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Re: *60 Minutes* Segment on Opioids

Dear Nick and Bill:

We represent Purdue Pharma L.P. ("Purdue"). I write regarding *60 Minutes*' reporting on Purdue, specifically with regards to the segment on the U.S. Food and Drug Administration ("FDA") and opioid medicines that *60 Minutes* is considering airing this Sunday, February 24, 2019.

Despite multiple meetings, phone calls, and email exchanges between representatives of Purdue and *60 Minutes* Associate Producer Sam Hornblower (during which detailed information was exchanged), we are still concerned that Mr. Hornblower and *60 Minutes* intend to air a biased and one-sided segment rife with significant errors and inaccuracies, and that *60 Minutes* will refuse to disclose to its viewers critical information about the sources it intends to rely on (and even put on the air), including their personal biases toward Purdue and their financial incentives in making false and misleading statements about the company and OxyContin.

With this letter, CBS and *60 Minutes* are on notice of the inaccuracies and errors we understand may be included in such a segment (and the contradicting facts demonstrating their falsity) and that *60 Minutes* has a duty to its viewers and to Purdue to make the following disclosures should it decide to air interviews with or statements from these biased sources.

I. *60 Minutes*' Intended Characterizations and Descriptions of the Timing and Make-Up of the FDA's Initial 1995 Approval of OxyContin and the FDA's Clarification and Narrowing of that Approval in 2001 are Inaccurate and Misleading.

Based on meetings, phone calls, and email exchanges with Mr. Hornblower, we have serious concerns that he and *60 Minutes* will falsely report that (1) in 1995, the FDA lacked sufficient evidence to approve OxyContin for distribution, and (2) in 1995, the FDA did not approve OxyContin for the treatment of chronic pain, and only in 2001 did the FDA first broaden its approval of OxyContin for use in the treatment of patients suffering from chronic and long-term pain. These purported statements are demonstrably false and create the misleading impression that OxyContin was not initially intended to be used for the treatment of chronic and long-term pain, and only after several years of such 'unapproved use' did the FDA take action. In fact, publicly available information demonstrates that the FDA, in its initial approval of OxyContin in **1995**, understood that its benefits extended to the treatment of patients suffering from chronic, long-term pain, and therefore included that intended and approved use in its initial approval. Then, six years later in 2001, the FDA, in light of unexpected widespread abuse of OxyContin, clarified its safety warnings to narrow the use of it to patients who are actually suffering from chronic and long-term pain (and to eliminate any notion that this important treatment should be used for any other purpose).

A. The FDA Approved OxyContin for the Treatment of Chronic and Long-Term Pain in 1995 Based on Sufficient and Extensive Data and Information.

We understand that *60 Minutes* intends to falsely report that the FDA lacked sufficient evidence to approve OxyContin in 1995. This is patently false. The FDA based its approval of OxyContin on a robust set of clinical trials, which the FDA dubbed at the time as the "*gold standard*." Though, at the time, only two clinical trials were usually necessary, Purdue submitted and the FDA reviewed six controlled clinical studies (involving over 700 patients) before it approved OxyContin. Three of these clinical trials were for cancer pain, and one for osteoarthritis, one for chronic low back, and one for post-operative pain. The new drug application for OxyContin consisted of over 40,000 pages in 120 volumes, including 14 pharmacokinetic studies. The FDA was in possession of an unprecedented amount of information and evidence demonstrating OxyContin's benefits and effectiveness in treating patients with debilitating pain before it approved it for use in 1995. Any statements that imply or suggest that the FDA somehow lacked sufficient information or evidence when it made its decision to approve OxyContin in 1995 is false.

In fact, in 2013, when denying a citizen's petition brought by Physicians for Responsible Opioid Prescribing, the FDA stated that "there are numerous uncontrolled studies that have evaluated patients on opioids for as long as a year; although some patients drop out of the studies over this period of time, many remain on opioid therapy, which may suggest that they continue to experience benefits that would warrant the risks of opioid use." And even today, the FDA continues to approve opioids for long-term, chronic pain use and recognizing that for select patients, opioids may be the only reasonable and effective therapy for patients seeking to manage their legitimate chronic pain.

B. The FDA Expressly Approved OxyContin for Use in the Treatment of Chronic and Long-Term Pain in 1995, and then Narrowed its Approval to Only Such Use in 2001.

We understand that *60 Minutes* intends to report – inaccurately – that in 2001, the FDA broadened the indication for OxyContin to include the treatment of chronic pain. This is simply not true; the changes to OxyContin's label that were required by the FDA in 2001 narrowed the patient population for which OxyContin was intended; importantly, however, it did **not** add a chronic pain indication as OxyContin has been approved for chronic pain since its initial approval in **1995**.

The FDA initially approved OxyContin "for the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days." The original label (which is enclosed with highlighted sections noted below for your reference) included numerous references to the medicine's use (and approval) for chronic or long-term pain, including the following statements:

> "During chronic therapy, especially for non-cancer pain syndromes, the continued need for around-the-clock opioid therapy should be reassessed periodically (e.g., every 6 to 12 months) as appropriate."
>
> "Physical dependence and tolerance are not unusual during chronic opioid therapy."
>
> "It should be expected, however, that a fraction of cancer patients will develop some degree of tolerance and require progressively higher dosages of OxyContin to maintain pain control during chronic treatment."
>
> "Neonates whose mothers have been taking oxycodone chronically may exhibit respiratory depression and/or withdrawal symptoms, either at birth and/or in the nursery."
>
> "The clinical relevance of a difference of this magnitude is low for a drug intended for chronic usage at individualized dosages, and there was no male/female difference detected for efficacy or adverse events in clinical trials."
>
> "There was no evidence of oxycodone and metabolite accumulation during 8 months of therapy."
>
> "There was a significant decrease in acute opioid-related side effects, except for constipation, during the first several weeks of therapy."
>
> "Patients should be advised that if they have been receiving treatment with OxyContin for more than a few weeks and cessation of therapy is indicated, it may be appropriate to taper the OxyContin dose,

> rather than abruptly discontinue it, due to the risk of precipitating withdrawal symptoms."
>
> "The intent of the titration period is to establish a patient-specific q12h dose that will maintain adequate analgesia with acceptable side effects for as long as pain relief is necessary. Should pain recur then the dose can be incrementally increased to re-establish pain control. The method of therapy adjustment outlined above should be employed to re-establish pain control."

And, these clearly identified statements on OxyContin's original label echo the FDA Medical Officer's review of OxyContin when it was first approved:

> "[C]ontrolled release oxycodone was studied in an adequate number of patients to reveal adverse events at the 1 % level....It showed an acceptable level of risk associated with its use in the chronic pain population."

In July 2001, the FDA, recognizing that OxyContin was being widely abused, added a black box warning and narrowed the indication to "the management of moderate to severe pain when a continuous, around the clock analgesic is needed for an extended period of time." The FDA's meeting notes and congressional testimony confirm that the purpose of the label changes was to add important safety warnings and limit the use of the medicine only to appropriate patients with chronic pain.

In April 2001, the FDA acknowledged in a meeting that:

> "The indication of ''moderate to severe pain for patients who need to be on opiates for more than a few days" is broad and may not adequately reflect the intended population. The label should clearly state that this drug product should only be used patients who require opiates for an extended period of time, that it should not be utilized for first-time treatment of pain, and that it is not for intermittent use."

Furthermore, the FDA's Dr. John Jenkins testified before the Senate in 2002 concerning this narrowing clarification of the approved uses of OxyContin (while also acknowledging Purdue's participation in that very process):

> "In July of last year Purdue Pharma, working in cooperation with FDA, significantly strengthened the warnings and precautions in the labeling for OxyContin....Furthermore, the labeling for OxyContin now makes clear that it is only approved by FDA for treatment of moderate to severe pain in patients who require around-the-clock narcotics for an extended period of time."

As the record demonstrates, the FDA, based on a mountain of data, research and evidence, approved OxyContin for use by patients seeking to manage and treat a specific type and level of pain

(which included chronic, long-term pain) originally in 1995. Then in 2001, the FDA determined, in consultation with Purdue, to add a strengthened warning to OxyContin's labels narrowing its approved and intended use to individuals suffering from chronic, long-term pain. Any statements by *60 Minutes* (or any sources or individuals it intends to interview or publish statements from)[1] in any forthcoming statement would be demonstrably false and should not be referenced.

II. ***60 Minutes*** **Intends to Include Interviews and Statements from Sources Who are Biased Against and Have a Personal and Financial Incentive to Negatively Comment About Purdue.**

As part of its one-sided segment on opioids, we understand that, based on conversations and communications with Mr. Hornblower, *60 Minutes* has already interviewed or intends to interview two individuals who are well-known and vocal critics of Purdue and OxyContin – Dr. Andrew Kolodny and former FDA Commissioner David Kessler. Both of these individuals are not only inherently biased towards (and vocally critical of) Purdue and OxyContin, but are also, based on their paid-for consulting and advising roles for both *60 Minutes* and for plaintiff-side law firms involved in litigation against Purdue, incapable of providing a neutral and fair perspective on the history and current state of opioid prescription use in the United States.

Dr. Kolodny has admitted, in the form of a court-filed expert disclosure report made under the penalty of perjury, to the fact that he is a paid consultant and advisor, earning $725/hour for his services.[2] He also lists on his CV that he submitted to the U.S. House of Representatives Committee on Energy and Commerce on February 27, 2018 as part of his required disclosures prior to his testimony under oath, that he served in a "CONSULTING AND ADVISING" role for "CBS *60 Minutes*" in 2017 as part of *60 Minutes*' "The Whistleblower" segment.[3] A copy of this expert disclosure report and Dr. Kolodny's CV he submitted for his congressional testimony is enclosed for your reference. The facts demonstrate that Dr. Kolodny admits that he worked for 60 Minutes as a consultant and advisor within the last two years (and on a segment that touched on substantially similar subject matter is this segment) and that he is also a paid consultant on behalf of plaintiffs currently involved in active litigation with Purdue.

In that same vein and upon information and belief, we understand that Dr. Kessler has also performed extensive work for and has long consulted with and on behalf of plaintiff-side law firms who are or have been engaged in litigation against Purdue regarding the very same issues he purports

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[1] A media defendant can be liable for republishing or participating in the publication of another's false statement if it acted with a reckless disregard for whether the statement was true or false. *Cianci v. New Times Pub. Co.*, 639 F.2d 54, 60 (2d Cir. 1980); *see also St. Amant v. Thompson*, 390 U.S. 727, 732 (1968) (recklessness may be found "where there are obvious reasons to doubt the veracity of the informant or the accuracy of his reports.").

[2] *See* Dec. 21, 2018 State's Expert Witness Disclosures, Exhibit J, Case No. CJ-2017-81.

[3] *See* Feb. 27, 2018 Andrew Kolodny's "Truth in Testimony" Witness Disclosure Requirement, Committee on Energy and Commerce, U.S. House of Representatives.

to comment on for *60 Minutes*' planned segment.[4] These types of consulting and advising roles for law firms involved in active or potential litigation are rarely if ever performed for free.

It is incumbent upon *60 Minutes*, as the ultimate publisher and airer of segments featuring biased and conflicted individuals like Dr. Kolodny and Dr. Kessler,[5] to thoroughly investigate and vet its own sources and intended on-screen interviewees to confirm any such biases and financial incentives for promoting certain viewpoints and commentary. And where such biases and financial or otherwise personal motives to provide one-sided, incomplete, and even false commentary on a subject matter such as opioid use in the United States exists (as it clearly does with Dr. Kolodny and Dr. Kessler who are, at a minimum, paid-for consultants by individuals and parties who are currently suing Purdue), *60 Minutes* has a duty to its viewers to clearly and unambiguously disclose such bias and the facts supporting their incentive and motivation for their viewpoints and commentary during any aired segment in which Dr. Kolodny and Dr. Kessler participate in, and to confront such bias head-on.

* * *

60 Minutes obviously has the right to make fair comment on matters of public concern, and that certainly extends to reporting on the opioid crisis in a balanced and fair-minded manner. However, reporting that includes demonstrably false and otherwise misleading commentary regarding the history of the FDA's thorough approval process for OxyContin and the clear and unambiguous warnings and precautions both the FDA and Purdue have taken over the years to promote appropriate uses of OxyContin and that relies on the biased and financially-incentivized opinions of vocal critics of Purdue is neither fair nor balanced reporting.

Purdue recognizes the significant public health challenge that the opioid and other addiction crises pose and the impact they have on families across the U.S. Purdue understands and has embraced the importance of addressing this issue head on, both through direct action and a balanced and fair national discussion. To that end, Purdue has submitted earlier today, under separate cover, an on-the-record statement to *60 Minutes* (enclosed for your reference). We fully expect that *60 Minutes* will include Purdue's full statement and otherwise accurately represent Purdue's statement in the segment (and in any articles or other accompanying reporting on the segment posted online or elsewhere).

We trust that you understand the seriousness of these issues. We request that you, in your respective capacities as counsel for CBS and as the Executive Producer of *60 Minutes*, (1) refrain from making the demonstrably false claims outlined in this letter on-air in any forthcoming segment and likewise ensure that the critical and necessary facts detailed above are fairly and accurately represented in any segment *60 Minutes* may air that references Purdue or OxyContin, (2) that CBS and *60 Minutes* thoroughly investigate and vet the bias and financial incentives of any sources it intends to rely on for any such segment (whether they are on-background or on-camera interviewees),

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[4] *See, e.g.*, July 27, 2016 Decl. of David Kessler, Case No: 30-2014-00725287-CU-BT-CXC (enclosed for your reference).

[5] *See Cianci*, 639 F.2d at 60; *St. Amant*, 390 U.S. at 732.

including Dr. Kolodny and Dr. Kessler, and to fairly and accurately include in any forthcoming segment the results of that vetting and investigation in order to fully disclose to viewers the nature of any such source's bias and financial motivation to comment negatively about Purdue or on the opioid crisis, and (3) to include Purdue's full, on-the-record statement (sent under separate cover) and to otherwise accurately and fairly represent Purdue's statement in any on-air segment or accompanying reporting (whether published online or elsewhere).

I look forward to your prompt response confirming receipt. I am available to discuss any questions you may have on these subjects.

Very truly yours,

Thomas A. Clare, P.C.

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CC: Sam Hornblower, Associate Producer, ***60 Minutes***, hornblowers@cbsnews.com

Enclosures