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By Email and Federal Express

Confidential
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Fabio Bertoni
General Counsel
The New Yorker
1 World Trade Center
New York, NY 10007
[redacted]

Re: *The Family That Built an Empire of Pain*

Dear Fabio:

We represent the family of Raymond Sackler ("the Sackler family").

On October 23, 2017, *The New Yorker* published an article by staff writer Patrick Radden Keefe titled, *The Family That Built An Empire of Pain* ("Article").[1] The Article is accompanied by a dramatized "illustration" featuring the "Sackler" name superimposed over crushed pills:

The Article contains numerous incorrect and damaging statements concerning the Sackler family. These statements serve as the foundation for the central theme of the Article: that the "Sackler dynasty's ruthless marketing of painkillers has generated billions of dollars — and millions of addicts" and that "...the Sacklers' firm, Purdue Pharma, bears the 'lion's share' of the blame for the opioid crisis."

I am writing you following the most recent conduct by *The New Yorker*. On Saturday, June 29, 2019, *The New Yorker* republished the error-ridden Article to a new audience when it tweeted the URL to more than eight million Twitter followers.[2] *The New Yorker* regularly engages in such republication with tweets directing new readers to the article.[3] Mr. Keefe also has repeated and republished statements from the Article in many different settings, including during a recent appearance on a widely-distributed podcast and in promotional materials for a book he is apparently writing based on the Article.[4]

The opioid crisis is a complex public health problem presenting important issues that must be resolved based on facts. The Sackler family has repeatedly expressed its commitment to helping identify and fund solutions that will save lives. That is why they recently agreed to help fund the new National Center for Addiction Studies and Treatment in Oklahoma, and why they have supported Purdue Pharma's efforts to prevent opioid abuse and diversion over nearly two decades. *The New Yorker* does its readers a disservice by ignoring essential facts and creating a biased narrative about what led to the current, urgent situation we face as a nation.

I. ***The New Yorker's* Article And Its More Recent Republications Are Driven By Pervasive Bias, And They Eschew Basic Requirements Of Reporting Ethics.**

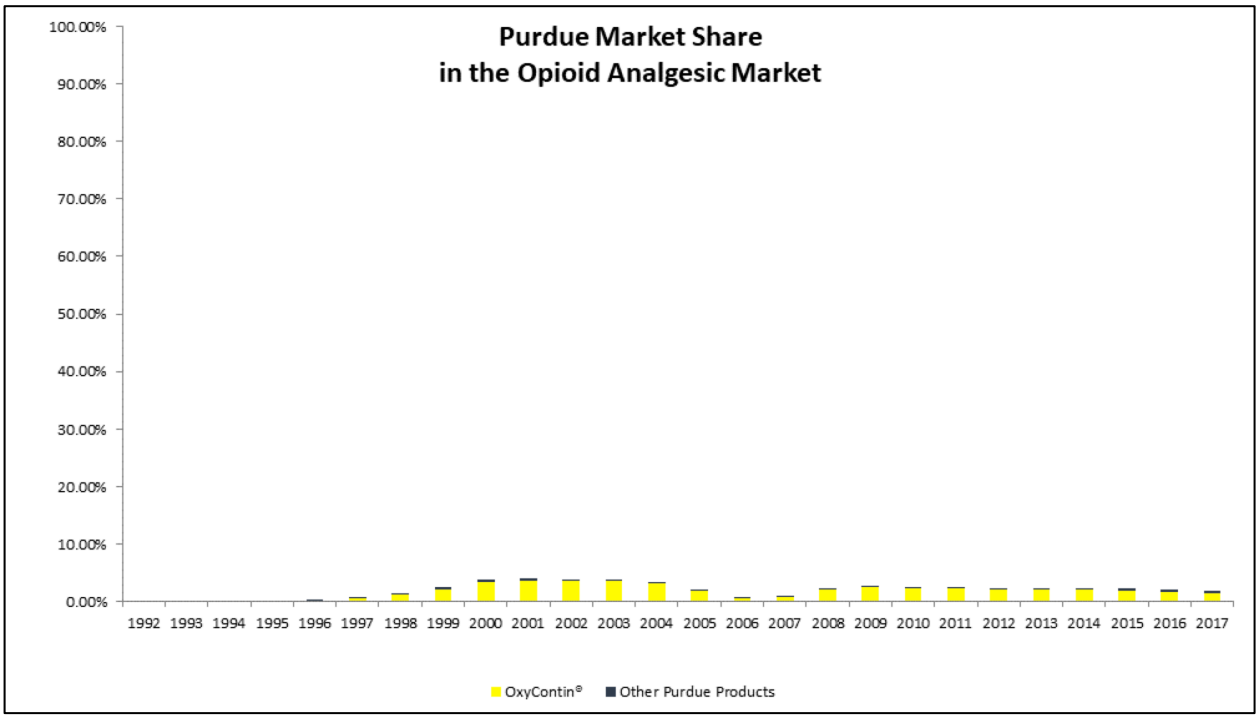
The entire premise of the Article — that the Sackler family deliberately and "ruthlessly" created addiction to painkillers for profit and that Purdue Pharma thereby bears the "'lion's share' of the blame for the opioid crisis"— is the product of biased reporting. The Article relies on biased and erroneous reports from individuals who benefit financially from republication of the Article (i.e., Mr. Keefe) or through litigation against Purdue (i.e, Dr. Kolodny), while at the same time it omits obviously critical facts and well-credentialed expert opinions that prove the falsity of *The New Yorker's* narrative.

Thus, the Article:

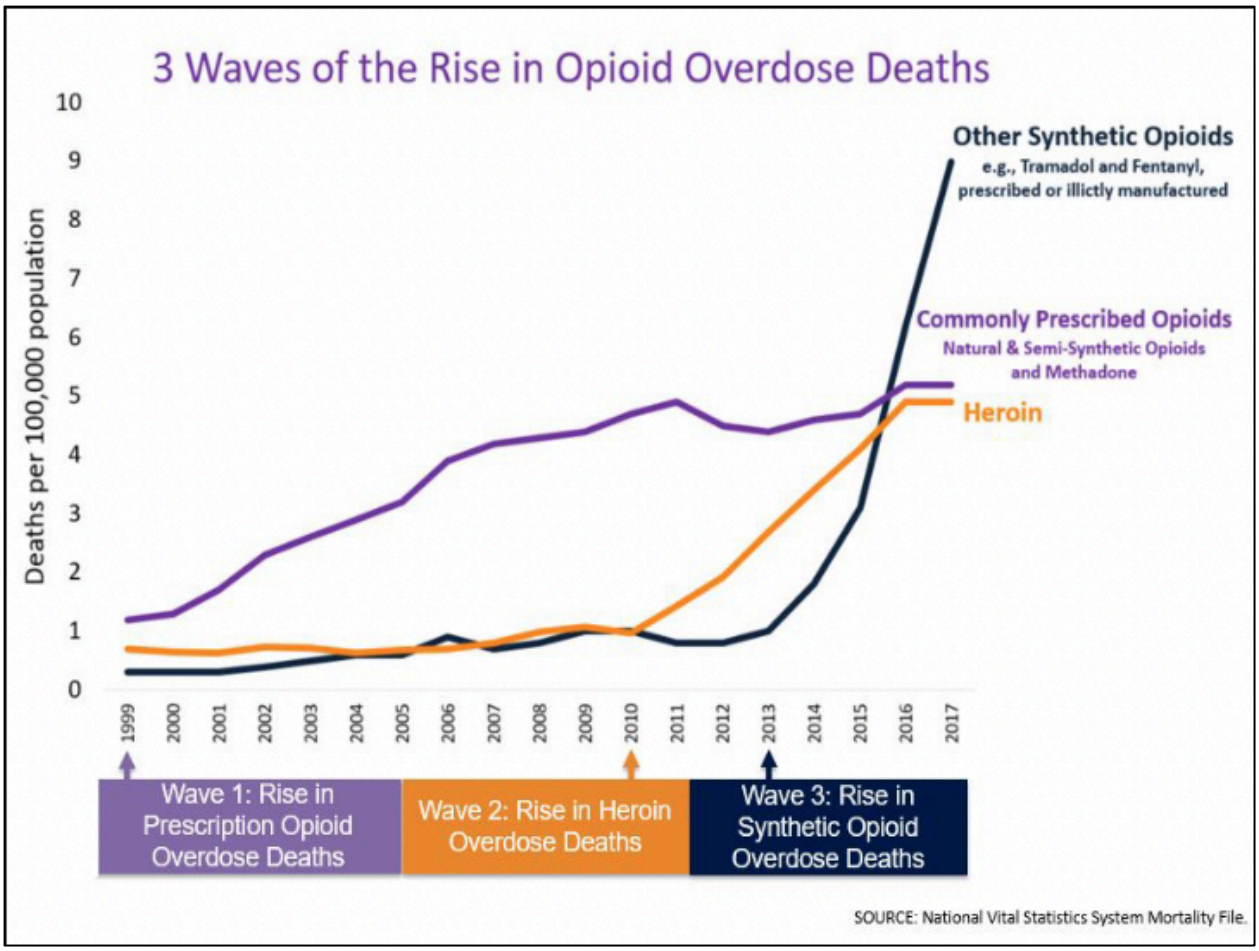
- Relies extensively on statements from Dr. Andrew Kolodny, but it is being republished today without disclosing the critical fact that Dr. Kolodny is now serving as a highly compensated witness and consultant to lawyers suing Purdue and the Sackler family.[5] As the code of ethics of the Society of Professional Journalists plainly states, *The New Yorker* is obligated to: "Identify sources clearly. The public is entitled to as much information as possible to judge the reliability and motivations of sources."[6] The republished Article does the opposite: it falsely touts Dr. Kolodny's experience, even as it leaves readers ignorant of his biases as a compensated advocate in litigation.

- Recites at length a 2004 "Citizens' Petition" by then-Connecticut Attorney General Richard Blumenthal, only to omit the critical fact that the FDA issued a detailed ***denial*** of that Petition. An equally detailed description of the FDA's response and denial would create the fair balance expected of a publication like *The New Yorker*, but the Article does not even disclose the bare minimum: that the applicable expert federal agency rejected it.

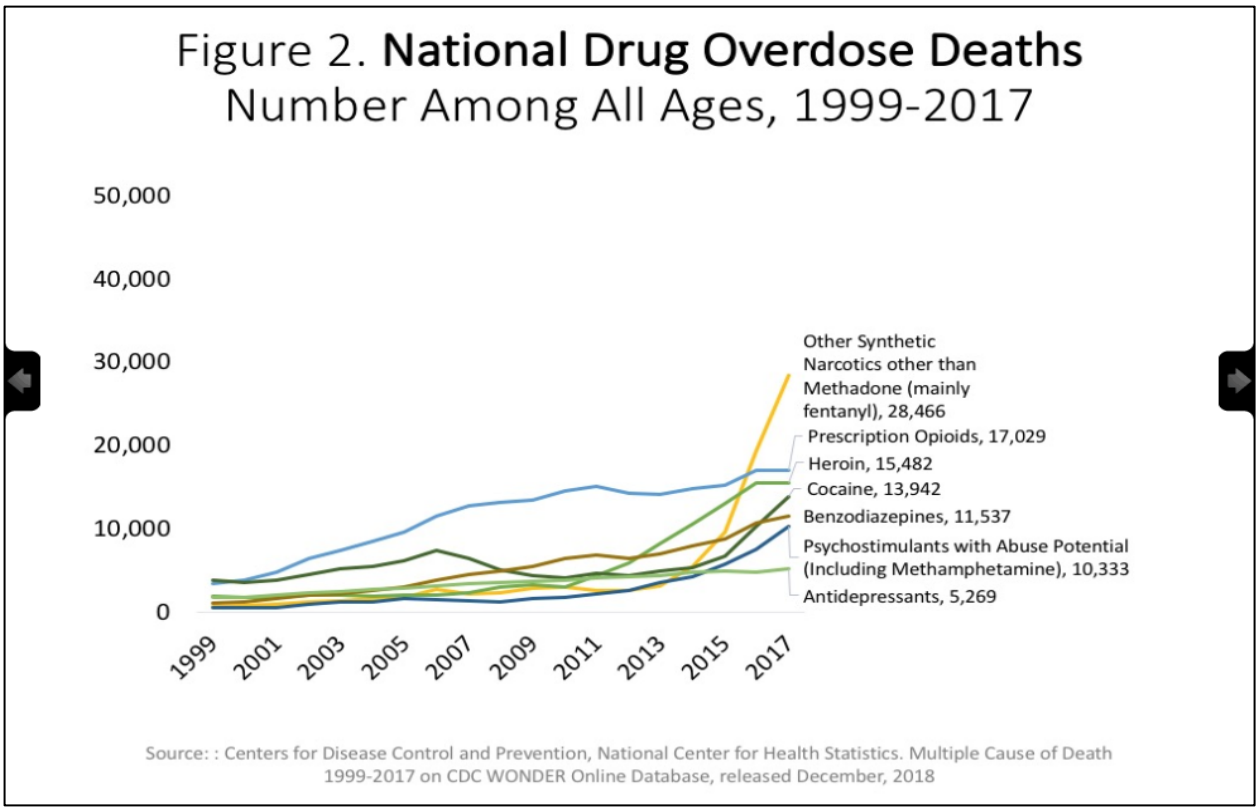
- Asserts that Purdue is responsible for the "lion's share" of the blame for the opioid crisis, but entirely omits and ignores the fact that OxyContin's market share of prescriptions written for opioids peaked in 2001 at approximatedly 4% and has been in overall decline ever since. It was approximately 1.5% of the market in 2017. This is in dramatic contrast to the remaining 98.5% of the market for prescription opioids.



- Relies upon decades-old events going back to the early days of OxyContin in service of blaming it for the opioid crisis of today, but omits the indisputable fact that the opioid crisis is currently being driven by the rapidly escalating use of street drugs, most prominently illicit fentanyl smuggled into the United States from China and Mexico. The federal government has emphasized this: "We needed to broaden our approach as this crisis continues to evolve. The epidemic is turning … to one that increasingly implicates the use of illicit drugs, including highly potent fentanyls."[7] Yet it is not even mentioned in the Article.



In fact, between 2013 and 2016, illicit fentanyl-related deaths have approximately doubled each year and have increased ***more than 1,000%*** from 2011-2016.[8] The largest average annual percent change during that same time period occurred among young adults – 100% per year for ages 25-34 and almost 94% for ages 15-24.[9] Furthermore, of the 47,600 opioid-related overdose deaths in 2017, 28,466 (59.8%) involved synthetic opioids, which is an increase of more than 45% from the 19,413 deaths from synthetic opioids (like fentanyl) in 2016 and a ten-fold increase in the last five years.[10] The chart below demonstrates how synthetic narcotics (primarily illicit fentanyl) are driving the current crisis and now account for the majority of overdose deaths – not prescription opioids, and certainly not OxyContin.



The pattern of bias reflected above is so obvious that it can only be intentional – repeatedly, the selective recitation of old evidence and biased sources is coupled with ommisions so egregious that they make both the premises and conclusions of the Article outright false. And the falsehoods are contrary to the very public health interests the Article purports to serve. Blaming the current and tragic fact of the ongoing opioid crisis on Purdue's admitted mis-branding of OxyContin that concluded prior to July 2001 (***eighteen years ago and sixteen years prior to the initial publication of the Article***) is not just factually incorrect, it intentionally misleads *The New Yorker's* readers as to what is actually fueling the opioid crisis today.

II. *The New Yorker* Article Is Replete With False And Misleading Statements About The Sackler Family.

In blaming the Sackler family for the opioid crisis, the Article presents myriad misleading statements and implications (and omits critical information) regarding the basic facts about (1) the FDA's approval process for OxyContin, including the FDA's carefully studied balance of OxyContin's efficacy and risks, (2) OxyContin's 12-hour dosing, (3) Purdue's marketing efforts, and (4) Purdue's ongoing actions to help combat the abuse and diversion of prescription opioids.

The relevant historical facts are simple:

- The FDA approved OxyContin following careful review of the need to help millions of Americans suffering from chronic pain – and not because of any pressure from or misrepresentations by Purdue about its benefits and risks;

- OxyContin's 12-hour dosing is based on what the FDA found to be "robust" clinical trial data that supports OxyContin's indicated use. The Article's statements to the contrary spurn the FDA's own determinations over the last 20-plus years;
- Purdue never marketed OxyContin to minors;
- Purdue did not ignore the abuse of OxyContin. With the Sackler family's support, Purdue has worked hard since 2001 to help combat abuse and diversion of OxyContin and other opioid medications.

1. <u>The FDA has approved OxyContin as a 12-hour dosing treatment since December 1995 because of what it has consistently determined to be significant benefits to patients suffering from chronic, long-term pain.</u>

The Article publishes the false claim that the FDA was duped by Purdue into approving OxyContin based on lies and misrepresentations. But it is the Article, not the FDA's approval, that is demonstrably false.

Prior to OxyContin's approval, there was a growing and widespread consensus among medical experts that prescription opioids were needed to help millions of Americans suffering from chronic pain.[11] Contemporaneous expert views at the time of OxyContin's approval show that prescription opioids were considered essential for treating chronic pain and also that their proper use under medical supervision was rarely associated with addiction.[12] For example, the second edition of Bonica's Management of Pain released in 1990 — widely regarded as the leading clinical reference in the field of pain medicine — reported that "the medical use of opioids is rarely associated with development of addiction."[13] Bonica's published a substantially identical view in 2001 (the same year OxyContin's label and prescribing information was updated with a Black Box warning): "Opioid addiction rarely occurs in patients receiving opioids for medical purposes."[14]

The contemporaneous views of other scientific and medical organizations, associations, and publications were likewise supportive of the FDA's approval of prescription opioids to treat chronic pain. These include the Agency for Health Care Policy and Research,[15] the National Institute on Drug Abuse,[16] and the American Medical Association,[17] as well as numerous other experts in the field.[18]

In fact, even before OxyContin's introduction, doctors were prescribing prescription opioids at a steadily increasing rate.[19] Furthermore, there were copious opioid therapies already on the market at the time of OxyContin's launch. These products had significant commercial success, were sold by large field forces of sales representatives, and included extended release products, such as Johnson & Johnson's Duragesic treatment. Duragesic was launched in the early 1990's – before OxyContin – and was a blockbuster.

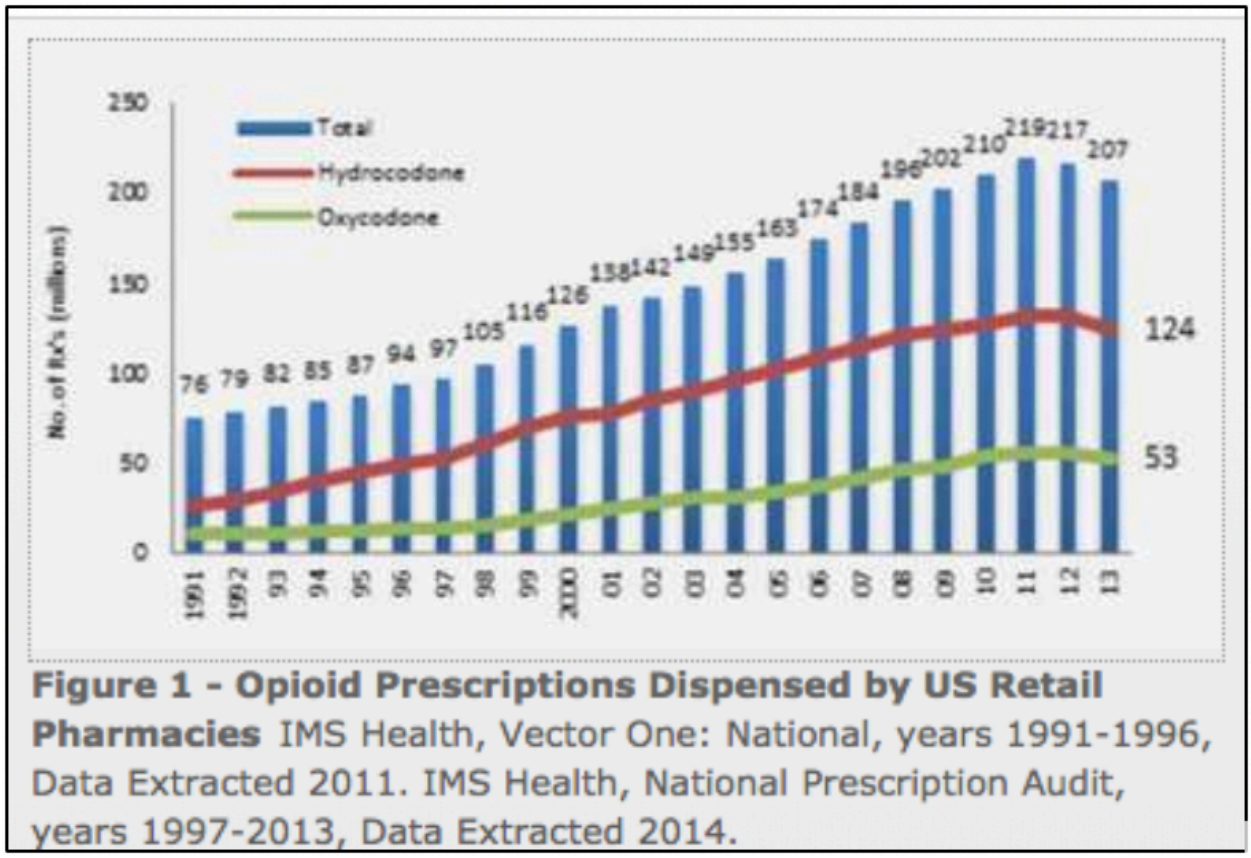


Figure 1 - Opioid Prescriptions Dispensed by US Retail Pharmacies IMS Health, Vector One: National, years 1991-1996, Data Extracted 2011. IMS Health, National Prescription Audit, years 1997-2013, Data Extracted 2014.

Abuse of these medicines also pre-dated OxyContin. In testimony before the U.S. Senate in 2002, Dr. H. Westley Clark, Director of the SAMHSA Center for Substance Abuse Treatment, stated that the "prescription opioid diversion and abuse problem . . . has been rising since the mid-1980's" and that "the number of new prescription opioid abusers has been rising steadily since well before the introduction of OxyContin."[20]

While all opioids have always been known to carry a risk of addiction and abuse, both Purdue and the FDA expected that any abuse of OxyContin would be similar to the experience with Purdue's long-acting morphine medication, MS Contin, which was introduced long before OxyContin. As *The New Yorker* and Mr. Keefe were aware well prior to publication of the Article, OxyContin had been tested in six controlled clinical trials over a period of seven years involving over 700 patients prior to the New Drug Application submission to the FDA. In those FDA-approved trials, less than 0.3% of patients exhibited any signs of abuse. At the same Senate hearing in 2002 where Dr. Clark testified, the FDA's Director of the Office of New Drugs, Dr. John K. Jenkins, described the circumstances under which OxyContin was approved:

> "At the time of approval, FDA determined that the benefits of OxyContin outweighed its risk when used to treat moderate to severe pain. At the time of approval, FDA also considered the abuse potential of OxyContin and determined that its abuse potential was similar to that of other Schedule II narcotics and we did not foresee

> the widespread abuse and misuse of OxyContin that has been reported in the past few years. Despite these troubling reports, however, FDA continues to believe that the benefits of OxyContin outweigh its risks when the drug is used according to the approved labeling."[21]

Thus, in 1995, the FDA carefully balanced the efficacy of OxyContin as a treatment for chronic pain with the known risks of addiction and abuse that are inherent in prescription opioids, and it determined that approval was warranted. Only the FDA has the role and authority to make such a public health decision. Since the FDA's approval of OxyContin, the OxyContin label and full prescribing information have continuously warned that there is a potential for abuse and addiction. OxyContin has always been labeled as a Schedule II medication,[22] and since 2001, every package insert for OxyContin has included a Black Box Warning. With Purdue's full support, as scientific understanding evolved and the unanticipated widespread abuse of OxyContin was confirmed, the label for OxyContin was updated more than once to reflect the risks of addiction.

The support for approval of prescription opioids, including OxyContin, continues today. The Department of Health and Human Services recently released its Final Report on Pain Management Best Practices (conducted in conjunction with the U.S. Department of Defense, the U.S. Department of Veterans Affairs, and the Office of National Drug Control Policy), which reports that 50 million adults in the United States experience chronic daily pain and that a balanced approach to treating that pain, including the continued prescribing and use of opioid pain medications, continues to be a necessary and critical element of such treatment.[23]

As to 12-hour dosing, the FDA's continuing approval of OxyContin rebuts the Article's false claim that OxyContin does not actually provide 12-hour relief and leads to abuse. The FDA's approval of OxyContin as a 12-hour drug is based on clinical trial data supporting 12-hour dosing. The FDA's Medical Officer Review of that data described it as "robust."[24] OxyContin's FDA-approved labeling specifically indicates that some patients may require "rescue medications" (i.e., smaller amounts of immediate-release medications). This is standard for managing chronic pain.

Since 1995, the labeling for OxyContin has noted that doses should be individualized due to variability between patients. Today, the Dosage and Administration section of the current labeling includes the statement, "Initiate the dosing regimen for each patient individually; taking into account the patient's severity of pain, patient response, prior analgesic treatment experience, and risk factors for addiction, abuse, and misuse." Furthermore, this section of the label states to "individually titrate OxyContin to a dose that provides adequate analgesia and minimizes adverse reactions. Continually reevaluate patients receiving OxyContin to assess the maintenance of pain control, signs and symptoms of opioid withdrawal, and adverse reactions, as well as monitoring for the development of addiction, abuse and misuse."

The Article simply ignores the FDA's response and rejection to the decade-old citizen petition on this very topic. The 2004 citizen petition submitted by then Connecticut Attorney General Blumenthal sought to revise OxyContin labeling to include additional warnings about the risk of taking the drug at more frequent intervals. In rejecting the petition, the Agency reinforced

the 12-hour labeling for OxyContin. As part of the response, the FDA noted that "while a 12-hour dosing schedule would be expected to be optimal for most patients, it is possible that some patients will require a more or less frequent dosing schedule to account for individual pharmacokinetic and pharmacodynamic differences." It ultimately concluded that the petition "failed to provide sufficient information to demonstrate an association between dosing OxyContin more frequently than q12h and an increased risk of developing side effects and potentially serious adverse reactions."[25]

Instead of acknowledging this decision, the Article recklessly and falsely states that "[t]he Sacklers disregarded [Blumenthal's] recommendation." The Article thereby provides false credibility to the the AG's rejected contention that "patients receiving OxyContin at intervals more frequent than [every 12 hours] are more at risk of developing side effects and potentially serious adverse reactions" or that "dosing OxyContin more frequently than [every 12 hours] may also increase the potential for diversion or abuse."[26] The Article's deliberate implication that the FDA's approval of OxyContin as a 12-hour dose medication was unwarranted or somehow fraudulently obtained is false and defamatory *per se*.

The FDA-approved label for OxyContin has been updated more than 30 times, including after allegations regarding 8-hour dosing had been raised publicly and by the Attorney General of Connecticut, and at no point has the FDA requested a change from 12-hour dosing. In fact, the label clearly states that "There are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours." And as the FDA-approved Medication Guide for OxyContin states, "Take your prescribed dose every 12 hours at the same time every day. Do not take more than your prescribed dose in 12 hours. If you miss a dose, take your next dose at your usual time." Because the FDA approved OxyContin to be administered to patients every 12 hours, Purdue is permitted to promote its medication to be dosed at that frequency. In contrast, less expensive generic versions of branded immediate-release opioids such as Percocet® and Vicodin® are approved to be dosed every 4 to 6 hours. A medication dosed every 12 hours is able to be taken less frequently – ***twice a day***.

In sum, the Article's efforts to demean the FDA's approval of OxyContin and thereby stigmatize and vilify OxyContin itself cannot be reconciled with the indisputable fact that:

- OxyContin has been approved by the FDA as a long-term-use pain medication for over 20 years, based on the FDA's independent determination that OxyContin is effective and that its medical benefits outweigh the risks associated with its use in accordance with the approved labelling.
- OxyContin remains an important, FDA-approved treatment option for many patients suffering from pain that requires daily, around-the-clock, long-term pain management. The indication in the current labelling reads: "OxyContin® (oxycodone HCl) is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."
- OxyContin's 12-hour dosing is FDA approved based upon sound clinical data.

2. Purdue *never* marketed or sought to market OxyContin to minors.

The Article alleges that:

> "But Purdue, facing a shrinking market and rising opprobrium, has not given up the search for new users. In August, 2015, over objections from critics, the company received F.D.A. approval to market OxyContin to children as young as eleven."

This statement that Purdue obtained pediatric approval in an attempt to grow OxyContin's market is demonstrably false. The Pediatric Research Equity Act ***requires*** that pharmaceutical companies conduct pediatric studies to ensure that prescribers have adequate information to treat young patient populations in a safe and effective manner.[27] Purdue did not voluntarily undertake these studies for OxyContin and did so ***only*** to comply with the FDA's mandate. The FDA itself has made this clear:

> "To give health care providers more information on the safe use of drugs in pediatric patients, FDA can use its authority to ask manufacturers of drug products to conduct studies to obtain pediatric-specific information. We requested the manufacturer of the pain management drug OxyContin perform studies evaluating safety and other important information about oxycodone and OxyContin when used in pediatric patients. These studies supported a new pediatric indication for OxyContin in patients 11 to 16 years old, and provided prescribers with helpful information about the use of OxyContin in pediatric patients."[28]

The studies were conducted at great expense and provided significant medical understanding of pain management for pediatric patients. But they ***never*** were undertaken to expand the market for OxyContin, as the article falsely suggests. At no time did Purdue ever promote OxyContin — or any other opioid — for any use by any children. Purdue also has publicly pledged that, even if it were granted such permission by the FDA without request, Purdue would not promote this product for pediatric use.[29] *The New Yorker* and Mr. Keefe were provided this pledge prior to publication of the Article, and therefore well aware of it before it recklessly included these false and defamatory *per se* statements in the Article.

3. Purdue, with the Sackler family's support, has worked to be an industry leader in helping combat abuse and diversion of opioids.

The Article falsely suggests that Purdue did nothing when it learned that OxyContin was being abused at far higher than expected rates, specifically claiming that the company "refused to concede that it posed risks." Again, this is simply not true.

In fact, Purdue has for years taken affirmative steps to help combat abuse and diversion of OxyContin and other opioid medications. This started with supporting local efforts to help combat diversion in 2000 and, in 2001, was expanded to include outreach to federal agencies to collaborate on local and national responses.

- In 2000, through communications with the US Attorney in Maine and subsequent reports in other states, Purdue became aware of local abuse and diversion of OxyContin in certain parts of the country. Purdue promptly supported local authorities in addressing the problem.
- In early 2001, Purdue reached out to the FDA and the DEA to provide information, take direction, and collaborate on solutions as abuse, diversion, and addiction to prescription opioids (including OxyContin specifically) became a national issue
- By July 2001, Purdue worked with the FDA to update the OxyContin label and include a Black Box warning further emphasizing the risks of abuse. Purdue also went on to write 'Dear Doctor' letters to inform physicians about the new label, update all of its marketing materials, and retrain its salesforce.

In addition, Purdue launched totally voluntary initiatives directed against abuse and diversion. Over the succeeding years, Purdue has worked to be a leader in the pharmaceutical industry by introducing more than 65 anti-abuse initiatives costing over $1.5 billion.

In what became its most ambitious and impactful undertaking, Purdue (with the Sackler family's support) developed an abuse-deterrent version of OxyContin, which was approved by the FDA in 2010. The new tablet was formulated with the intent to make it more difficult to crush than the original formulation. In 2013, the FDA found that the new formulation has physical and chemical properties that are expected to make abuse by injection more difficult and to reduce intranasal abuse. Since then, both the FDA and NIDA have stated that using abuse-deterrent opioid formulations are important to addressing the opioid crisis.[30]

Other proactive efforts by Purdue and supported by the Sackler family include:

- Supporting the development and implementation of Prescription Drug Monitoring Programs, which are now used in 49 states to monitor and deter doctor-shopping and to prevent prescription duplication;
- Developing the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS) system in 2001 to detect and study abuse, misuse and diversion on a nationwide basis. Purdue transferred ownership of RADARS in 2006 to an independent, not-for-profit third party so that pharmaceutical companies and government agencies could more readily access valuable data;
- Developing a bottle-tracking program to address theft of medication from pharmacies, with more than 500 devices employed in more than 30 states, leading to over 190 arrests and clearance of more than 200 robberies; and

- Developing nalmefene, a strong opioid antidote that may be particularly useful in treating fentanyl overdoses where existing treatments might fail, without making any profit on this initiative.[31]

These important facts were deliberately omitted from the Article because they did not support Mr. Keefe's predetermined storyline.

III. Mr. Keefe And *The New Yorker* Have Repeatedly Republished These False And Defamatory Statements, Including Through Mr. Keefe's Efforts To Promote A Forthcoming Book Modeled On *The New Yorker* Article.

In addition to *The New Yorker's* own republication of the false and defamatory Article by posting it regularly on Twitter, Mr. Keefe is seeking to cash in on his false and misleading reporting by using the Article to aggressively promote a forthcoming book. As part of this campaign, Mr. Keefe appeared on the April 18, 2019 podcast hosted by Chris Hayes called, "Why Is This Happening?" ("Keefe Podcast"). Mr. Keefe restated and republished many of the same demonstrably false and defamatory statements that appear in the Article and then plugged the "new book on opioids and the Sackler Family" he is writing.[32] *The New Yorker* is on notice that, should Mr. Keefe again republish and further disseminate any of the demonstrably false and defamatory statements noted in this letter, *The New Yorker* and Mr. Keefe will run significant risks of defamation liability for the foreseeable republication of its prior false and defamatory statements.[33]

* * *

As set forth above, *The New Yorker's* publication of a false narrative, its reliance on provably biased sources, its misleading presentation of material to create false implications, and its willful failure to inform readers of publicly-available facts that directly contradict the Article's basic premises are persuasive evidence of a reckless disregard for the truth.[34] *The New Yorker's* irresponsible decisions to continue to republish and recirculate the Article continue to cause harm to the Sackler family.

We trust that you appreciate the seriousness of these issues. We expect that *The New Yorker* will take prompt action to correct the inaccurate Article that remains on its website and continues to mislead readers, and that *The New Yorker* will cease its efforts to republish those false claims to new audiences. We further expect that Mr. Keefe will not repeat these false assertions in any future publications or statements, whether that be in his forthcoming book or elsewhere.

Until this matter is resolved, Mr. Keefe, *The New Yorker*, and any editors, employees, agents, and/or representatives who were involved in reporting or promoting coverage about Purdue or the Sackler family — or in the development, marketing, or any other work performed to assist with the republication of that same reporting in any other medium (including but not limited to Mr. Keefe's planned book on the same subject) — preserve and retain all documents, data, and electronically stored information relating in any way to the Article, Purdue, or the Sackler family. These items should be preserved regardless of the medium, format, or device on which they are stored or hosted, and regardless of whether they appear in documents, drafts, notes, emails, text messages, voicemail

messages, social media posts, or in any other form. Failure to adhere to this request could subject *The New Yorker* to significant penalties, including claims and sanctions for spoliation.

This letter is not a full recitation of the rights and remedies of the Sackler family, which are expressly reserved. Please confirm receipt of this letter.

We look forward to your prompt response.

Very truly yours,

Thomas A. Clare, P.C.

Thomas A. Clare, P.C.

CC: Patrick Radden Keefe, Staff Writer, *The New Yorker*, [redacted]

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[1] *See* https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain (the Article was likewise published in the October 30, 2017 issue of the hardcopy magazine).

[2] *See* https://twitter.com/NewYorker/status/1145045838781198337.

[3] *See* https://twitter.com/NewYorker/status/1128708947370762244.

[4] *See* April 18, 2019 "Bonus: The First Family of Opioids with Patrick Radden Keefe," Why Is This Happening? With Chris Hayes (herein "Keefe Podcast"), available at https://podcasts.apple.com/us/podcast/why-is-this-happening-with-chris-hayes/id1382983397?i=1000435211479.

[5] *See* Sept. 8, 2008 FDA Response to Office of the Attorney General State of Connecticut, Dkt. No. FDA-2004-P-0294 (available at https://www.regulations.gov/contentStreamer?documentId=FDA-2004-P-0294-0051&attachmentNumber=1&disposition=attachment&contentType=pdf).

[6] The Society of Professional Journalists Code of Ethics (available at https://www.spj.org/pdf/spj-code-of-ethics.pdf).

[7] *See* Statement by FDA Commissioner Scott Gottlieb, M.D., on the agency's ongoing work to forcefully address the opioid crisis, August 29, 2018, 3 (emphasis added); *see also id.* at 4 ("But the public health impact from these reductions in prescription opioid use could be offset by the rising availability of illicit opioids, and principally fentanyl, that's coming into America."); see also Statement by FDA Commissioner Scott Gottlieb, M.D., on balancing access to appropriate treatment for patients with chronic and end-of-life pain with need to take steps to stem misuse and abuse of opioids, July 9, 2018 ("We have evidence that we'll release soon showing that based on a measure of morphine equivalents, the flow of illicit opioids, particularly fentanyl, dwarfs the entire market for prescription drugs.").

[8] *See* National Vital Statistics Report, "Drug Overdose Deaths Involving Fentanyl, 2011-2016, Vol. 68, No. 3, Mar. 21, 2019, available at https://www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68_03-508.pdf. In 2011, deaths from fentanyl totaled 1,663; in 2016, they totaled 18,335.

[9] *See id.*

[10] *See* Scholl L, Seth P, Kariisa M, Wilson N, Baldwin G. Drug and Opioid-Involved Overdose Deaths — United States, 2013–2017. MMWR Morb Mortal Wkly Rep 2019;67:1419–1427. DOI: http://dx.doi.org/10.15585/mmwr.mm675152e1, available at https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s_cid=mm675152e1_w.

[11] *See* D. Friedman, Director of Preclinical Research, National Institute on Drug Abuse (NIDA), *Perspectives on the Medical Use of Drugs of Abuse*, J. Pain and Symptom Management, Vol. 5 No. 1, Feb. 1990; Acute Pain Management Guideline, Acute Pain Management: Operative or Medical Procedures and Trauma. Clinical Practice Guideline. AHCPR Pub. No.

92-0032 (Rockville. MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services. Feb. 1992) at iii and 1; American Medical Association, Council on Science and Public Health, Report 4 of the Council on Scientific Affairs (A-95), June 1995.

[12] *See, e.g.*, Pain Management, Controlled Substances, and State Medical Board Policy: A Decade of Change, Journal of Pain and Symptom Management (available at http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.387.1608&rep=rep1&type=pdf); M. Phillips, Donald, JCAHO Pain Management Standards Are Unveiled. JAMA (2000). 284(4): 428-29, 10.1001/jama.284.4.423b (available at https://jamanetwork.com/journals/jama/article-abstract/2552036); Bonica's Management of Pain, 2nd edition: Edited by Bonica JJ, Philadelphia, Lea & Febiger 1990, pg. 180, 1654, 1672; July 2001 National Institute on Drug Abuse Research Report (NIH Publication Number 01-4881).

[13] Bonica's Management of Pain, 2nd edition, pg. 1654.

[14] Bonica's Management of Pain, Third Edition, edited by Loeser, John D., et al., Lippincott Williams and Wilkins (June 2001), pg. 1695.

[15] *See* Acute Pain Management Guideline, Acute Pain Management: Operative or Medical Procedures and Trauma. Clinical Practice Guideline. AHCPR Pub. No. 92-0032 (Rockville. MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services. Feb. 1992) at iii and 1.

[16] *See* D. Friedman, Director of Preclinical Research, National Institute on Drug Abuse (NIDA), *Perspectives on the Medical Use of Drugs of Abuse*, J. Pain and Symptom Management, Vol. 5 No. 1, Feb. 1990 ("The treatment of severe pain requires the use of potent opioid analgesic medications. Many patients with opioid sensitive pain are being undermedicated. This results in increased morbidity and needless suffering.").

[17] *See* American Medical Association, Council on Science and Public Health, Report 4 of the Council on Scientific Affairs (A-95), June 1995 ("Concern about addiction should never result in undermedication for acute pain. The occurrence of addictive behaviors after chronic pain therapy is also rare. Fear of inducing addiction should never be the basis for withholding opioid agents from a patient without a history of substance abuse. Patients with a history of opioid abuse present a special problem, but opioids can be used safely and effectively to control pain in such individuals and should be used when indicated to control pain.").

[18] *See, e.g.*, D. Brookoff, Abuse Potential of Various Opioid Medications, J. Gen. Intern. Med., 8:688-690 (1993) ("Opioid mediations are essential for the adequate treatment for many types of severe pain" and "Undertreatment for pain not only accounts for significant morbidity but also results in lengthened hospital stays and increased health care costs. Recognition of this fact has led to a situation in which certain government agencies are restricting the prescription of opioid analgesics while others are encouraging their expanded use. Opioid mediations are essential for the adequate treatment for many types of severe pain."); Charles S. Cleeland et al., Pain and Its Treatment in Outpatients with Metastatic Cancer, 330 New England J. Medicine 592 (1994) (noting that "Despite published guidelines for pain management, many patients with cancer have considerable pain and receive inadequate analgesia," and that "When asked which medications [physicians] preferred to use to treat prolonged moderate-to-sever cancer pain, 38 percent did not choose a morphine-class opioid first. This conservative approach to pain management is liable to be at least partially responsible for the large percentage of patients with inadequate analgesic orders.").

[19] *See e.g.*, "America's Addiction to Opioids: Heroin and Prescription Drug Abuse, May 14, 2014 Presentation to the Senate Caucus on International Narcotics Control, Nora D. Volkow, M.D., The National Institute on Drug Abuse.

[20] *See* Oxycontin: Balancing Risks & Benefits: Hearing on Examining the Effects of the Painkiller Oxycontin, Focusing on Fed., State & Local Efforts to Decrease Abuse & Misuse of this Prod. While Assuring Availability for Patients Who Suffer Daily from Chronic Moderate to Severe Pain Before the Comm. on Health, Educ., Labor & Pensions, 107th Cong. (2002) (available at https://www.govinfo.gov/content/pkg/CHRG-107shrg77770/html/CHRG-107shrg77770.htm).

[21] *See id.*

[22] *See* DEA, Diversion Control Division, Controlled Substancew Schedules (available at https://www.deadiversion.usdoj.gov/schedules/ ("Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence.")).

[23] *See* U.S. Department of Health and Human Services (2019, May). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. Retrieved from U. S. Department of Health and Human Services website: https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html.

[24] FDA, Medical Officer Review (MOR), *Integrated Summary of Safety: Oxycodone Controlled Release*, completed May 19, 1995 ("The NDA is unusually robust for such a drug as it contains a large number (6) of controlled clinical trials, most of which included population pharmacokinetic measures, 'a-priori' population pharmacodynamic measures. and clinical efficacy outcomes as well as conventional adverse effect measures.").

[25] *See* Sept. 8, 2008 FDA Response to Office of the Attorney General State of Connecticut, Dkt. No. FDA-2004-P-0294 (available at https://www.regulations.gov/contentStreamer?documentId=FDA-2004-P-0294-0051&attachmentNumber=1&disposition=attachment&contentType=pdf).

[26] *See id*.

[27] *See* FDA, Pediatric Research Equity Act (PREA) (available at https://www.fda.gov/drugs/development-resources/pediatric-research-equity-act-prea); *see also* S.650 – Pediatric Research Equity Act of 2003, 108th Congress (2003-2004) (Summary available at https://www.congress.gov/bill/108th-congress/senate-bill/650).

[28] FDA, CDER Conversation: Pediatric pain management options (available at https://www.fda.gov/drugs/news-events-human-drugs/cder-conversation-pediatric-pain-management-options).

[29] *See* August 24, 2015 letter from Gail Cawkwell, Chief Medical Officer of Purdue, to the Honorable Joe Manchin, Senator, United States Senate.

[30] *See, e.g.*, Statement from FDA Commissioner Scott Gottlieb, M.D., on agency's efforts to encourage the development of and broaden access to generic versions of opioid analgesics that are formulated to deter abuse, July 20, 2018 ("Opioids with abuse-deterrent formulations . . . make it harder for people to manipulate the opioid product so they can't be easily abused to deliver an immediate 'high.' . . . We believe that transitioning from the current market, dominated by conventional opioid analgesics, to one where most opioids have abuse-deterrent properties may have the potential to further reduce misuse and abuse."); Testimony by Dr. Nora Volkow, Director of the National Institute of Drug Abuse, Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives, October 25, 2017 ("FDA's emphasis on assessing the full public health effects of opioids is reflected in the Agency's ongoing work to support the development of forms of prescription opioids that deter abuse. The Agency strongly supports a transition from the current market dominated by conventional opioids to one in which the majority of opioids have meaningful abusedeterrent properties.").

[31] For a more complete list of initiatives, visit https://www.purdueopioidinfo.com/app/uploads/2019/05/actions-timeline.pdf.

[32] Keefe Podcast.

[33] *See Accadia Site Contracting, Inc. v. Skurka*, 129 A.D.3d 1453, 1454, 10 N.Y.S.3d 772, 774 (N.Y. App. Div. 2015) (original publisher and false and defamatory statements is "responsible for any damaged cause by the publication" of that statement if it was foreseeable that it would be republished); *Campo v. Paar*, 18 A.D.2d 364, 368, 239 N.Y.S.2d 494, 498 (1963).

[34] *See Curtis Pub. Co. v. Butts*, 388 U.S. 130 (1967) (departing from "the standards of investigation and reporting ordinarily adhered to by responsible publishers" is evidence of actual malice); *Eramo v. Rolling Stone LLC*, 209 F. Supp. 3d 862, 871-74 (W.D. Va. 2016).