Andrew Kolodny, MD (Corresponding Author)
Medical Director, Opioid Policy Research Collaborative, Brandeis University
akolodny@bradeis.edu

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Dr. Sharon K. Inouye, MD, MPH
Editor, JAMA Internal Medicine
American Medical Association
330 N. Wabash Avenue, Suite 39300
Chicago, IL 60611

Re: Roth, SH et al. "Around-the-clock, controlled-release oxycodone therapy for osteoarthritis-related pain: placebo-controlled trial and long-term evaluation." *Archives of Internal Medicine* 160.6 (2000): 853-860.

Dear Dr. Inouye,

We, the undersigned clinicians and researchers with expertise in anesthesiology, psychiatry, addiction medicine, primary care, internal medicine, rheumatology, clinical pharmacology, medical toxicology, public health, and related fields, respectfully request that *JAMA Internal Medicine* retract the article "Around-the-Clock, Controlled-Release Oxycodone Therapy for Osteoarthritis-Related Pain" by Roth et al.

We note that one of the undersigned, Dr. Roy Fleischmann, was a co-author of the original Roth et al. article. His support for this request underscores the seriousness of the omissions described below.

Documents made public during the federal criminal proceedings against Purdue Pharma (see attached) show that Purdue, the study sponsor, omitted material evidence and possessed information demonstrating that key statements and conclusions in the article were unreliable because they were based on an incomplete and materially misleading presentation of the available evidence.[1] Among the article's most influential conclusions was its claim that controlled-release oxycodone could be discontinued abruptly at doses up to 60 mg/day (approximately 90 morphine milligram equivalents/day) without causing withdrawal. Yet Purdue's own analyses identified study participants with symptoms

[1] United States v. The Purdue Frederick Co., Inc. Agreed Statement of Facts. Attachment B to Plea Agreement. United States District Court for the Western District of Virginia; 2007; Public Statement by the U.S. Attorney's Office for the Western District of Virginia, *The Purdue Frederick Company, Inc. and Top Executives Plead Guilty to Misbranding OxyContin, Will Pay Over $600 Million* (May 10, 2007). See Page 4-5.

consistent with opioid withdrawal, and a subsequent internal review by Purdue identified additional withdrawal events that were never disclosed.

Rather than correcting the scientific record, Purdue withheld these findings because it feared they might "add to the current negative press."[2] The subsequently disclosed documents show that these findings were not disclosed to readers despite being known to the study sponsor at the time of publication.

The Roth et al. article states:

> "Withdrawal syndrome was not reported as an adverse event for any patient during scheduled respites."

It further concludes:

> "Withdrawal syndrome was not reported as an adverse event during scheduled respites, indicating that CR oxycodone at doses below 60 mg/day can be discontinued without tapering the dose if the patient's condition so warrants."

The first attachment is a statement issued by the United States Department of Justice (DOJ) on May 10, 2007, detailing Purdue Pharma's felony guilty plea. Please see the highlighted text on pages 4 and 5, which describes the following:

1) One year before the publication of Roth et al. (The Osteoarthritis Study), Purdue received an analysis indicating that eight patients in the study "had symptoms recorded that may possibly have been related to opioid withdrawal," and stated that "[a]s expected, some patients did become physically dependent on OxyContin tablets, but this is not expected to be a clinical problem so long as abrupt withdrawal of drug is avoided."

2) At the time of publication, Purdue's Medical Services department was receiving many calls ("at least 3 calls in the last 2 days") from patients who were unable to discontinue OxyContin without experiencing withdrawal symptoms.

3) Within one year of publication, Purdue received a review of the withdrawal data presented in the Roth et al. paper that listed 11 study patients who reported adverse experiences due to possible withdrawal symptoms during respite periods, stating that "upon review of all comments for all enrolled patients, it was noted that multiple had comments which directly stated or implied that an adverse experience was due to possible withdrawal symptoms." This information was withheld by Purdue because of concerns that it might "add to the current negative press."

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[2] Public Statement by the U.S. Attorney's Office for the Western District of Virginia, *The Purdue Frederick Company, Inc. and Top Executives Plead Guilty to Misbranding OxyContin, Will Pay Over $600 Million* (May 10, 2007). See item 2C on Page 5 of U.S.

Editors, peer reviewers and readers of the Roth publication were entitled to assume that the sponsor-authors had reported all relevant safety information generated during the study. Yet documents subsequently made public show that these findings were withheld from readers despite being known to the study sponsor at the time of publication. Simply put, this made OxyContin seem safer than it actually is.

The article's recommendation that patients receiving up to 60 mg/day of controlled-release oxycodone (approximately 90 morphine milligram equivalents/day) can discontinue treatment without tapering is inconsistent with guidance from the United States Centers for Disease Control. If followed in clinical practice, this recommendation would predictably result in severe opioid withdrawal and substantial patient harm.

Prompt action by the journal is especially important because the Roth et al. article continues to influence the medical literature and clinical practice. It has been cited hundreds of times and, notably, appears in at least two clinical practice guidelines.[3] The continued citation of a publication containing unreliable conclusions—including in contemporary documents intended to guide patient care—underscores the importance of correcting the scientific record.

Both the International Committee of Medical Journal Editors and the Committee on Publication Ethics have articulated when retraction is warranted. ICMJE guidance provides that when an investigation confirms scientific misconduct or otherwise compromises the integrity of a published article, the editor should publish a retraction.[4] COPE's retraction guidelines likewise provide that retraction may be warranted where there is clear evidence of major errors, irregularities, or misrepresentation that compromise the reliability of the published findings.[5] This case satisfies these standards.

For these reasons, we respectfully request that *JAMA Internal Medicine* retract the Roth et al. article or, if the journal concludes that retraction is not warranted, publish a formal correction informing readers that the article's conclusions regarding opioid withdrawal and the safety of abrupt discontinuation are not supported by the complete evidence.

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[3] Altmetric. *Around-the-Clock, Controlled-Release Oxycodone Therapy for Osteoarthritis-Related Pain: Altmetric Details.* JAMA Network Altmetric. Accessed June 30, 2026. https://jamanetwork.altmetric.com/details/16031269

[4] International Committee of Medical Journal Editors. *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals: Scientific Misconduct, Expressions of Concern, and Retraction.* https://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/scientific-misconduct-expressions-of-concern-and-retraction.html

[5] Committee on Publication Ethics (COPE) Council. *COPE Guidelines: Retraction Guidelines*, Version 3 (August 2025). https://doi.org/10.24318/cope.2019.1.4

Sincerely,

G. Caleb Alexander, MD, MS
Professor of Epidemiology and Medicine
Johns Hopkins Bloomberg School of Public Health

Barry Bockow MD FACP
Clinical Associate Professor of Medicine
University of Washington

Roy Fleischmann, MD MACR
Co-author, Roth et al. (2000)
Co-Medical Director Metroplex Clinical Research Center
Adjunct Professor of Medicine
University of Texas Southwestern Medical Center

Ravi Gupta, MD, MSHP
Assistant Professor of Medicine
Johns Hopkins University School of Medicine

David N. Juurlink MD, PhD, FRCPC
Professor of Medicine, Pediatrics,
& Health Policy, Management and Evaluation
University of Toronto

Andrew Kolodny, MD (Corresponding Author)
Medical Director, Opioid Policy Research Collaborative, Brandeis University
President, Physicians for Responsible Opioid Prescribing

Anna Lembke, MD
Professor, Psychiatry and Addiction Medicine
Stanford University

Mark D. Sullivan, MD, PhD
Professor, Psychiatry and Behavioral Sciences
Adjunct Professor, Anesthesiology and Pain Medicine,
Bioethics and Humanities
University of Washington