

**MANUFACTURER RESPONSES TO “FUELING AN EPIDEMIC”  
A REPORT FROM SENATE HOMELAND SECURITY & GOVERNMENTAL AFFAIRS COMMITTEE  
MINORITY STAFF**

**PURDUE PHARMA:**

*We have supported third-party organizations, including with annual dues and unrestricted grants, that are interested in helping patients receive appropriate care. We agree that the CDC's Guideline is an important public health tool and have been directing prescribers to the Guideline and its recommendations since it issued in March 2016.*

**STATEMENT FROM INSYS THERAPEUTICS**

**Context on breakthrough cancer pain, the TIRF product class, and its relation to the U.S. opioid epidemic:**

We recognize and understand why, as a manufacturer of an opioid in the strictly regulated TIRF\* class, we are subject to significant scrutiny and criticism. Like many within the healthcare industry, we have taken so many steps over the past several years to put patients first and are more than willing to explain our practices within the full context of our decision-making process.

Based upon available information and independent studies, many medical experts and healthcare providers believe that breakthrough cancer pain is significantly undertreated in the U.S. At the height of their utilization in 2015, TIRF products were prescribed to approximately 25,000 patients, less than 0.05 percent of the total of all people prescribed opioids in the U.S. The consequences suffered by patients diagnosed with this excruciating and debilitating pain can be physical, emotional and financial in nature. If not properly treated, breakthrough cancer pain can exact a terrible toll—not only on patients, but also on their families and caregivers, the healthcare system and society at large.

Another fact that bears consideration is that the number of units of TIRF products prescribed to patients in Europe in 2017 was over 10 times HIGHER than in the U.S. (more than 50 million units in Europe vs. about 4.5 million in the U.S.). This difference highlights the significant issue that many cancer patients with breakthrough pain in the U.S. may not be receiving treatment with medication approved by the FDA specifically for this condition.

\* Transmucosal Immediate Release Fentanyl (TIRF) products are a special and highly restricted class of medication. 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 unless each of them is enrolled in the Food and Drug Administration's 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

**Characterization of contributions to non-profit foundations and changes to physician speaker programs:**

As reflected in our mission, we are committed to improving the quality of patient care and bringing significant innovation to disease areas with unmet medical needs, including breakthrough cancer pain, refractory pediatric epilepsy and anaphylaxis.

We believe that our 2017 charitable contributions, which have become the subject of media attention, are patient focused. With regard to the U.S. Pain Foundation specifically, our donation was directed to a disease-state fund for cancer patients with breakthrough pain, which many medical experts and

healthcare providers believe is significantly undertreated in the U.S. Existing regulations and laws, including guidance from the Office of Inspector General (OIG), permit these types of charitable contributions that benefit patients. We strived to comply with all such laws and regulations in making such contributions. It's important to highlight that under current guidelines, manufacturers are not privy to, and do not receive information about, specific patients who are helped by these foundations' programs. Furthermore, these guidelines do not permit donors to have visibility into the number of patients who are prescribed their products.

It is also worth noting that in the second half of 2017, INSYS's contributions to these foundations decreased by approximately 77 percent. There are a number of reasons why this is the case. Principally, our new management team believes that the best way we can assist patients in serving unmet medical needs within our budgetary constraints is to deliver on our innovative R&D pipeline, which will require significant investment as well as optimizing spending across our organization.

On another subject, the number of physician speaker programs and the amount in honoraria paid to physician speakers went down by 87 percent and 82 percent, respectively, in 2017 compared to 2015.

#### **Cooperation with Sen. McCaskill's inquiry:**

INSYS has been cooperating with Senator McCaskill's inquiry since approximately July 2016, including providing a briefing by company executives, producing more than 1.6 million pages of documents, responding to each of the requests contained in the Senator's March 2017 letter, and providing detailed financial information as reflected in this report. INSYS provided all the requested information concerning the U.S. Pain Foundation promptly after the Senator's staff informed the company that the request covered support for patient assistance, which was not among the purposes enumerated in the Senator's original letter. More importantly, this was fully corrected before the Senate report was final. Indeed, all the manufacturers were aware that the staff was cross-checking all submissions with each non-profit organization.

#### **DEPOMED**

##### **STATEMENT FROM DEPOMED REGARDING SENATE HOMELAND SECURITY COMMITTEE'S MINORITY STAFF REPORT**

- Depomed held the commercialization rights to the Lazanda® franchise for 4 years 3 months (July 2013 – November 2017) and the NUCYNTA® franchise for 2 years and 9 months (April 2015 – January 2018)
  - o In November 2017, Depomed divested Lazanda to Slán Medical Holdings [\[release\]](#)
  - o In December 2017, Depomed announced the transfer of NUCYNTA commercialization rights to Collegium [\[release\]](#) (the deal closed in January 2018) [\[release\]](#)
- During this period, Depomed made contributions to 9 of the 14 foundations identified in the report
- Total annual contributions from these two franchises to these 9 foundations during the years of our ownership ranged from a little over \$70k to around \$300k for a total over the 6 years of \$1.07M
- This equates to an average of approximately \$178k/ year spread across the 9 foundations
- This equates to an average of \$20k/ year per recipient
- To put the \$178K/year in contributions into perspective, in 2016 the NUCYNTA franchise generated \$281M in annual sales
- These contributions covered corporate advertising, conference booth fees, sponsoring training certifications and membership fees

- Depomed believes that has acted responsibly with respect to the marketing and advertising of the Lazanda and NUCYNTA franchises
- Depomed believes it has a strong Compliance program in place that oversaw the marketing, advertising and corporate sponsorship activities tied to the Lazanda and NUCYNTA franchises

## JANSSEN

*Our contributions to the organizations referenced in the report were made to support efforts to educate the public about the appropriate use of opioid pain medicines, and were transparently disclosed.*

*We stopped developing and promoting opioid products in 2015, and since 2008, the volume of our opioid medications has amounted to less than one percent of the total prescriptions written per year in this class.*

*We acted responsibly when we marketed these medicines, and also recognize that opioid abuse and addiction are serious public health issues. Finding solutions will require collaboration among many stakeholders, and we are committed to being part of the ongoing dialogue to help address this crisis.*



## MYLAN:

### **Mylan Media Statement regarding Senator McCaskill report**

Mylan has always made the health and safety of patients its top priority and believes the opioid epidemic must be addressed. Consistent with that belief, Mylan has cooperated with Senator McCaskill's investigation and during the last eleven months shared data demonstrating its miniscule role in the opioid marketplace as primarily a generics manufacturer and supplier. In 2016, Mylan supplied approximately 1% of opioids sold in the U.S., which placed Mylan 17th among pharmaceutical companies. Regarding payments to third parties, as the Report acknowledges, Mylan made very limited payments to only one of the fourteen organizations cited in the Report, totaling \$20,250 over 3 years. This amounts to only 0.2% of the more than \$10 million cited in the Report.

Senator McCaskill's welcomed revisions to the [Executive Summary](#), which expressly state that Mylan is "[a]t the other end of the spectrum" from the four other companies, and her [public comments](#) that "the Report lays it out black and white that this is not a problem that Mylan has", now clearly show that Mylan never belonged in this report's grouping of manufacturers.

## **FOUNDATION RESPONSE TO “FUELING AN EPIDEMIC” A REPORT FROM SENATE HOMELAND SECURITY & GOVERNMENTAL AFFAIRS COMMITTEE MINORITY STAFF**

### **U.S. PAIN FOUNDATION**

U.S. Pain Foundation is a nonprofit that offers dozens of free programs to serve the 100 million Americans living with chronic pain. Like most patient advocacy organizations, we receive funding from a number of sources, including pharmaceutical companies.

When it comes to funding, we pride ourselves on our transparency and our independence. All of our donors are listed publicly on our website, and the funding we receive is not used to promote one type of treatment over another.

As an organization run entirely by pain patients and their loved ones, we advocate only for fellow patients' best interests. The source of any funding received does not influence our mission or our core values.

One of those values is the belief in balanced, multidisciplinary pain management, with an emphasis on nonpharmacological treatment whenever possible. US Pain believes no one single answer is available for people suffering with pain and we need to each find what works best for us on this journey and we should have as many options as possible to treat our pain.

U.S. Pain Foundation is proud of our independence and our longstanding efforts to offer hope and healing to those who are suffering

### **ACADEMY OF INTEGRATIVE PAIN MANAGEMENT**

We determine our policy advocacy positions on the basis of an annual survey of our members and other stakeholders (i.e., other professional groups and patient advocacy groups, NOT our funders). Each year for the last 3-4 years, they have told us that our primary emphasis should be on increasing access to non-pharmacological methods of treating pain. That's what we've emphasized—a position that, if anything, should DECREASE opioid prescribing. When we have advocated on opioid issues, we've advocated against policies that would tie the hands of our members to such a degree that they would be unable to provide optimal care to their patients, some of whom, like it or not, need opioids for pain relief. We have supported some legislation that limits the amount of medication that can be prescribed for acute pain; we've supported legislation that requires prescribers to check the PDMP before prescribing opioids; we've supported legislation that requires continuing education on pain management and substance use disorders; and we've worked with regulators to craft treatment guidelines that direct prescribers toward safe opioid prescribing. We're more than happy to share all of the letters we've written regarding various policies—there are a very large number of them, and we're confident that a thorough review will show that we have taken a balanced approach that is not inappropriately “opiophilic”.

If anything, we are the group that Sen. McCaskill and others in Congress and the administration who are trying to address the opioid crisis should be working with to find solutions. We have positive relationships with a number of groups in the substance use disorder community, and we believe we have been good partners for those groups as we try, together, to address the two public health crises we are encountering: opioid misuse and overdose, and inadequately treated chronic pain. Unfortunately, Sen. McCaskill and the others haven't spent the necessary time talking to us to understand how we do things and what we have to offer. They've simply looked at how much money we got from a set of pharma companies, constructed a narrative about what that means, and published it.

## **AMERICAN ACADEMY OF PAIN MEDICINE**

The American Academy of Pain Medicine (AAPM) supports the 12 recommendations of the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain. While the Academy believes the use of an opioid analgesic should balance both the benefits and risks of therapy, it did voice some concerns around arbitrary limits of opioid use for acute pain, which could bias prescribers' thinking and potentially lead to the under treatment of pain.

As noted in the CDC guideline, when determined to be appropriate by the prescriber, opioids should be considered as part of a comprehensive pain management plan including non-opioid medications, physical therapy, interventional procedures, behavioral health treatments, such as cognitive behavioral therapy, integrative therapies, such as acupuncture and massage, and pain patient education. Prescribing opioids should always be done in conjunction with, close monitoring, including appropriate time limited trials, ongoing psychological screening, use of urine toxicology testing to monitor for diversion and misuse, regular checking of state prescription monitoring databases, and other interventions to help ensure safe use and limit risks to others. Additionally, for chronic pain patients and people with substance abuse problems, the Academy supports increased access to medication assisted therapy (MAT) and addiction-related counseling.

Finally, the Academy supports the findings and recommendations of the National Pain Strategy (NPS) and the National Academies of Sciences, Engineering, and Medicine (NASEM) that there is a need for an increase in advocacy for public awareness, research, and funding for chronic pain.

The American Academy of Pain Medicine (AAPM) is committed, as a professional medical society, to act with integrity and transparency in all of its activities. Like many other professional medical societies, the Academy relies on a number of sources of revenue, including membership dues, registration fees, unrestricted educational grants, sponsorships, and the sale of trade show exhibit space and advertising. Sponsorships, trade show and advertising sales all represent business transactions with external companies that are seeking to reach the Academy's constituents with their messaging. While the Academy has policy that helps to ensure appropriate standards of accuracy are maintained in these transactional messages it does not impose strict editorial control over them.

In the area of unrestricted educational grants, however, the Academy adheres to the standards established by Accreditation Council for Continuing Medical Education (ACCME), which accredits nearly 2,000 organizations across the country. The [ACCME Standards for Commercial Support](#) require that professional medical societies exclude industry from any influence, direct or indirect, over speakers and educational content. February 9, 2018

## **About AAPM**

The American Academy of Pain Medicine is the premier medical association for pain physicians and their treatment teams with some 2,000 members. Now in its 34th year of service, the Academy's mission is to optimize the health of patients in pain and eliminate pain as a major public health problem by advancing the practice and specialty of pain medicine through education, training, advocacy and research. Information is available on the Academy's website at [www.painmed.org](http://www.painmed.org)

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## **AMERICAN PAIN SOCIETY**



RESEARCH  
EDUCATION  
TREATMENT  
ADVOCACY

### **Statement from the American Pain Society**

#### **McCaskill Report on Pharma Company Financial Support for Pain Organizations**

CHICAGO, Feb. 13, 2018 -- The American Pain Society (APS) said today it is disappointed that Senator Claire McCaskill's report on financial support for pain organizations from companies that manufacture and market opioid pain medications, released last night, contains simplistic, misleading and insulting conclusions regarding support that APS has received in recent years from the pharmaceutical industry.

We also are disturbed that no one from the Senator's staff contacted APS to inquire and learn the truth about our policies and procedures governing industry grants. Had they done so, we would have explained in detail the educational and pain research initiatives APS continues to pursue to help resolve the opioid crisis. APS leaders were major contributors to the landmark National Pain Strategy (NPS). The Society is active in developing policy recommendations to implement the NPS goals to expand opioid education and training for prescribers and to increase funding for pain research to improve treatment options that mitigate the use and need for opioids in the clinical setting.

In any given year, APS revenues from industry are devoted to unrestricted grants for education and specific projects, such as young investigator research (whereby the grantors are not allowed to influence content), advertising, and exhibits. It appears Sen. McCaskill unfairly and naively equates financial support with undue industry influence and control. This simplistic and incorrect assumption damages our reputation for scientific integrity and advocacy on behalf of pain management clinicians, researchers and patients. We wish the Senator's office had taken the time to speak with APS leadership before writing its report.

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