Why and How to Make an International Crime of Medicine Counterfeiting

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Abstract

The article explores why — when the counterfeiting of medicines is so prevalent, hard to detect and quietly dangerous or fatal — it remains totally unaddressed and therefore legal in international criminal law. It is argued that criminalizing the counterfeiting of medicines on an international scale would present no legally insurmountable barriers, and would offer significant advantages over the current national-scale approaches. The authors propose a legal definition of ‘counterfeit’, canvass the current legal doctrines that could be arrayed to better criminalize medicine counterfeiting, including classifying the severest instances as crimes against humanity, and explain the mechanisms necessary to close the jurisdictional gaps that are currently exploited by organized criminals who trade in counterfeit medicines across borders. They suggest that a counterfeit medicine treaty should be drafted under the auspices of the World Health Organization, and illustrate the feasibility of doing so with existing and developing treaty law on another health danger, tobacco.

Borders should not be considered as a shield against the reach of the law and as a protection for those who trample underfoot the most elementary rights of humanity.¹

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¹ Decision on the Defence Motion for Interlocutory Appeal on Jurisdiction, Tadić (IT-94-1-AR72), Appeals Chamber, 2 October 1995, § 58.
1. Introduction

The counterfeiting of medicines is a global public health crisis. Recent estimates are that perhaps 15% of the global medicine supply is counterfeit, while in developing regions of Africa, Asia and Latin America over 30% of the medicines on sale may be counterfeit. It is a trade that kills. Even medicines sold for notoriously deadly diseases such as malaria are faked. In some countries, the evidence is that fully half of anti-malarial treatments sold are counterfeits.

Like the counterfeiting of money, the counterfeiting of medicines is highly globalized — pills are fairly easy to smuggle. But unlike the counterfeiting of money, the criminals who deal in counterfeit medicines do so with little fear and few consequences. For remarkably, there is today no international legal framework to pursue and punish those who counterfeit medicines and traffic them across borders.

Yet, there is strangely little outrage at this globalized, deadly evil. As the International Federation of Pharmaceutical Manufacturers and Associations so pithily notes, ‘If you’re caught with a kilo of heroin at a border crossing you’ll go to jail for a very long time. If you’re caught with a kilo of counterfeit medicines, that penalty may be the same if you’re caught with a kilo of counterfeit T-shirts.’ The problem is one of transnational jurisdiction, or more accurately, the lack of it. Currently, if a counterfeiter from country A produces and exports useless, perhaps deadly, drugs to country B, normally only country A has the authority to prosecute the criminal for counterfeiting because that criminal act occurred on its territory. Country B, despite having its citizens victimized, usually has little criminal jurisdiction over the matter. Country B might have criminal jurisdiction over acts ancillary to the counterfeiting — such as fraud, or smuggling — but that is not the same crime; it may not even be committed by the same person; and odds are that it will not carry an appropriate penalty. And with no international agreement to treat medicine counterfeiting as a serious crime, judicial and police cooperation between countries A and B cannot be taken for granted. Impunity for medicine counterfeiters is largely the result.

Plainly, knowingly making fake medicines that do not help people, or that harm and kill them, ought to be considered a more serious transnational crime than it is. Other evil acts that deliberately endanger life on a
transnational, widespread and systematic basis — for example, terrorism or hijacking — receive a far stronger legal treatment today. So too does the counterfeiting of currency, which though an age-old scourge, became an international crime in 1929. On that occasion, the international legal community declared that those who faked money should, ‘without ever being allowed impunity’, be placed under universal jurisdiction and made liable to prosecution in any country, not just the country where the counterfeiting took place. Almost a century after this development, humanity and the defence of public health requires doing likewise for the trade in counterfeit medicines.

This article is an exploration of why — when the counterfeiting of medicines is so prevalent, hard to detect and quietly dangerous or fatal — it has escaped the attention of international criminal law. We demonstrate that criminalizing the counterfeiting of medicines on an international scale would present no legally insurmountable barriers, and would offer significant advantages over the current national-scale approaches.

This article is organized in three parts. In Section 2, we describe the international nature of the counterfeit medicine trade and explain how existing laws are permitting deadly counterfeiting to go unpunished. In Section 3, we canvass the legal doctrines that could be arrayed to better criminalize medicine counterfeiting, ranging from the fundamental legal definition of ‘counterfeit’, to the possible imposition of a new crime against humanity for the most egregious offences. Finally, in Section 4, we discuss the international governance mechanisms, particularly at the World Health Organization (WHO), available to negotiate and agree upon a counterfeit medicine treaty. We conclude with some critical observations on current public health politics, which are preventing action.

2. The Unsatisfactory Medical and Legal Realities of the Counterfeiting of Medicine

Myriad medicinal products are counterfeited. Patients seeking antibiotics, hormones, steroids, painkillers, anti-histamines or medicines for cancer, hypertension and high cholesterol, have been, and are continuing to be victimized by fakes. The size of the counterfeit market is probably unknowable: the number of reported cases increases every year, but in some locations the situation may be improving. WHO quotes an estimate by the Centre for

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7 WHO, supra note 3.
Medicine in the Public Interest that the counterfeit drug market could reach US$ 75 billion globally in 2010.\textsuperscript{10} If correct, the collective market for counterfeit medicines is several-fold larger than the market for the world’s best selling legitimate medicine.

Medicine counterfeiting is organized crime. It is not usually the case that the person who makes the counterfeit medicine acts alone. Rather, for counterfeits to infiltrate markets for legitimate medicines, highly sophisticated criminal enterprises must mimic the business model of the genuine pharmaceutical industry. The manufacturing branch of that criminal enterprise makes the fake medicines, for example, pressing ersatz ingredients into pills, or printing plausible-seeming packaging, often with forged trademarks. The marketing branch coordinates the covert distribution of counterfeit outputs, to trick inspectors and wholesale customers (and a separate retail branch exists downstream of them). Finally, the financial branch launders the revenues of these illegal sales.

A criminal enterprise of the sort just described above is not a small undertaking. It cannot be haphazard, or it would fail. There are possibly links between medicine counterfeiting and other crimes: Interpol believes that some of the revenues from medicine counterfeiting flow to terrorist organizations, including Al Qaida.\textsuperscript{11}

A. The Complexities of National Enforcement of a Transnational Crime

WHO has highlighted a variety of factors which contribute to the proliferation of counterfeit drugs. These include:

(i) insufficient national regulation of drug manufacturing and distribution;
(ii) poor enforcement of existing legislation;
(iii) weak penal sanctions for violations of drugs legislation;
(iv) poor regulation by exporting countries and within free trade zones;
(v) complex transactions involving many intermediaries;
(vi) high demand and prices for curative and preventive drugs and vaccines;
(vii) inefficient cooperation among stakeholders.\textsuperscript{12}


\textsuperscript{12} Counterfeit Drugs: Guidelines for the development of measures to combat counterfeit drugs, UN Doc. WHO/EDM/QSM/99.1, 1999.
In reality, current efforts to mitigate these obstacles are mainly aimed at the first two points of bettering national-scale legislation and enforcement. While these steps are certainly necessary and welcome, they are an incomplete solution, for factual and legal reasons.

Factually, the trade in counterfeit medicine is often transnational, and media or scientific reports of fake medicines abound. For example, a recent forensic study documented the movement of counterfeit medicines from China to nearby Cambodia, Laos, Myanmar (Burma), Thailand and Vietnam. The products in this study were all fakes of artesunate — a highly effective cure for life-threatening *falciparum* malaria — but in the samples collected at retail level, the tablets or capsules contained no active ingredients or merely derisory, sub-therapeutic amounts. Not only do these products cause completely avoidable illness and death — particularly among children, who are most affected by malaria — but they also promote artesunate resistance in the malaria parasite, in the long run destroying the clinical efficacy of the genuine drug and undermining the confidence of the public and health care workers in drug treatments of all sorts. Both are catastrophic in public health terms.

A national-scale approach to criminalization and enforcement also means that enforcement and penalties for counterfeiting vary widely. On the one hand, in some countries medicine counterfeiting simply is not a crime, though governments may hasten to enact a law after the problem manifests itself, as Syria recently did. Other countries, such as China, propound draconian penalties including the death penalty, but often as a façade for selective and inconsistent enforcement. Too few countries adopt a flexible approach, with judicial discretion as to imprisonment and monetary fines. Some positive examples of that kind are found in the Philippines (up to life imprisonment.

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16 Ibid.
and US$ 25,000 fines) and India (up to 10 years’ imprisonment and US$ 32,000 fines).21

Such sharp differences in the criminal law treatment between countries create difficulties in transnational enforcement. Extradition laws often contain a requirement of double (or dual) criminality, meaning that a person is only extraditable from country ‘A’ at the request of country ‘B’ if the act for which he or she is accused is criminalized in substantially identical terms and with comparable penalties in both countries.22 By not even agreeing on the basic fact that counterfeiting is a crime, countries afford criminals the basis to resist or avoid extradition.

WHO has tried to better harmonize national legal approaches, but faces limits because its mandate is public health, not law enforcement.23 Further, within the public health field, law is underutilized. Only a few countries (20%) have well-developed drug regulation, while most (50%) have limited regulation, and many (30%) have practically no regulation.24 Corruption and poor governance thrive in the latter category. The poorest developing countries such as Kenya or DR Congo do not have sufficient resources to evaluate the quality of drugs on the market,25 many of which are unregistered with the drug regulatory authorities.26 Other poor countries, such as Cambodia, are dogged by cozy relationships that appear to join counterfeit medicine distributors with powerful figures in the government.27

B. The Extent and Effects of Medicine Counterfeiting

Nobody really knows the extent of medicine counterfeiting. Certainly, it is large: recall the estimate quoted by WHO that it is a $75 billion market. In any case, fixing a dollar value on the problem, while important, does not

impart a sufficient understanding of the dimensions of the counterfeit trade networks nor does it draw attention to health and societal impacts.28

While counterfeiting is particularly rampant in poorer countries having weak regulatory systems, thanks to globalization no part of the world is totally secure against its dangers. Even the United States, which has probably the world’s best-regulated pharmaceutical market, experienced an 800% increase in reported instances of counterfeit drugs between 2000 and 2006.29 Essentially, no part of the world is exempt.30

28 Consider malaria, a disease that kills nearly a million people, mostly children, annually. Those suffering from the disease in Africa, Asia and elsewhere often self-diagnose and self-treat, without medical supervision and using drugs they purchase in the market. Problem is, the leading treatments in the market (the artemisinin-class drugs) are increasingly counterfeited. Recent studies show that in South-East Asia, a staggering 33–53% of these medicines contain no active ingredient, and scientists warn that the trend is similar in Africa. See, Dondorp, supra note 4; Newton, supra note 17. In some cases, the fakes are so poorly done, and the counterfeiters are so unafraid of being caught in countries with weak or corrupt regulatory systems, that there are spelling mistakes in the product’s name. Official estimates are lacking, but it would be surprising if counterfeit malaria medicines did not kill tens of thousands of people annually. See J. Harris, P. Stevens and J. Morris, ‘Keeping It Real: Combating the Spread of Fake Drugs in Poor Countries’, (International Policy Network) available at http://www.policynetwork.net/sites/default/files/keeping.it.real.2009.pdf (visited 24 November 2010).


30 In Haiti, India, Nigeria and Bangladesh, some 500 children died after consuming counterfeit paracetamol (acetaminophen) cough syrup made with diethylene glycol, a renal toxin used in antifreeze. WHO, supra note 3.


In Brazil, about 200 unplanned pregnancies occurred when a test batch of oral contraceptives made by Schering Brasil containing wheat flour rather than active ingredient was stolen, packaged as if it was real, and sold. (C. Claudio, ‘Epidemic of Counterfeit Drugs Causes Concern in Brazil’, 352 Lancet (1998) 553). Schering executives, deplorably, covered up the theft.

In Canada, pharmacies in Ontario were discovered selling a counterfeit version of a blood pressure medicine, Norvasc, after 11 patients inexplicably died. (See Criminal Intelligence Service Canada, ‘Counterfeit Pharmaceuticals in Canada’ (Government of Canada) available at http://www.cisc.gc.ca/pharmaceuticals/pharmaceuticals.e.html (visited 24 November 2010)). A Coroner’s enquiry was unable to rule out ‘possible unauthorized medication substitution’ in some of those deaths. See Ontario College of Pharmacists, ‘Discipline Case: Bhusmang Mehta’, available at http://www.ocpinfo.com/client/ocp/opchome.nsf/ab26815c7d6d78e58525732b00626f24/aa604517b9733ec9852570d1006081d1?OpenDocument (visited 24 November 2010).

In the United States, the Food and Drug Administration recalled 18 million tablets of an anti-cholesterol drug, Lipitor, after counterfeiters infiltrated distribution channels. A subsequent investigation by Lipitor’s manufacturer revealed an incredibly audacious global criminal enterprise at work: ‘the counterfeiters had been manufactured in Costa Rica using tooling and excipients from the United States and a pharmaceutical ingredient shipped from the Hong Kong office of Swiss company.’ See Pfizer, ‘Case Study: Lipitor US Recall’, available online at http://media.pfizer.com/files/products/LipitorUSRecall.pdf (visited 24 November 2010).
Counterfeiters are engaged in sophisticated, well-orchestrated crimes. The most skilful counterfeiters can copy medicines to near perfection. Counterfeiters have gone so far as to copy trademarks embedded in security holograms, and to prepare their products using cheaper ersatz ingredients that mimic the chemical characteristics of the proper ingredients in laboratory tests. Small quantities of the proper ingredients may be added to preparations in order to slip past basic analytical techniques.

Ultimately, we do not know precisely how much damage is done by this criminal arsenal of tricks. The regulatory systems to detect counterfeiters are weak and the available estimates are imperfect, such as one much-cited estimate that counterfeiters kill 700,000 people annually. But even so startling a number in a sense underestimates the problem, because in focusing solely on the tangible killing of people, it omits the more intangible damage done to public health. Patients who take counterfeiters and fail to get better understandably lose faith in the healing powers of modern medicine, and especially in poor countries they may turn instead to traditional healers or quacks. Especially insidious are counterfeiters for infectious diseases containing too little (i.e. sub-therapeutic) amounts of active ingredients, since they destroy the clinical efficacy of the genuine medicine by promoting drug resistant pathogens — a phenomenon observed with malaria drug resistance in South-East Asia. Medicines lost to resistance in this way are not just lost to the single patient; they are lost to the practice of medicine, possibly worldwide, and possibly forever.

3. Goals, Doctrines and Proposals for a Counterfeit Medicines Treaty

Plainly, the national-scale responses to medicine counterfeiting which prevail today leave much to be desired, and criminalizing the trade at an international level could only improve matters. According to Bassiouni, crimes are deserving of being elevated to 'international crimes' if they either amount to an offence against the entire international community, or if international cooperation is necessary for effective control over the transgression, or both.

32 Editorial, supra note 29.
34 Harris, supra note 28.
By this rubric, medicine counterfeiting deserves to be an ‘international crime’. The public health consequences of counterfeiting, particularly drug resistance, transcend borders, and many, or perhaps most, counterfeit medicines are internationally traded. Successful prosecution is beyond the ability of any country acting alone, but depends on cooperation between countries in matters such as extradition. The case for international criminalization could hardly be more persuasive.

Others are tentatively coming to this same conclusion. The Declaration of Rome, arising from the WHO International Conference on Combating Counterfeit Medicines in February 2006, holds that counterfeiting medicines is ‘widespread and has escalated to such an extent that effective coordination and cooperation at the international level are necessary for regional and national strategies to be more effective.’ The following year, a taskforce of legal experts convened by WHO-IMPACT reached consensus on a proposal first made by one of the authors that counterfeiting should be a crime of universal jurisdiction prosecutable by all countries, but fell short of recommending a treaty to bring that about. Strangely, it was delegates from the pharmaceutical industry who led the opposition to a treaty, although it is their firms who bear the brunt of financial loss and reputational risk when medicines are faked.

Thus for several years, progress stalled at an odd halfway point, with agreement on the need for an international crime of universal jurisdiction, but disagreement on the need for a treaty to achieve it. The only progress of that kind emerged from the Council of Europe, which in November 2009 quietly published the ‘Draft Council of Europe Convention on counterfeiting of medical products and similar crimes involving threats to public health’, also called the MEDICRIME Convention. That draft has very serious flaws, discussed later, but is helpful if only for broaching the taboo of having a treaty against counterfeiting.


39 The industry delegation was headed by Michael J. Muller, the Director of Global Anti-Counterfeiting Operations for Eli Lilly & Company: see ibid. Mr. Muller appeared influential in persuading other industry participants that a treaty was undesirable, and expressed this point of view to one of the authors (Attaran). Apparently it is feared that more robust enforcement against counterfeit medicines would draw publicity, and potentially undermine public confidence in the industry’s products.

During the past few decades, acts including aircraft hijacking, hostage-taking, narcotics trafficking and currency counterfeiting have each been made international crimes by way of multilateral treaties. With similar endangerment to life and similar international criminal networks at play, the counterfeiting of medicines should surely be made the subject of such a treaty. The already-established legal doctrines of these forerunner treaties provide precedent.

We emphasize: to internationally criminalize counterfeit medicines, one should not begin with a clean slate or invent new legal doctrines, as doing so would needlessly invite controversy. It is more modest and efficient to borrow existing doctrines from current treaties on currency counterfeiting, hijacking, narcotics trafficking and so forth, assembling these, mutatis mutandis, into a new whole.

The treaties just named share certain features: (i) they precisely define the basic ‘evil’, such as terrorism or hijacking or counterfeit currency, to which the treaty is directed; (ii) they set out several wrongful acts on which there is an international consensus to achieve criminalization, and require states to enact legislation to forbid and to punish the specified criminal acts when committed within their territorial jurisdiction or by their nationals; (iii) they set out a shared understanding on the severity or scale of the crimes, and for the most terrible may declare them to be crimes against humanity; (iv) they require states to arrest alleged offenders within their territory, whether the criminal acts were committed inside or outside their territorial jurisdiction, by nationals or foreigners; (v) they require states either to prosecute alleged offenders in their custody, or to extradite them to prosecution in another state; and, finally, (vi) they commit the states to mutual assistance in matters of prevention or enforcement such as information and evidence sharing, or cooperation with agreed international organizations. Space does not permit us to discuss all these commonalities in the coming sections, and we focus on the most important or less obvious ones.

A. Goal One: the Wrongful Acts

An international treaty requires a consensus on the spectrum of wrongful acts that it means to prohibit. Moreover, it requires of most states party to the

42 International Convention against the Taking of Hostages, GA Res. 34/146 (XXXIV), 34 UN GAOR Supp. (No. 46) at 245, UN Doc. A/34/46 (1979); 1316 UNTS 205; TIAS No. 11081; 18 ILM 1456 (1979).
44 Currency Convention, supra note 6.
treaty (though perhaps not those with monist legal systems) to enact national laws making those wrongful acts criminal offences.

Leaving aside for now the exact definition of medicine counterfeiting, which is the subject of the next section, it appears uncontroversial that the practice is one requiring multiple offences to stop. The supply chains for counterfeit medicines can be long, and those responsible can belong to sophisticated criminal enterprises in which there are specialized divisions of labour. To be thoroughly effective, the treaty must impose a criminal prohibition at each step of that chain, on each participant. Taking inspiration from the 1929 *International Convention for the Suppression of Counterfeiting Currency* (the ‘Currency Convention’), here are some acts which, when carried out intentionally, appear appropriate to punish as ordinary crimes within national jurisdiction, in accordance with a treaty:

(i) the manufacturing or preparation of counterfeit medicine;
(ii) the provision or possession of equipment, instruments or ingredients used in the manufacturing or preparation of counterfeit medicine;
(iii) the sale, offering for sale, dispatch, transportation, and import or export of counterfeit medicine, or equipment or ingredients used in the manufacturing or preparation of counterfeit medicine;
(iv) the falsification of documents in relation to a counterfeit medicine or its ingredients;
(v) the entering into a conspiracy to commit, or the making of an attempt to commit, or the aiding, abetting, facilitating, or counselling to commit, any of the foregoing offences.

It is important to note that none of these proposed offences relates to intellectual property. There are already plenty of multilateral and bilateral treaties which require countries to provide for intellectual property offences in their jurisdiction, so reiterating these offences in a new treaty for counterfeit medicines would be redundant, and likely deal a setback to current intellectual property standards.45

Procedural fairness requires that these proposed crimes be strictly limited to cases where the accused has acted with guilty intention. One would not wish, for example, to make a criminal of a person who, being fooled himself or herself, unwittingly offers a counterfeit medicine for sale. Equally, one would not want to make a criminal of a person who supplies ingredients, or equipment, used in making counterfeit medicines, without knowledge of that nefarious use. It would be inappropriate for absolute liability to prevail over any of the proposed offences, and instead, *mens rea* should be necessary to secure conviction.

45 Intellectual property diehards who are tempted to include that subject in a counterfeit medicine treaty would be wise to recall that the last time public health and pharmaceutical intellectual property concerns collided — in the 2001 *Doha Declaration on the TRIPS Agreement and Public Health* — an enormous controversy erupted which in the end weakened, rather than strengthened, intellectual property protection.
There are two possible ways to introduce this necessary element of intentionality. The approach used in the Council of Europe’s draft treaty is to tie the requirement of intention to specific offences: e.g. to write that the ‘intentional manufacturing’ of a counterfeit, as opposed to unintentional manufacturing, is criminalized.46 A less obvious approach, but one that is certainly wiser, is to embed the element of intentionality into the definition of a ‘counterfeit’ itself, so a medicine never crosses the threshold of being ‘counterfeit’ without evidence of intentional deception. The difference appears subtle, but as explained in the next section, there are overwhelming reasons to reject the Council of Europe’s treatment.

B. Goal Two: Defining Counterfeit Medicines

If there is to be a treaty against counterfeit medicines, it requires a standardized definition of that term. Unfortunately, countries disagree on the definition, and as WHO correctly observes, ‘the definitions used in...different countries differ enough to create problems in the...implementation of measures to combat counterfeit drugs.’47 The nearest there has ever been to a consensus is the WHO’s definition of ‘counterfeit medicines’ as formulated in the 1990s:

A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.48

This WHO definition, while not perfect, has the great, underappreciated virtue of including the phrase ‘deliberately and fraudulently mislabelled’. By embedding these words of intent or mens rea into the definition of what is ‘counterfeit’, the WHO definition usefully removes doubt as to what is or is not truly wrongful. Under WHO’s definition, there can be no such thing as an accidental counterfeit.

However, under the Council of Europe’s draft definition, there can be such a thing as an accidental counterfeit, and this is such a deep problem as to make its approach unacceptable, particularly from the perspective of the legitimate medicine industry. To illustrate, consider a hypothetical, honest medicine company. One day, an employee of this honest company makes an honest mistake — he puts wrong or defective ingredients in a tablet machine, or seals the tablets in the wrong packages, or stores the tablets at the wrong temperature.

46 Council of Europe, supra note 40, at Art. 4(j), and the offences at Arts 5–9.
48 Counterfeit Drugs, supra note 12, at 8.
where they spoil. What is manufactured in all these cases is certain to be an incorrectly labelled medicine. Mistakes happen.

Under WHO’s definition, these medicines cannot be termed ‘counterfeit’ because they are not ‘deliberately and fraudulently mislabelled’. The hypothetical company and employee have a serious problem on their hands, but need not worry about being prosecuted as criminals.

But astonishingly, they would be criminals under the Council of Europe’s approach. Its draft treaty criminalizes the ‘intentional manufacturing’ of a counterfeit,49 which is sensible, but muddies this by defining a ‘counterfeit’ in such a way that a product need only contain ‘a false representation as regards identity and/or source’,50 regardless of whether that false representation was intentional. The draft treaty is phrased so that the adjective ‘intentional’ modifies the gerund ‘manufacturing’: it neither modifies the adjective ‘counterfeit’, nor is it subsumed in the definition of ‘counterfeit’. This formulation criminalizes those who intentionally manufacture a medicine that they have accidentally made a false representation about — exactly the problem of our hypothetical company and its employee.

In sum, while WHO’s definition accurately targets only those who deliberately misrepresent a medicine, the Council of Europe’s draft treaty makes criminals of those who purely by error misrepresent a medicine — accidental counterfeiters, basically. Such an overreach is totally inconsistent with precept of mens rea as a foundation for guilt in criminal law, and ignores precedent: there is no such mistake in the 1929 Currency Convention.51 No drug company that has ever erred (i.e. all of them) is likely to find the Council of Europe’s draft treaty tolerable.

Yet despite its superiority, the WHO definition is now eclipsed by controversy, owing to an ill-timed attempt by WHO to revise and improve the definition in 2009. WHO’s laudable intention was to make the definition go beyond counterfeit medicines, and to apply to counterfeit medical products of all sorts, such as medical devices. Unfortunately, that change coincided with an already seething debate brought about by serious misunderstandings around the definition of ‘counterfeit’ products and intellectual property.

49 Council of Europe, supra note 40, at Art. 5(1).
50 Ibid. at Art. 4(j).
51 Art. 3 of the Currency Convention, supra note 6, reads in part:

The following should be punishable as ordinary crimes:
(1) Any fraudulent making or altering of currency, whatever means are employed;
[...]
(4) Attempts to commit, and any intentional participation in, the foregoing acts;

Note it is the ‘intentional participation’ (subparagraph 4) in the ‘fraudulent making’ (subparagraph 1) of currency that is criminalized. This intelligent wording totally rules out accidental counterfeiting, since the manufacturing both has to be fraudulent, and the person doing the manufacturing must have intent to participate in the fraud.
The confusion began when the European Union pressed Kenya to pass an overbroad law which branded medicines ‘counterfeit’ if made without the authorization of intellectual-property holders not just in Kenya but anywhere in the world, which if applied literally would make many legitimate generic medicines illegal and criminal in Kenya.52 The European Union countries also foolishly seized shipments of generic medicines en route from India to Brazil as counterfeit, simply because they momentarily transited European ports where patents existed.53 Brazil and India interpreted these European gestures as provocative, and rightly brought suit at the World Trade Organization, but incorrectly denounced WHO’s anti-counterfeiting efforts for promoting intellectual property rather than protecting public health, when actually WHO had nothing to do with either incident.54

The Council of Europe’s draft treaty is now poised to repeat these same mistakes, but on a larger and more dangerous scale. Its wording obliges countries to criminalize ‘the manufacturing, the keeping in stock for supply, importing, exporting, supplying [and other acts involving] medicinal products without authorization where such authorization is required under the domestic law of the Party.’55 What this wording overlooks, however, is that domestic law normally requires more than one ‘authorization’ when dealing in medicines — the government’s authorization under health and safety laws, of course, but also the patent holder’s authorization under intellectual property laws — and in intentionally or carelessly failing to denote which ‘authorization’ is at issue, the Council of Europe’s draft treaty makes criminal subject matter of all of them. Thus even a reputable manufacturer of a top-quality generic medicine could be charged, prosecuted and punished as a criminal for any instance of patent infringement, which heretofore has never been the case in Europe. Such a change is very likely to deny patients access to legitimate and necessary generic medicines, for reasons explained in the current medical literature, which makes the Council of Europe’s draft treaty an extremely foolish way of fighting counterfeit medicines.56

Overreaches such as the Council of Europe’s, which were guided by the brand-name pharmaceutical industry, rightly inflame non-governmental

55 The full text of Art. 8(a)(i) of the Council of Europe’s Draft Treaty, supra note 40, reads that parties to the treaty are required to criminalize ‘the manufacturing, the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market of... medicinal products without authorization where such authorization is required under the domestic law of the Party.’
However, the NGOs can be a problem too, where they over-react and indulge illogical or knee-jerk opposition to all anti-counterfeiting measures. For example, the Third World Network argues incorrectly that because ‘counterfeit’ is defined in trade law with reference to trademarks, then WHO's campaign against counterfeit medicines inexorably ‘undermines public health’.

Such reflexive fears about an intellectual property ‘agenda’ obstruct otherwise necessary steps toward eliminating medically dangerous counterfeits.

To solve this, there should be more assiduous separation between the public health meaning of ‘counterfeit’ (i.e. non-therapeutic) and the intellectual property meaning of ‘counterfeit’ (i.e. infringing). Therefore, a new treaty on counterfeit medicines should not follow pre-existing definitions of ‘counterfeit’ found in intellectual property treaties — and it would be redundant if it did. Rather, the treaty should define ‘counterfeit’ medicines solely to capture threats to public health and safety, taking the old (pre-2009) WHO definition as a starting point. By emphasizing the criminal wrongdoing of persons who deliberately trade in treatments that can injure or kill, the word ‘counterfeit’ takes on a wholly different — and much more sinister — complexion from how the word is used in intellectual property treaties. It also avoids wrongly criminalizing the trade in legitimate, quality generic medicines, as Kenya’s overbroad law did, or the Council of Europe’s ineptly worded draft treaty would.

Framed in this way, a treaty against counterfeit medicines will not elevate intellectual property concerns over public health concerns, and will not imperil the supply of proper generic medicines. Indeed, were advocates of public health or generic medicines such as Third World Network to continue in knee-jerk opposition, they would score an extremely foolish own-goal, in which the current treaties that protect the intellectual property of brand-name medicines remain in force, but no treaty to safeguard public health and the safety of the generic medicine supply can come into being.

In an act of dubious judgment, the Council of Europe welcomed Sanofi-Aventis to participate in the working group on the draft treaty, but without including generic medicine companies and NGOs from those discussions. See Bate and Attaran, ibid.


more aggressively than the generics companies — so in turn the intelligent counterfeiter will focus on making fake generic products, because the risk of getting caught and punished is less. Since this cannot possibly be the result that advocates for proper generic medicines want, there is a need for a treaty that criminalizes counterfeit medicines whatever their intellectual property status.

C. Goal 3: Classifying the Worst Cases of Medicine Counterfeiting as Crimes Against Humanity

Once it is decided which fraudulent acts involving medicines give rise to criminal offences, the question arises of how thoroughly those offences ought to be stigmatized and punished by the law. The principle of proportionality means of course that lesser offences, such as to supply a small amount of counterfeit medicine, should be punished less severely. In this section, however, we are only concerned with the most brazen and egregious instances of counterfeiting, which by their large scale and severity can be classified as crimes against humanity.

Take, for example, the case of a Canadian internet pharmacy, called RxNorth.com, which did business selling ‘Canadian’ (or so it claimed) medicines to American and other global consumers. Pharmaceutical company investigators and journalists pieced together that RxNorth.com actually sourced medicines from China — a country notorious for counterfeits. From there, the medicines ‘went to Hong Kong, then to the United Arab Emirates and the Bahamas’, before finally being mailed from the UK so as to disguise their circuitous route. RxNorth.com told its employees to conceal the fact from customers that their medicines were not from Canada. When the authorities acquired and tested some of RxNorth.com medicines, they found counterfeits, including of life-saving medicines.

RxNorth.com has since closed. Its founder, Andrew Strempler, lost his pharmacy licence and left Canada — but not before becoming a very rich man.

62 Ibid.
At last report, Strempler is in Panama, selling medicines from an office within a free trade zone on a small Caribbean island.  

Those who deal in counterfeits like Strempler should be brought to justice and if found guilty, severely punished. ‘I fully believe we are going to be chased around this globe’, Strempler once said — but actually he has enjoyed nothing but wealth and impunity. Shamefully, Canada refuses to say if it investigated Strempler, and took nearly a decade to strip his pharmacy licence; basically Canada shielded and protected him. The other countries in the supply chain — the United Arab Emirates, UK and the Bahamas — did investigate and/or prosecute the intermediaries, but lacked jurisdiction to pursue Strempler and RxNorth.com. As a frustrated American official said of the situation: ‘They are not regulated by the United States because we don’t have jurisdiction, they’re not regulated from Canada because they are shipping to the Bahamas, and they are not regulated by the UK for the same reason’. 

This, in a nutshell, is why the counterfeit medicine trade cannot be stopped except by treating it as an international crime. Its kingpins, like Strempler, do strange business. While normal companies work tirelessly to make their supply chains short and economical, RxNorth.com deliberately made its supply chains long and convoluted to provide fake provenance to consumers, to throw off the authorities, and to evade prosecution.

A supply chain of such intricate deceptiveness suggests, in our view, a resolute intention to commit crimes on a widespread, systematic basis. The words ‘widespread’ and ‘systematic’ have special importance in international criminal law: specifically, in Article 7(1) of the Rome Statute of the International Criminal Court (hereafter, ICC Statute), where they form part of the definition of ‘crimes against humanity’, and distinguish offences that so deeply shock the conscience that their perpetrators are hostis humani generis (enemies of humankind). In the jurisprudence, ‘widespread’ generally refers to the scale of the crime, while ‘systematic’ refers to its methodology. These terms are better explained in G. Mettraux, ‘Crimes Against Humanity in the Jurisprudence of the International Criminal Tribunals for the former Yugoslavia and for Rwanda’, 43 Harvard International Law Journal (2002) 237. See also, the International Criminal Tribunal for Rwanda (ICTR) Trial Chamber decision in Akayesu (ICTR-96-4-T), 2 September 1998, § 580: The concept of “widespread” may be defined as massive, frequent, large-scale action, carried out collectively with considerable seriousness and directed against a multiplicity of victims. The concept of “systematic” may be defined as thoroughly organized and
largest and most organized forms of medicine counterfeiting are not just widespread or systematic; actually they are often widespread and systematic. RxNorth.com sold counterfeit medicines on widespread scale to Americans, and had systematic plans to acquire Chinese counterfeits and fraudulently misrepresent them as ‘Canadian’ medicines. Where the counterfeiting of medicines is linked to organized crime, or a particular counterfeit recipe is found throughout a geographic area, or 100,000 counterfeit tablets are possessed by a single pharmacy, all of which has happened, it cannot be said that the perpetrators are petty criminals enmeshed in random or contained occurrences, for the crimes are too widespread in scale and systematic in method.

Moreover, the most egregious cases of medicine counterfeiting will also constitute attacks directed against a civilian population, which is another requirement of crimes against humanity. Under Article 7(2)(a) ICC Statute, such an attack entails ‘a course of conduct involving the multiple commission of a specified criminal act against civilians, pursuant to or in furtherance of a State or organizational policy to commit such attack’. The latter words should not be read as creating a requirement that a non-state organization must somehow share links with a state in a common policy concerning the attacks, and recent jurisprudence indicates that such a requirement does not exist. The ICC Pre-Trial Chamber, in authorizing an investigation in the Situation in the Republic of Kenya, decided that ‘organizations not linked to a State may … elaborate and carry out a policy to commit an attack against a civilian population’. That jurisprudence is consistent with the fact that in the ICC Statute, there are already various crimes against humanity which by their nature are committed by private criminal organizations, and rarely or never by states, such as trafficking in persons. In that respect, medicine counterfeiting is much the same.

These doctrinal considerations apply without distinction to all persons in the counterfeit medicine trade, whether kings or pawns. One’s hierarchy in the criminal enterprise is unimportant, but one’s mens rea of perpetrating the


73 Hall, supra note 33.


75 Prior to recent jurisprudence, there has been debate about applying crimes against humanity to non-state criminal organizations (e.g. terrorist groups), and as Schabas writes, ‘Whether crimes against humanity also reach into [this realm] ... can hardly be considered to be settled as a matter of law.’ See W. Schabas, ‘Punishment of Non-State Actors in Non-International Armed Conflict’, 26 Fordham International Law Journal (2002) 907, at 929.

76 Decision Pursuant to Article 15 of the Rome Statute on the Authorization of an Investigation into the Situation in the Republic of Kenya (ICC-01/09-19), Pre-Trial Chamber II, 31 March 2010, § 92 et seq.
criminal plan is important. The accused will have *mens rea* and be criminally responsible where he or she has ‘actual or constructive knowledge of the broader context of the attack, meaning that the accused must know that his act, even if small or seemingly insignificant when viewed in isolation, is part of a widespread or systematic attack on a civilian population and pursuant to some kind of policy or plan.’ If that criterion is met, the case law of international tribunals holds that one’s own motive for participation is irrelevant, and the accused ‘need not share the purpose or goal behind the attack.’

While it is our recommendation that medicine counterfeiting should be made a specific crime against humanity, currently the crime against humanity known as ‘extermination’ comes close to this idea. Extermination is defined in international law as ‘the intentional infliction of conditions of life, inter alia the deprivation of access to food and medicine, calculated to bring about the destruction of part of a population.’ No instance of medicine counterfeiting has ever exterminated a population, but even so, it is very notable that within the definition of extermination, it is already established in international law that denying access to a medicine can be a technique of attacking a civilian population, and can be at the root of a crime against humanity. Denying access to a medicine is exactly what counterfeiters do, when they supply a fake medicine lacking the therapeutic qualities of real medicine.

International law also possesses a miscellaneous category of crimes against humanity, comprising ‘other inhumane acts of a similar character intentionally causing great suffering, or serious injury to body or to mental or physical health.’ International tribunals have used the ‘other inhumane acts’ category liberally, so as to prosecute atrocities including: mutilation and other

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79 Ibid., §103.
80 Art. 7(2)(b) ICCSt.; It is of interest, here, to differentiate between extermination and murder — another act enumerated at Art. 7. In the *Akayesu* case, the ICTR Trial Chamber clarified that ‘[e]xtermination is a crime which by its very nature is directed against a group of individuals’ and that ‘it requires an element of mass destruction which is not required for murder’ (Judgment, *Akayesu* (ICTR-96-4-T), Trial Chamber, 2 September 1998, §§591–592).
82 Art. 7(1)(k) ICCSt.
types of severe bodily harm, beatings and other acts of violence, serious physical and mental injury, forcible transfer, inhumane and degrading treatment, forced prostitution and forced disappearance.\footnote{Judgment, \textit{Kvočka and others} (IT-98-30/1-T), Trial Chamber, 2 November 2001, § 208. The ICTY Trial Chamber in \textit{Kupreškić} declared that the category was intended to evade any notion that the list of enumerated crimes against humanity was exhaustive and that ‘a]n exhaustive categorization would merely create opportunities for evasion of the letter of the prohibition’} \footnote{Judgment, \textit{Krolović and others} (IT-95-16-T), Trial Chamber, 14 January 2000, § 563.}

Within this framework, it normally would not be difficult to establish that a medicine counterfeiter who intentionally switched fake medicines for real ones possessed criminal \textit{mens rea}, and performed an act capable of causing great suffering or serious injury to health. Importantly, it would not be a defence that the counterfeiter’s victims got sick but healed, or that their suffering passed, for the International Criminal Tribunal for the former Yugoslavia (ICTY) case law is clear that suffering ‘does not need to be lasting so long as it is real and serious.’\footnote{Judgment, \textit{Krnojelac} (IT-97-25-T), Trial Chamber, 15 March 2002, § 131.} Severity, not permanence, is the hallmark.

In summary, while there is not now a crime against humanity specifically of medicine counterfeiting, current legal doctrine definitely makes that possible. Our belief is that such a crime against humanity should be used very sparingly and only in the most egregious counterfeiting cases which meet the legal standard of widespread or systematic attacks on a civilian population; it should never be deployed in lesser, pedestrian cases of medicine counterfeiting, which are the vast majority. But for those whose crimes reach the highest degrees, and who knowingly participate in organized criminal enterprises that can sicken or kill multitudes, the law must possess and occasionally use its most exceptional measures — for to prosecute that sort of criminal as \textit{hostis humani generis} is truly appropriate.

\textbf{D. Goal Four: Address Jurisdictional Gaps When Counterfeit Medicine is Internationally Traded}

Jurisdiction to prosecute crimes is usually accorded to the state on whose territory the criminal act was committed. Thus national criminal laws for fraud, homicide, or perhaps even medicine counterfeiting, are commonplace, and making use of those laws to prosecute an offender of those laws in one’s own territory is uncontroversial.

But prosecuting counterfeiters who act or dwell extraterritorially is harder, because most countries presume their criminal law to have territorial limits. For example, in Canada, section 6(2) of the \textit{Criminal Code} provides that ‘no person shall be convicted or discharged of an offence committed outside Canada’ except where Canadian law makes a permissive exception.\footnote{\textit{Criminal Code of Canada}, R.S.C. 1985, c. C-46.}
Yet, the territorial limit to jurisdiction is not one that international law requires. The Permanent Court of International Justice in the *Lotus* case entertained the question of territorial limits nearly a century ago, and decided:

Far from laying down a general prohibition to the effect that States may not extend the application of their laws and the jurisdiction of their courts to persons, property and acts outside their territory, [international law] leaves them in this respect a wide measure of discretion, which is only limited in certain cases by prohibitive rules; as regards other cases, every State remains free to adopt the principles which it regards as best and most suitable.86

The *Lotus* case is authority that states may criminalize and punish acts occurring outside their territory. Where states consider it ‘best and most suitable’, they may seek the prosecution of offenders acting or dwelling extraterritorially, and request the assistance of other states to arrest and extradite those persons. Where states think a problem pressing or egregious enough, they may even choose to exercise universal jurisdiction — that is, jurisdiction without a nexus between the prosecuting state and the offence, the criminal, or the victim.87 No doubt, such decisions to broaden the state’s jurisdiction are politically difficult and are never taken lightly for diplomatic reasons, but as far as international law is concerned, they are allowed.

In the next three subsections, we discuss how a treaty can help make the international pursuit of those who trade in counterfeit medicines easier. Specifically, treaties can oblige countries not to be havens for counterfeiting, can lend credibility to the otherwise difficult imposition of universal jurisdiction, and can ease the work of police and prosecutors across international borders.

1. The *Aut dedere aut judicare* Clause

International criminal law is only as useful as the quality of international cooperation that makes it enforceable. Thus, treaties concerned with international crimes spell out the forms of cooperation necessary to prosecute offenders within their territory, or to extradite offenders to face trial elsewhere. The duty either to extradite or to prosecute is known as the *aut dedere aut judicare* principle, and as others note:

[It] is contained in a number of multilateral treaties aimed at securing international cooperation in the suppression of certain kinds of criminal conduct. This obligation essentially requires a state which has hold of someone who has committed a crime of international concern either to extradite the offender to another state which is prepared to try him or else to take steps to have him tried before its own courts.88

86 *The Case of the S.S. ‘Lotus’ (France v. Turkey)* (1927) PCIJ Ser. A. No. 10, at 19.
88 Bassiouni, *supra* note 22, at 3.
The preference whether to extradite or to prosecute has changed through time. Early in the last century, extradition was preferred over prosecution. For example, Article 9 of the 1929 Currency Convention stipulates that: ‘[t]he obligation to take [criminal] proceedings is subject to the condition that extradition has been requested and that the country to which application is made cannot hand over the person accused for some reason which has no connection with the offence.’

More recent treaties level the two options, and express no preference as between extradition and prosecution. States therefore choose extradition or prosecution in accordance with their domestic criminal law — but they cannot do nothing. For example, Article 7 of the 1971 Convention for the Suppression of Unlawful Seizure of Aircraft (the ‘Hijacking Convention’) reads that:

The Contracting State in the territory of which the alleged offender is found shall, if it does not extradite him, be obliged, without exception whatsoever and whether or not the offence was committed in its territory, to submit the case to its competent authorities for the purpose of prosecution. Those authorities shall take their decision in the same manner as in the case of any ordinary offence of a serious nature under the law of that State.

Thus, the aut dedere aut judicare principle provides that the mere presence of a currency counterfeiter or aircraft hijacker on a particular state’s territory obliges that state to prosecute, or if it is unable or unwilling, to extradite; impunity is not an option.

Extradition, however, is not straightforward. To begin with, there is a widespread custom or rule in some countries that extradition requires ‘double criminality’, meaning that the criminal offence exists in substantially equivalent terms in both the requesting and the requested state. The double criminality requirement highlights yet again why a treaty is so crucially needed, for without international agreement on the definition of medicine counterfeiting and its associated criminal offences, extradition is often made impossible. Extradition also entails a distinct legal process — an extradition hearing — quite apart from the trial of the offence. These extradition hearings may be governed by special legal regimes. For example, between Canada and the United States, the aut dedere aut judicare principle of the Hijacking Convention is given effect thanks to wording in a bilateral extradition treaty.


90 Currency Convention, supra note 6, at Art. 9.

91 Hijacking Convention, supra note 41, at Art. 7.


93 The Treaty on Extradition Between the Government of Canada and the Government of the United States of America, CTS 1976 No. 3, states in its Schedule that it applies to extradite persons alleged to have carried out ‘any unlawful seizure or exercise of control of an aircraft, by force or violence or threat of force or violence, or by any other form of intimidation, on board such aircraft.’
Therefore, any treaty against medicine counterfeiting containing aut dedere aut judicare language would need affirmation in many extradition treaties such as this one, or it would lack efficacy.

The prosecution option is easier to implement. Assuming that a state’s domestic criminal law prohibits the offences set out in a counterfeit medicine treaty, and the treaty contains aut dedere aut judicare language, then normally the state also will make an exception and extend its domestic criminal law to offences occurring outside its territory. For example, in Germany, under Article 6(9) of the German Penal Code, ‘German criminal law shall further apply, regardless of the law of the place of their commission, to... acts which, on the basis of an international agreement binding on the Federal Republic of Germany, shall also be prosecuted if they are committed abroad.’ Most if not all countries have an exception of this kind for treaty-based offences — even Canada, where the law expressly contains a general rule of territorial jurisdiction, as discussed earlier.

2. Universal Jurisdiction

There are, however, cases where the aut dedere aut judicare principle is not enough. That principle stipulates what a country must do when it apprehends an offender in its territory — extradite or prosecute — but it is silent on the threshold question of which country is wronged and in a position to request extradition or to undertake prosecution. These are closely related, but separate, jurisdictional considerations.

Recall the Lotus case, which says that legally countries may decide within their discretion when to apply their laws extraterritorially. Normally that discretion is held within diplomatically comfortable limits, by insisting on a factual nexus between the accused’s crimes and the state that is requesting extradition or undertaking prosecution: e.g. the accused is on its territory, or harmed its citizens or their property (jurisdiction ratione loci and ratione personae, respectively). Where that factual nexus is missing, the state’s decision to request extradition or undertake prosecution normally would be met coolly, unless by prior international agreement — that is, by treaty — it was understood no nexus is needed.

Simply put, universal jurisdiction is that agreed-upon absence of a need for a nexus. It is found in numerous international criminal law treaties. Legal experts define universal jurisdiction as ‘criminal jurisdiction based solely on the nature of the crime, without regard to where the crime was committed, the nationality of the alleged or convicted perpetrator, the nationality of...’
the victim, or any other connection to the state exercising such jurisdiction.'96 Universal jurisdiction means that ‘all States’ — not just those with a nexus — can exercise their jurisdiction in prosecuting a perpetrator ‘without regard to where the crime was committed.’97 Importantly, universal jurisdiction is accepted only as a last resort, to avoid giving offenders impunity when a better-situated country is unable or unwilling to enforce the law.98

With regard to the counterfeiting of medicines, universal jurisdiction fills a need had by third-party states, being neither the source nor the destination of a counterfeit — for example, a state whose territory is used as a trans-shipment point. Currently, if a third-party state detects a shipment of counterfeits on its territory, it may impound the shipment, and it may notify the source and destination states — but that is all it is likely to do. The counterfeit is neither made nor supplied on its territory, and does not harm its citizens. Thus the third-party state would be criticized for overreach if it took its Lotus discretion to the fullest and prosecuted these extraterritorial crimes.

What this means, practically speaking, is that the middle of the counterfeit medicine supply chain is largely without law enforcement, because there is not the usual factual nexus. Ironically, that nexus only reappears when the counterfeit medicine reaches its destination and is supplied to patients, possibly sickening or killing them. Thus in its current, narrow jurisdictional view, the law today is responsible for heightening the risk of criminal injury by counterfeit medicines — a bad outcome.

To solve this problem, medicine counterfeiting needs the same treatment as currency counterfeiting, where the 1929 Currency Convention denies impunity to criminal offenders, regardless of nationality, and regardless of where the crime occurs — basically, universal jurisdiction. Article 18 of the Currency Convention reads that crimes ‘should in each country, without ever being allowed impunity, be defined, prosecuted and punished’. While it falls slightly short of totally ‘universal’ jurisdiction because it only binds states party to the Convention, the plain meaning of that passage is to reject impunity in every circumstance, including those where jurisdiction ratione loci and ratione persona

e do not apply.

Were there a ‘no impunity’ rule for counterfeit medicines — and that is not too radical a suggestion, given that international law reached this point for counterfeit currency almost a century ago — it would fill the omission of indolent or corrupt governments that tolerate the counterfeit medicine trade. A country like Canada, which never showed an inclination to criminally investigate Andrew Strempler or the other players in the RxNorth.com counterfeit medicine ring, much less prosecute them, would have its omission filled by investigators and prosecutors exercising universal jurisdiction in more serious

97 Ibid.
countries such as the United Arab Emirates, UK and the Bahamas, which acted in that case. For if a country like Canada can turn a blind eye or coddle counterfeit traders on its own territory, while depriving concerned third-party countries of the jurisdiction to bring highly organized international criminals to justice, the current international legal regime must be incredibly backwards and unsatisfactory.

3. Ancillary Legal Assistance

Quite apart from the high level decisions whether a state chooses extradition or prosecution to deal with an offender in its territory, or invokes universal jurisdiction to pursue criminals sheltered by another state, there is a need for intergovernmental cooperation to achieve successful prosecutions. Cooperation may take the form of furnishing real or testimonial evidence, sharing police investigations, or engaging in joint surveillance or sting operations, etc. Most international criminal law treaties make this kind of legal assistance mandatory.\(^99\) For example, the Hijacking Convention reads that ‘[c]ontracting States shall afford one another the greatest measure of assistance in connection with criminal proceedings brought in respect of the offence and other [prohibited] acts ...’.\(^100\)

The need for such international cooperation is greatest when, as is often the case, the source country where a counterfeit drug is manufactured is unaware of any crime, until the counterfeit is exported and discovered in a recipient country.

Consider what may be history’s most appalling example of counterfeiting, because the criminals targeted children’s vaccines. During the 1995 meningitis epidemic in Niger that we mentioned in the footnotes earlier, Niger launched a vaccination campaign, and received a donation of 88,000 vaccines from neighbouring Nigeria, courtesy of pharmaceutical companies Pasteur Mérieux and SmithKline Beecham.\(^101\) Only once the immunization campaign began did workers from Médecins Sans Frontières notice that the vaccine powder behaved strangely when dissolved, which led to the terrible discovery that someone had switched the real vaccines supplied by the companies with perfect-looking fakes, containing no active ingredient at all. Sadly, by then, 60,000 people had been inoculated. Thousands died.

Clearly, those who switched the real for the fake vaccines committed crimes — even crimes that would, if the law existed, count as crimes against humanity. But unless police and prosecutors are made to give legal assistance across borders, appropriate convictions can be hard to achieve. Imagine that, as seems likely, the act of fraudulently switching the vaccines happened in one country (Nigeria), while the attack on the civilian population only came to fruition in another country (Niger). Without international cooperation, odds are

99 Bassiouni, supra note 36.
100 Hijacking Convention, supra note 41, at Art. 10(1).
101 Pinel, supra note 30.
very slender that the authorities in Niger could do more than prove minor crimes within their own territory, such as fraud or trademark infringement.\textsuperscript{102} Even if the case were prosecuted as the severer offence of medicine counterfeiting, Nigeria’s maximum fine was around US$ 70 — hardly meaningful as punishment.\textsuperscript{103}

On every level, this episode teaches the daunting realities that the justice system faces, when there is no treaty and hence no international agreement to pursue and punish medicine counterfeiting as the extremely dangerous organized crime that it is.\textsuperscript{104} The international community can forget about stopping this venal trade, unless it is serious about putting that treaty in place.

4. WHO Authority to Negotiate a Treaty Against the Counterfeiting of Medicines

Treaties need a forum in which to be negotiated; this political reality can be as daunting as deciding on a substantive legal text itself. The obvious reason why there is not a counterfeit medicine treaty, when there is a decades-old counterfeit currency treaty and numerous anti-terrorism treaties, is that diplomats have innumerable fora to meet and discuss the worst financial or security contingencies, but only a single forum — the World Health Organization — to talk about the realities of health, illness and death.

As unsatisfactory and narrow-minded as this is, it simplifies tactical choices. Making use of WHO as a negotiating forum requires a diplomatic understanding of the levers of power within WHO. To begin with, there is the right to health, which is enshrined in most of the internationally ratified human rights instruments, and which is always evocative when trying to drive an agenda at WHO.\textsuperscript{105} Counterfeit medicines are, of course, anathema to the

\textsuperscript{102} Even that, however, did not happen, and SmithKline Beecham was criticized for not taking legal action — even for trademark infringement — so as not to hamper trade relations with Nigeria. See A. Raufu, ‘Nigeria leads fight against killer counterfeit drugs’, \textit{84 Bulletin of the World Health Organization} (2006) 685–764.


\textsuperscript{104} This is not to say that successful cooperation cannot occur between nations over counterfeit drugs, just that it is rare and not systematic. Nigeria is cooperating with both the Chinese and Indian governments to attempt to bring counterfeiters to book; personal communication by one of the authors (Bate) with Paul Orhii, the Director of the Nigerian anticounterfeit drug agency (NAFDAC), 26 February 2010.

\textsuperscript{105} See, for example: \textit{Universal Declaration of Human Rights}, GA Res. 217 A (III), 1948 at Art. 25 which stipulates that ‘[e]veryone has the right to a standard of living adequate for the health and well-being of himself and of his family, including \ldots medical care’; \textit{International Covenant on Economic, Social and Cultural Rights}, GA Res. 2200A (XXI), 1976 at Section 12.2 which enshrines ‘the right of everyone to the enjoyment of the highest attainable standard of physical and mental health’. This encapsulates, inter alia, ‘the prevention, treatment and control of epidemic \ldots diseases’ and ‘the creation of conditions which would assure to all medical service and medical attention in the event of sickness’; \textit{Convention on the Rights of the Child}, GA Res. 25, 1990 at Section 24.
right to health. There is also the WHO Constitution of 1948, which establishes the organization’s raison d’être as ‘the attainment by all peoples of the highest possible level of health’.106 The WHO Constitution grants the organization numerous competences, the most important of which for present purposes is the power ‘to develop, establish and promote international standards with respect to … pharmaceutical … products’.107 The Constitution also permits WHO ‘to propose conventions, agreements, and regulations, and make recommendations with respect to international health matters’.108

Thus WHO is a suitable institution within which new international law for health can be proposed, negotiated and constructed. Others have noted that it is held back both by a bureaucratic culture of conservatism, and a historical lack of attention to the possibilities of international law.109 It also is handicapped by its own Constitution, which requires a supermajority of two-thirds of the WHO member states to adopt a treaty.110 These criticisms have some merit, but they are not necessarily impasses when compared to the alternatives. Even a barrier as difficult as a supermajority vote may be less daunting than the onerous, probably impossible task of convening an ad hoc conference of the parties to negotiate a treaty outside of WHO.

WHO has exercised its treaty-making power only once, for the Framework Convention on Tobacco Control (‘FCTC’).111 The preamble to the FCTC acknowledges a number of issues of resemblance with counterfeiting. Tobacco addiction is labelled ‘a global problem with serious consequences for public health that calls for the widest possible international cooperation’.112 In particular, the FCTC calls for ‘cooperative action ... to eliminate all forms of illicit trade in cigarettes and other tobacco products, including’ — and this is an interesting addition — ‘illicit manufacturing and counterfeiting’.113

As this article is being written, the FCTC member states are negotiating a Draft Protocol to Eliminate Illicit Trade of Tobacco Products, which aims to give shape to their anti-counterfeiting intent, and their ways of international cooperation.114 The Draft Protocol’s language contains several (but not all) of the features that this paper advocates for a treaty to stop medicine counterfeiting.

106 Constitution of the World Health Organization, 14 UNTS No. 185, 7 April 1948, at Art. 1 (hereafter the ‘WHO Constitution’).
107 Ibid., at Art. 2(u).
108 WHO Constitution, supra note 106, at Art. 2(k).
112 Ibid., at preamble.
113 Ibid., at preamble.
114 Draft Protocol to Eliminate Illicit Trade of Tobacco Products, UN Doc. FCTC/COP/INB-IT/4/7, 14–21 March 2010.
There are provisions to define criminal offences including ‘counterfeiting tobacco products’ (Article 12), to govern international legal assistance (Articles 21, 24, 28 and 30), and to trigger aut dedere aut judicare obligations (Article 31).115

We propose that if WHO’s treaty power can be aimed at the scourge of counterfeit cigarettes, the same can be true for counterfeit medicines. The history of how the FCTC came to be international law is instructive, and is worth copying.

The first step toward the FCTC began with a resolution of the World Health Assembly, which is the annual congress of WHO member states. In 1996, the Assembly passed a Resolution (WHA49.17) requesting the WHO Director-General to initiate the development of the FCTC. Crucially, this Resolution offered no detailed roadmap toward a treaty, and to avoid controversy, it stuck to the most anodyne and general terms: the entire Resolution was only one page long!116

WHO struggled for a time to know what to do with the Resolution’s open-ended mandate. Two years later, the incoming WHO Director-General, Dr Gro Harlem Brundtland, declared global tobacco control a priority, and launched a work programme that returned the issue to the World Health Assembly in 1999. This time, the Assembly passed a more detailed Resolution (WHA52.18), and established both a FCTC Working Group and an Intergovernmental Negotiating Body.117 The Working Group began meeting and the following year delivered a report to the World Health Assembly, which in a third Resolution (WHA53.16) authorized WHO to begin negotiating the FCTC.118

Thus in just three years, WHO and its member states turned the idea of a treaty against tobacco from a skeletal notion, so minimal as to fit on a single page, into a mandate to negotiate a treaty. It then took another three years to reach agreement on the FCTC text, which has proved highly successful. There are 171 parties to the treaty at this writing.

There are salutary lessons in the FCTC experience. Creating a public health treaty should never be done with a fully-formed version of the treaty already in hand — the error made by the Council of Europe with its deeply flawed

115 The only notable difference is that, unlike for medicines, counterfeit tobaccos cannot be blamed for any distinct attack on a civilian population, certainly no more so than legitimate tobaccos which also kill efficiently. Hence it is inappropriate to use the extraordinary doctrines of crimes against humanity or universal jurisdiction to criminalize counterfeit tobacco, since it is tobacco primarily, and counterfeiting only secondarily, which causes harm, and these are not found in the Draft Protocol.
116 International framework convention for tobacco control, UN Doc. WHA49.17, 25 May 1996.
117 Towards a WHO framework convention on tobacco control, UN Doc. WHA52.18, 24 May 1999.
draft. Nor should it be strangled in the crib by objections over what the final treaty might say — the error made by Brazil and India in their hasty objection to WHO’s anti-counterfeiting efforts. Much wiser was the decision of the World Health Assembly to embark on the FCTC project with little more than a notion, and to invite countries to bring forward their concerns and objections to the Intergovernmental Negotiating Body. No credence at all can be given to the thought that countries as sophisticated as Brazil and India, having some of the most talented diplomats in the world, could not hold their own in such negotiations.

We emphasize: by proceeding this way, incrementally and from the most rudimentary initial agreement imaginable — an agreement only that tobacco is bad for health — it was possible in due course for WHO to create a fully fledged tobacco treaty. The same outcome probably would have been unreachable had countries delivered their *fait accompli* for a treaty, or waged battles about tobacco from the first day, rather than showing the restraint necessary to reflect and to safeguard their interests in the detailed process of negotiating the treaty. If one agrees that a similarly basic consensus is possible for counterfeit medicines — that they are bad for health — then one has to agree that a treaty is, after a fashion, certainly possible.

### 5. Conclusion

To protect the global community against counterfeit medicines, one has to arrest, prosecute and punish the counterfeiters — that is obvious. But doing so is currently fraught, because few countries take the crime seriously, and there is no treaty to underscore the gravity of the crime or to oblige international cooperation to bring perpetrators to justice.

This article has championed the creating of a treaty against counterfeiting, and argued that all its necessary parts — the definition of counterfeiting, the preconditions for prosecuting the most egregious counterfeiting cases as crimes against humanity, the doctrines of *aut dedere aut judicare* or universal jurisdiction to fill the jurisdictional gaps — are already well established in the law, and all that remains is to negotiate a treaty that stitches these parts together into a coherent whole. That this is feasible and not too ambitious is proved by other treaties such as the Currency Convention or the Hijacking Convention (among many others), the refinement of crimes against humanity doctrine in ICTY and ICTR jurisprudence, and of course the public health precedent of the *Framework Convention on Tobacco Control* and its emerging Draft Protocol. We are not proposing anything sweepingly ‘new’, so much as borrowing and creatively reassembling the best ideas that these forerunners offer.

This article also provides evidence that counterfeiting of medicines is a global public health crisis — one that will escalate so long as efforts against it remain woefully uncoordinated. When asked why no international treaty against counterfeiting of medicines exists as there is for tobacco, a WHO
representative pointed the finger at a lack of political will. However, that is a somewhat mistaken assessment, because some countries — notably Brazil and India — expend considerable political will, albeit in the misguided direction of halting WHO’s necessary efforts against counterfeits. Their resistance arises from the understandable worry, backed up by some troubling occurrences for which the European Union and the Council of Europe countries bear responsibility, that anti-counterfeiting measures conceal a covert intellectual property agenda. Competing resolutions put forward at the 2010 World Health Assembly underscore that countries are not lacking the will to address counterfeit medicines — but they very unfortunately are deploying that will against one another, rather than against the problem.

The public interest must not be held back by this narrow calculus of fear. Individual countries surely have this conviction, but collectively, they are failing to harness it into constructive work such as to negotiate a treaty, and never more so than at the 2010 World Health Assembly. Meanwhile, counterfeit medicines go on killing their citizens; absolutely no country is immune. A more dismal commentary on the contemporary state of public health diplomacy is scarcely imaginable.

It is hoped that this paper will spawn constructive debate and that it will be recognized that — as in 1929 when currency counterfeiting was curbed by international action — an opportunity exists to address the growing criminality and impunity of medicine counterfeiters. Justice for the sick or dead victims of counterfeit medicines requires it.