Public Comments for ICR 202412-0920-006

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Comments Received :

1. This public comment responds to the Proposed Data Collection Submitted for Public Comment and Recommendations" notice on October 1, 2024 and extended by 30 days on December 20, 2024.

2. I am a nationally recognized subject matter expert on the intersection of US public health policy, regulation of prescription opioid analgesics and regulation of clinicians who prescribe them in managing their patients' pain. I write on behalf of millions of US patients and clinicians whose lives and clinical practices have been wrecked by the US CDC 2016 and 2022 guidelines on prescription of opioid analgesics. You may easily verify my qualifications to comment by the simple expedient of doing a citation search on Google Scholar, or a review of correspondence records archived by the US CDC Office of the Executive Secretary.

The CDC announcement as published addresses several requests as noted below with my comments: "The Office of Management and Budget is particularly interested in comments that:"

"(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;"

My comment: the proposed collection of information is substantially misdirected and completely lacks utility. It is immediately apparent that the questionnaire incorrectly assumes the scientific validity of the 2022 CDD guidelines on prescription of opioid analgesics to adults with severe chronic pain. Nothing could be further from the truth. The CDC guidelines are egregiously in error on fundamental science; moreover, the authors and approving officials of this misguided document could not have been unaware of their errors prior to publication. These errors include (among many others):

i. Gross over-emphasis on risks of opioid prescribing while deliberately and inappropriately ignoring the benefits thereof;

ii. Continuing over-emphasis on tapering of legacy patients to opioid dose levels that are inadequate to control pain, regardless of a well-established clinical record of patient health crises and medical collapses associated with such tapering.

iii. Deliberate refusal to address effects of genetic polymorphism in mediation of opioid metabolism. The guidelines ignore at least a 12-to-1 range in minimum effective dose levels and sensitivity to side effects between individuals. Failure to address this wide range has resulted in the confounding of almost the entire clinical trials literature on safety and effectiveness of opioid therapy.

iv. Assertion of a threshold of diminishing returns in opioid benefits at 90 Morphine Milligram Equivalent Dose, without reference to any source of such an assertion in the medical literature. Likewise, organization of the guidelines around MMED as a metric is completely inappropriate, given that the metric itself is a medical mythology unsupported by large scale trials and lacking scientific validity.

v. Recommendations that "non-opioid" therapies are preferable to opioid therapy despite a complete lack of published clinical trials demonstrating any such outcomes. vi. Deeply flawed methodology in key studies conducted by the Agency for Healthcare Research and Quality and referenced in support of equally flawed conclusions of the CDC Guidelines.

[Comments completed in the attached document]