I am a clinical scientist with the Bruyère Research Institute in Ottawa, and a respiratory therapist that has worked in clinical anesthesia throughout Canada since 2005. I continue to provide frontline patient care in anesthesia, where I use ketamine as an adjunct in my anesthetic care, and also work as a health systems and public health specialist in fragile and conflict-affected states, including in several humanitarian emergencies. I can attest not only to the importance of effective surgical and anesthetic care for reducing the suffering of patients in low-income countries and in reducing preventable mortality from common conditions such as obstetrical emergencies, but also to the unbelievable gap in these essential services that exists throughout much of the world.

It is in these settings where the availability of safe anesthetic care relies largely on the availability of one medicine: ketamine. Rather than reiterate the facts and context concerning the integral nature of this medicine, predominantly in low- and middle-income countries, I want to instead focus on the procedural issues that face this committee and this issue, and would like to respectfully advise the committee to reconfirm its previous recommendations that ketamine not be placed under international control.

First, I believe that the ECDD should be most concerned that in spite of having reviewed ketamine three times, and amidst wide recognition of the value of this medicine, several member states and the INCB have persisted in their calls to consider placing ketamine under international control, passing resolutions at the Commission on Narcotic Drugs, and framing it as a substance of abuse, rather than an essential medicine.

Most problematically, this lack of respect for the role and authority of the ECDD and, frankly, the World Health Organization, on a medical and scientific matter was patently obvious when following the 36th session of the ECDD in which this committee found that ketamine should not be placed under international control, the United Nations Office on Drugs and Crime chose to allow a proposal to list ketamine under Schedule I of the 1977 Convention to be placed on the agenda of the 58th session of the Commission on Narcotic Drugs in March of this year.

Article 2, Paragraph 5 of the 1971 Convention states that the WHO assessment “shall be determinative as to medical and scientific matters”. As explained in the official Commentary to the 1971 Convention, the Commission must accept the views expressed by the WHO in a formal communication with regard to medical and scientific matters, but can supplement them with economic, social, legal, administrative and other factors it may consider relevant. The Commentary clarifies that there are cases in which the Commission “would be bound to act in accordance with recommendations of WHO”. Therefore, if the WHO finds that a substance does not meet the basic criteria for international scheduling, and “by consequence expressly or impliedly recommends in its communication to the Commission that the substance should not be controlled, the Commission would not be authorized to place it under control. Doing so would be incompatible with the provision that the WHO assessment should be ‘determinative as to medical and scientific matters’, and also with the basic assumptions of the authors of the Vienna Convention which is intended to deal only with problems arising from the abuse of substances which have dangerous qualities”. The criteria for ‘dangerous qualities’ are defined in the 1971 Convention, Article 2, Paragraph 4 and are assessed in the WHO critical review process.

At its intersessional meeting held on January 29, 2015, the Commission on Narcotic Drugs (CND) discussed substantive and procedural matters related to the scheduling of ketamine. At that meeting, the Secretariat was requested to seek a legal opinion on whether the Commission could schedule a
substance under the 1971 Convention if the WHO has recommended that the substance should not be placed under international control.

The Office of Legal Affairs issued a legal opinion on this matter, finding that “WHO assessments are determinative as to medical and scientific matters of a substance,” but then continues by, paradoxically, saying: “but the ultimate authority to decide whether the substance should be added in a Schedule rests with the Commission. In doing so, the Commission is required to take into account factors broader than medical and scientific factors.”

This opinion has been challenged by several member states and legal scholars. Even within the legal opinion, itself, the Principal Legal Officer in charge acknowledged that parties to the Convention and the Commission may take a different view to the responses provided. As such, OLA’s response should not in any way be construed as the only or definitive view. I would, therefore, suggest that the ECDD should critically examine OLA’s legal opinion and carefully consider its consequences for the future functioning of the UN drug control treaty system.

As part of this, I strongly recommend that the ECDD also obtain legal advice both from within WHO as well as independent legal advice as to its authority and mandate under the Convention, which is clearly under attack. The opinion of many who are knowledgeable in the treaty is that the CND has ignored the recommendation of the WHO on this matter and has acted beyond its authority by suggesting that the Commission may vote on the scheduling of a medicine contrary to WHO’s opinion. Given the outcome of three reviews of the medicine by this committee which have consistently found that ketamine should not be scheduled, the matter should never have made it onto the agenda of the CND. The fact that it did was procedurally incorrect and draws into question the role of this committee as a part of the UN drug control system.

Second, I want to remind the committee that in examining ketamine at this session, the Committee is updating a review, and not conducting a new Critical Review. The procedures established in the ECDD Guidance Document on the Review of Psychoactive Substances for International Control, which has been approved by WHO’s Executive Board, require that in order to issue a recommendation to the CND, this needs to be preceded by a Pre-Review and a Critical Review. A critical review requires a Critical Review report to have been published, which has not happened, and there has been no Pre-Review report issued, either. Therefore, it is not possible for this updated review to constitute a Critical Review and as such, no new recommendation can be made to the CND.

Therefore, only one option remains for the ECDD on this matter today, and that is to reconfirm the Committee’s previous recommendation that ketamine not be placed under international control and say that it still stands.

As a reminder of what that recommendation included, I quote from your previous report which states that: “[c]oncerns were raised that if ketamine were placed under international control, this would adversely impact its availability and accessibility. This in turn would limit access to essential and emergency surgery, which would constitute a public-health crisis in countries where no affordable alternative anaesthetic is available”

What we have heard today from all of these organizations present is that this public-health crisis is very real and the stakes are very high. I strongly encourage the ECDD to reaffirm its position on this matter, and also to take a stand on the legal and procedural issues that are threatening to undermine the role of
the WHO in the international drug control system. I encourage you to do this openly and transparently by obtaining and sharing advice not only from WHO’s legal advisors, but from the many legal experts who have spoken out against this procedure.

In closing, I would like to respectfully draw your attention to some wording in last year’s CND resolution inviting Member States “where the domestic situation so requires, to consider controlling the use of ketamine by placing it on a list of substances controlled under their national legislation, while simultaneously ensuring access to ketamine for medical and scientific purposes.”

Evidence collected by many researchers and organizations active in the area of access to essential medicines has not found any research or framework that shows how, in low-income countries, a substance such as ketamine can be placed under international control, while simultaneously ensuring access for medical and scientific purposes. Perhaps it can be done. However, at present, there are no good models, and implementing a proposal such as placing ketamine under international controls without good evidence as to how to ensure that a public health crisis would not result from doing so, would be unethical at best.

Again, I reiterate my call that this Committee reconfirm its previous recommendations that ketamine not be placed under international control.

Thank you.