FDA decisions and we cannot allow the FDA to continue underestimating the risks associated with opioids, approve new uses or formulations, or shorten approval processes.

We, the undersigned organizations fighting the epidemic of opioid addiction, are particularly disturbed by Dr. Gottlieb's current and past ties to the pharmaceutical industry. Media reports indicate that Dr. Gottlieb has accepted several hundred thousand dollars from drugmakers in recent years, served on numerous drug and medical device

manufacturer company boards and has established numerous corporate ties as a current venture capitalist. More disturbingly, Dr. Gottlieb has advocated for expediting the drug approval process for new drugs -- advocating that efficacy requirements associated with that process be eliminated. At a time when there are over 30 opioid painkiller alternatives available on the US market and our country consuming over 80% of the world's opioid painkillers, we need more careful and considered review processes in place to protect the health and safety of all Americans and not less.

To bring our nation's epidemic of opioid addiction to an end, we must reduce the overprescribing and overuse of opioids. This goal will be difficult to achieve if the FDA continues to be complicit in the expansion in available opioid drugs in the US. The FDA mission should be to protect the health and safety of our citizens and not the business models of pharmaceutical companies.

We urge you to oppose the nomination of Dr. Gottlieb to be the next Commissioner of the FDA. Many lives are at stake.

Sincerely,

Addiction Haven Advocates for the Reform of Prescription Opioids, Inc. Altus Treatment Center Consoling Partners/Addiction Loss FED UP! Coalition to End the Opioid Epidemic Justice's Fight Mid-Shore Restoring Hope in Women National Coalition against Prescription Drug Abuse National Physicians Alliance Norfolk District Attorney, MA (Michael W. Morrissey) OvertakenLives.org Physicians for Responsible Opioid Prescribing (PROP) Recovering U Shatterproof Steve Rummler Hope Network **STOPPNOW** The Open Doorway of Cape Cod, Inc