The Global Movement to Preserve Access to Ketamine and Raise Awareness of the Global Disparity in Access to Controlled Medicines

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For the past 3 years, the medical community has rallied to oppose attempts to place ketamine, a medicine that is indispensable for anesthesia and pain relief in many developing countries, under restrictive international controls. In many parts of the world, ketamine is a lifeline for patients who need surgery for obstetric emergencies, traumatic injuries, and many other medical conditions. Published data from some surgical programs shows that close to half of all surgeries may be performed using a ketamine anesthetic, allowing patients to breathe spontaneously while receiving a general anesthetic without the need for endotracheal intubation. Reducing access to ketamine would be disastrous for access to safe surgery, and the World Health Organization has rightly warned that doing so would create a public health crisis in countries where no affordable alternatives exist.

Ketamine is but the latest collateral damage of the failed war on drugs. Responding to domestic concerns of misuse, the Chinese government, in 2015, notified the Commission on Narcotic Drugs that it intended to propose placing ketamine under Schedule I of the 1971 *Convention on Psychotropic Substances*. Schedule I requires the strictest of controls to be placed on substances – including medicines – listed within it, and is reserved for substances for which there is little to no medical or therapeutic value. This is clearly inappropriate for a medicine considered essential by the World Health Organization that millions, possibly billions, of people depend on for access to safe surgery. In response to the international pressure from medical, veterinary (ketamine is widely used in veterinary anesthesia), and human rights organizations, China amended its scheduling proposal to Schedule IV, which represents the least strict of the schedules.

The fundamental problem relates to the barriers imposed by national and international controls that are placed on essential medicines such as morphine and pethidine. Any level of scheduling, even Schedule IV (the least strict under the 1971 Convention), poses a serious threat to access due to increased and cumbersome regulatory, administrative, and import/export procedures. Furthermore, while Schedule IV may be less strict, this assumes that countries' legislation contains an equal degree of nuance, which too often is not the case: many countries have only a small number of schedules, thus the difference between the international Schedule I and Schedule IV within countries implementing these controls may be non-existent, placing needed medicines behind cumbersome and unnecessary regulatory regimes. At the national level, where these procedures are largely implemented, these processes can quickly become serious impediments to patients and providers accessing the medicines that they need. When combined with poor provider knowledge of effective pain management, fears of prosecution for prescribing controlled substances, or unrealistic fears of addiction, too often the result is that patients are unable to access the medicines that they need to effectively manage their pain.

Earlier this year, Human Rights Watch documented these barriers in Armenia, where only patients with a cancer diagnosis can have access to strong opioids, must fail on several other analgesics before a morphine prescription can be issued, and a panel of 5 specialists must examine the patient at home before a morphine prescription can be approved. Once approved, a prescription requires 4 stamps and 3 signatures and patients receive only enough medicine for 1-2 days. These restrictions are not required

under the international drug control conventions, but rather are imposed within the country, itself. If similar restrictions were applied to ketamine in countries that rely on it as the only safe anesthetic available, access to safe surgery would plummet, unquestionably placing lives in danger.

There are legitimate reasons for controlling access to medicines like morphine or fentanyl: used improperly, there is a clear potential for harm and this needs to be acknowledged. The point is not to "open the floodgates", but rather to achieve an appropriate level of balance in restricting inappropriate access and use with ensuring access for necessary medical purposes, whether that be in a hospital or in a patient's home. No other classes of medicines are as tightly controlled as those listed under the three drug control treaties, despite the potential for widespread harm to public health from other classes of medicines. Consider, for example, the rise of antimicrobial resistance attributable to the inappropriate manufacture and use of antibiotics globally – despite the widespread harms now attributable to inappropriate use of these medicines, they remain far more accessible than controlled medicines, and are not restricted by any treaties.

Controlled medicines clearly have a role to play in effective patient care, whether that be in the management of pain in palliative care, the provision of safe anesthesia, or in psychiatric care. Yet, the system has failed to achieve the balance that is required to ensure that essential medicines under national and international control are available to patients who need them. Perhaps this balance can be struck in developing countries; however to date, there is no evidence that this is true to guide this implementation in resource-poor settings where regulatory compliance in line with the treaties is difficult, if not impossible, to achieve. Given this, continuing to add essential medicines like ketamine to international schedules is irresponsible and dangerous for public health.

The international medical community has demonstrated the ability to have a credible voice in this discussion through our collective work to ensure the continued availability of ketamine, raising awareness of the essential nature of this medicine in anesthetic care in developing countries. We must, first, recognize that the challenges to ketamine are not yet over: the scheduling proposal has not been withdrawn, it has simply been deferred for two consecutive years, and is likely to re-emerge at subsequent sessions of the Commission on Narcotic Drugs. Second, even as ketamine continues to be available for medical uses, millions of patients continue to lack access to the controlled medicines that they need, resulting in a massive disparity between those countries where patients have access to effective pain relief, and those that do not.

By raising awareness of the medical necessity of ketamine, many members of the global medical community have become engaged in discussions about the gap in the availability of controlled medicines. This conversation must extend beyond ketamine and this momentum must push to address barriers locally, nationally, and internationally to improve the availability of essential medicines and ensure effective pain relief for all.