## Congress of the United States Washington, DC 20515

May 3, 2017

Dr. Margaret Chan
Director-General
World Health Organization
Avenue Appia 20
1211 Geneva 27
Switzerland

Dear Dr. Chan:

We write to warn the international community of the deceptive and dangerous practices of Mundipharma International—an arm of Purdue Pharmaceuticals. The greed and recklessness of one company and its partners helped spark a public health crisis in the United States that will take generations to fully repair. We urge the World Health Organization (WHO) to do everything in its power to avoid allowing the same people to begin a worldwide opioid epidemic. Please learn from our experience and do not allow Mundipharma to carry on Purdue's deadly legacy on a global stage.

Mundipharma International is a network of pharmaceutical companies owned by the Sackler family. The Sacklers also own and operate Purdue Pharmaceuticals, the privately held company that developed and marketed OxyContin. Internal documents revealed in court proceedings now tell us that since the early development of OxyContin, Purdue was aware of the high risk of addiction it carried. Combined with the misleading and aggressive marketing of the drug by its partner, Abbott Laboratories, Purdue began the opioid crisis that has devastated American communities since the end of the 1990s. Today, Mundipharma is using many of the same deceptive and reckless practices to sell OxyContin abroad.

OxyContin was approved by the U.S. Food and Drug Administration (FDA) in 1995. Though executives at Purdue were aware that their dosing recommendations were ineffective for many patients, and that the formulation and dosing raised the risk of addiction, they advertised OxyContin as a solution for day-to-day pain. Purdue and its marketing partner Abbott used

<sup>5</sup> See note 2.

<sup>&</sup>lt;sup>1</sup> The Man at the Center of the Secret OxyContin Files, Stat News (May 12, 2016) (online at www.statnews.com/2016/05/12/man-center-secret-oxycontin-files/).

<sup>&</sup>lt;sup>2</sup> 'You Want a Description of Hell?' OxyContin's 12-Hour Problem, Los Angeles Times (May 5, 2016) (online at www.latimes.com/projects/oxycontin-part1/).

<sup>&</sup>lt;sup>3</sup> Secret Trove Reveals Bold 'Crusade' to Make OxyContin a Blockbuster, Stat News (Sep. 22, 2016) (online at www.statnews.com/2016/09/22/abbott-oxycontin-crusade/).

<sup>&</sup>lt;sup>4</sup> OxyContin Goes Global—"We're Only Just Getting Started," Los Angeles Times (Dec. 18, 2016) (online at: www.latimes.com/projects/la-me-oxycontin-part3/).

gifts and free meals to develop relationships with physicians, who would then prescribe the painkiller to patients with ordinary pains, rather than the severe, long-term pain associated with end-stage cancer. Purdue's efforts were effective: at their height, OxyContin sales reached \$3 billion a year.

Meanwhile, cases of opioid-related substance use disorder skyrocketed. By 2009, emergency room visits related to prescription drugs reached 1.2 million cases, with opioid pain relievers, and especially OxyContin, being the most prominent cause for visits and fatalities. People were dying.

Moreover, as the rate of prescription opioid use and related overdoses rose, increased demand also spilled into the illicit drug trade. The enormous market for opioids created in the wake of the OxyContin boom, combined with the much lower cost of heroin compared with prescription medications, meant an explosion in heroin use and dramatic increase in the rate of overdoses. As many as 80 percent of heroin users started out using prescription opioids. 10

Today, in spite of intensive efforts to address this crisis, the rate of overdose deaths continues to rise. In 2015 alone, more than 33,000 people died as a result of opioid overdoses in the United States.<sup>11</sup>

A major piece of the current U.S. strategy to address the opioid epidemic is to provide physicians and patients with information about the risks associated with opioids, as well as effective alternatives for pain management. With collaboration between prescribers and lawmakers, prescriptions for OxyContin in the U.S. have dropped nearly 40% since 2010.<sup>12</sup>

In response to the growing scrutiny and diminishing U.S. sales, the Sacklers have simply moved on. On December 18, the Los Angeles Times published an extremely troubling report detailing how in spite of the scores of lawsuits against Purdue for its role in the U.S. opioid crisis, and tens of thousands of overdose deaths, Mundipharma now aggressively markets OxyContin

<sup>7</sup> See note 2.

<sup>&</sup>lt;sup>6</sup> See note 3.

<sup>&</sup>lt;sup>8</sup> Food and Drug Administration, *Timeline of Selected FDA Activities & Significant Events Addressing Opioid Misuse & Abuse* (Jan. 2017) (online at www.fda.gov/downloads/drugs/drugsafety/informationbydrugclass/ucm332288.pdf).

<sup>&</sup>lt;sup>9</sup> Heroin Deaths Surpass Gun Homicides for the First Time, CDC Data Shows, Washington Post (Dec. 8, 2016) (online at www.washingtonpost.com/news/wonk/wp/2016/12/08/heroin-deaths-surpass-gun-homicides-for-the-first-time-cdc-data-show/?utm\_term=.ed516c8727b2).

<sup>&</sup>lt;sup>10</sup> Hospitalizations Among Teens for Opioid Poisonings Increase, Study Shows, Teen Vogue (Feb. 13, 2017) (online at www.teenvogue.com/story/teens-opioid-poisonings-painkillers-hospitalizations-teen-story).

White House, Continued Rise in Opioid Overdose Deaths in 2015 Shows Urgent Need for Treatment (Dec. 8, 2016) (online at obamawhitehouse.archives.gov/the-press-office/2016/12/08/continued-rise-opioid-overdose-deaths-2015-shows-urgent-need-treatment). <sup>12</sup> See note 4.

internationally.<sup>13</sup> In fact, Mundipharma uses many of the same tactics that caused the opioid epidemic to flourish in the U.S., though now in countries with far fewer resources to devote to the fallout.

In some places, Mundipharma companies hold "training seminars," where doctors are encouraged to overlook their concerns about opioids and prescribe painkillers for chronic pain. Some Mundipharma materials have attempted to downplay the risk of addiction, recalling Purdue's early OxyContin marketing in the 1990s. Those marketing materials eventually led to federal drug misbranding charges and a \$635 million judgment against Purdue. Mundipharma also brings American doctors to other countries to promote the use of opioid painkillers to local physicians. This, too, was a common practice by Purdue to push OxyContin in the U.S.

The international health community has a rare opportunity to see the future. Though the rate of opioid use disorder remains relatively low outside of the United States, that can change rapidly. The rate is likely to rise if events follow the same pattern as in the United States, starting with the irresponsible—and potentially criminal—marketing of prescription opioids. From 1999 to 2014, the rate of opioid-related overdose deaths in the United States nearly quadrupled. Opioid use disorder is on the rise globally now—current European rates are similar to rates in the United States in the early 2000s, and the WHO has struggled to address rising dependence on Tramadol in at least eight countries. 15

We urge the WHO to learn from our experience and rein in this reckless and dangerous behavior while there is still time.

Do not allow Purdue to walk away from the tragedy they have inflicted on countless American families simply to find new markets and new victims elsewhere.

Sincerely,

Katherine Clark

Member of Congress

Hal Rogers

Member of Congress

<sup>&</sup>lt;sup>13</sup> Id.

<sup>&</sup>lt;sup>14</sup> Department of Health and Human Services, *The Opioid Epidemic: By the Numbers* (Jun. 2016) (online at: www.hhs.gov/sites/default/files/Factsheet-opioids-061516.pdf).

<sup>&</sup>lt;sup>15</sup> See note 11; Opioids: Sierra Leone's Newest Public Health Emergency, Al Jazeera (Feb. 14, 2017) (online at www.aljazeera.com/indepth/features/2017/01/opioids-sierra-leone-newest-public-health-emergency-170119093804569.html).

Theodore E. Deutch Member of Congress

Marcy Kaptur Marcy Kaptur Member of Congress

Ann McLane Kuster Member of Congress

James P. McGovern Member of Congress

Carol Shea-Porter Member of Congress Raúl M. Grijalva Member of Congress

William R. Keating Member of Congress

Stephen F. Lynch Member of Congress

Tim Ryan

Member of Congress

Paul D. Tonko

Member of Congress