A Response to the Comments by Boister and McGrady

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Abstract
The authors contend Neil Boister’s and Benn McGrady’s arguments for situating a treaty against the illegal trade in counterfeit medicine under the auspices of the United Nations Office of Drugs and Crime (UNODC), and update readers on developments, since the publication of their earlier paper proposing the creation of such a treaty, at the World Health Organization (WHO).

We thank Professors Boister and McGrady for their contribution on achieving a treaty against counterfeit medicines.1 In this reply, we both respond to their argument for situating such a treaty under the auspices of the UN Office of Drugs and Crime (UNODC) — a proposal we consider to be on balance a poor idea — and update readers on the latest developments at the World Health Organization (WHO). We remain convinced that WHO is, for now, still the best institution under which to negotiate and achieve a treaty for improving the quality of medicines.

But first, we must provide an update on an important issue of nomenclature. Our paper referred to deliberately false medicines as ‘counterfeit’ medicines.2 That was the WHO-approved term for about two decades, but it is now obsolete, after a decision in March 2011 by a WHO Working Group to reject it.3

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The Working Group acted because the word ‘counterfeit’ is confusing: it both denotes affronts to human health (which is how we used it), and affronts to patent or trademark rights (which is how it is used in international intellectual property law, particularly the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement). Several WHO Member States protested that this ambiguity could be exploited to turn a treaty against ‘counterfeit’ medicines into an implement to heighten intellectual property rights, rather than to protect human health.

We agree. As we wrote in our paper, exactly this confusion has caused trouble before. Now that the WHO Member States have rejected the use of the word ‘counterfeit’, we do likewise, and henceforth call them ‘falsified’ medicines, which is the best nomenclature being considered by the WHO Working Group right now (other options are ‘spurious’ and ‘falsely-labelled’).

Following publication in the *Journal* of our paper proposing the creation of a treaty against the falsified medicine trade, the WHO Working Group met, and some countries spoke in favour of a treaty.4 So too did the editorial board of *The Lancet*, arguably the world’s leading medical journal.5 The WHO Working Group will continue deliberating this year and next.

In contrast, Boister and McGrady propose a UNODC-led solution. The idea is not originally theirs, for Boister and McGrady fail to cite or otherwise credit the Government of Argentina, which on 11 April 2011 presented a Resolution to UNODC’s Commission on Crime Prevention and Criminal Justice concerning the international criminalization of ‘fraudulent medicines’.6 As passed, Argentina’s Resolution does not separate or distinguish intentionally falsified medicines, which are the deliberate result of criminal activity, from accidentally substandard medicines, which are the result of non-criminal negligence — and this is a very serious problem.7 Nevertheless, Argentina’s approach easily could be adjusted, and it would then be a serious proposal for a UNODC-led process. We hope Argentina does so, and express our thanks for its visionary leadership.

Argentina’s Resolution mentions the ‘potential utility of the United Nations Convention against Transnational Organized Crime’ (CTOC). The CTOC is in essence a framework convention for various international criminal offences in

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4 Ibid.
7 Argentina’s Resolution reads: ‘the term “fraudulent medicines” includes medicines whose contents are inert, are less than, more than or different from what is indicated, are misbranded or have expired...’. That wording does not distinguish between intention and accidental causes. It treats identically those medicines that are inert because they were falsified by organized criminals, and those medicines that are inert because of a manufacturing error by honest pharmaceutical manufacturers. The lack of such a distinction is so serious that it should be considered fatal to the proposal as it now stands.
which there is an organized criminal group as perpetrator. There are currently three Protocols under CTOC, which criminalize: (1) the trafficking of persons; (2) the smuggling of migrants; and (3) the smuggling of firearms. The first two Protocols were adopted by the UN General Assembly as a package and at the same time as CTOC in 2000, and the third Protocol followed separately soon thereafter, in 2001. All of the Protocols specify that their secretariat is the UN Secretary-General’s office, which has assigned the day-to-day responsibility over the Convention to the UNODC in Vienna.

So how about engaging UNODC to create a new CTOC Protocol for medicines? History teaches that there would be advantages and disadvantages, compared with a WHO-led treaty. As we shall show, the UNODC route is diplomatically less demanding, but the WHO route is practically more effective.

Definitely the greatest advantage of the UNODC option is that it is comparatively fast and easy. Creating a new protocol under CTOC requires nothing more than a decision of the UN General Assembly, which could be passed in a single sitting. In contrast, a WHO-led treaty probably would take years of hard negotiations at Intergovernmental Negotiating Conferences (INC). The complexity and cost could hardly be more different.

But the same ease that makes CTOC attractive is arguably also its worst disadvantage. Treaty negotiations are not just an arduous and expensive waste to be avoided. On the contrary, the iterative process of negotiations helps countries refine their interests and objectives, and cements their political will. A Protocol that shortcuts that process is likely to be ignored by countries and to have no actual effect.

And that is a point Boister and McGrady do not address, for in declaring that UNODC is the ‘preferable venue for negotiation’, they overlook the undeniable failure of CTOC Protocols in the recent past.

Consider for example the Protocol on Firearms, to date the only freestanding CTOC Protocol (i.e. it was not enacted together with CTOC itself). The Protocol has been a disappointment precisely because most countries hardly noticed or cared when it came into being. In the decade since it was opened for signatures, under half of UN Member States, and only seven of the G-20 countries, have ratified or otherwise accepted it. Thus the Protocol on Firearms, while technically in force, is practically a dead letter.

This history augurs poorly for Argentina’s efforts to create a new CTOC Protocol against ‘fraudulent’ medicines — would it too be ignored? Even if not, CTOC also suffers from serious limitations in what can be criminalized. As its name suggests, CTOC is a framework convention for the development of international criminal law against organized groups, involving several criminals acting concertedly. The definition of an ‘organized criminal group’


requires that there be ‘a structured group of three or more persons, existing for a period of time and acting in concert with the aim of committing one or more serious crimes or offences...’. Not all criminals would be caught by this formulation. For example, if a manufacturer in Country X, a middleman in Country Y and a smuggler in Country Z informally form a supply chain for falsified medicine, only the middleman in Country Y is obviously in a conspiracy involving three persons, because he did business with persons before and after him in the chain. The smuggler in Country Z, who is the closest to the patient and the most likely to be caught by police, could escape punishment altogether, unless prosecutors proved to a high criminal law standard that he knowingly entered into a conspiracy with the others. A CTOC Protocol is therefore more suited to prosecuting the biggest criminals who orchestrate the falsified medicine trade — for example, those who internationally trade fake drugs in large quantities — but would let escape lesser criminals.

Which brings us to the final reason that CTOC is less than ideal: it is purely a criminal law treaty. Thus it can do an excellent job on issues such as cooperation in investigations, extradition, witness protection and so forth, but it cannot embrace the other actions needed to better the global medicine supply. Here, we must remember that the legal challenge is twofold: criminal law is needed to stop criminally falsified medicines, but regulatory law is also needed to avoid accidentally substandard medicines. It is a grave error to apply criminal law to both, as Boister and McGrady propose, and as Argentina’s Resolution in its current incarnation does. As we wrote in our paper, in many developing countries, the quality of drug regulation is weak or even non-existent. A treaty therefore must both internationally criminalize falsified medicines, and fortify drug regulatory agencies in poorer countries to block substandard medicines. A WHO-led treaty could do both these things, but a CTOC protocol certainly could not. Lamentably, the word ‘health’ does not appear even once in the many pages of CTOC, though the drafters managed to mention just about every other subject matter (inter alia: ‘money-laundering, corruption, illicit trafficking in endangered species of wild flora and fauna, offences against cultural heritage and the growing links between transnational organized crime and terrorist crimes’).

But even supposing that the CTOC could be harnessed for health, which is plainly not what the drafters contemplated, drug regulatory agencies in impoverished countries cannot be strengthened by words alone, and so the treaty must raise foreign aid money. Here again the evidence shows that a WHO-led treaty is the better option. Following the WHO Framework Convention on Tobacco Control, development assistance for tobacco control rose to about $240 million annually.10 That sum far outstrips CTOC’s Crime Prevention and

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10 C. Callard, ‘Follow the money: how the billions of dollars that flow from smokers in poor nations to companies in rich nations greatly exceed funding for global tobacco control and what might be done about it’, 19 Tobacco Control (2010) 285.

Therefore to summarize: a UNODC-led protocol under CTOC offers one apparent advantage only — an easy way to create international law on medicine quality by only a General Assembly decision. But even that so-called advantage is debatable, since the shortcut of using a General Assembly decision to create a new CTOC protocol could result, as with the Protocol on Firearms, in a legal instrument that is unnoticed, sparsely ratified and ineffective. Further there are three major limitations intrinsic to CTOC: (1) that lesser criminals will likely go free; (2) that measures to improve routine national drug regulation are not within reach, and; (3) that the Crime Prevention and Criminal Justice Fund is short of money.

So what should be done? For the moment, there is emerging support in the WHO Working Group for a treaty, and this should be nurtured, rather than possibly being preempted or thrown into confusion by efforts aimed at a UNODC-led treaty or CTOC protocol. However, it should not be forgotten that UNTOC contains some superb language in the international criminal law domain, and that UNODC knows the criminal law domain best. Thus the optimal outcome would be to negotiate a new WHO-led treaty, but to do so with UNODC as a major partner, including perhaps even sharing the secretariat function. Medicine falsification is quintessentially a multidisciplinary problem, and if the UN is flexible enough, a multiagency solution would be best.