

## **Resolving dysfunctional pharmaceutical arbitrage and counterfeit drugs through the proposed Pharmaceutical R&D Treaty**

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**Abstract:** One obstacle to the widespread rollout of compulsory licensure or greatly expanded access to essential pharmaceuticals is the fear that drugs intended for the poor will be diverted into high income markets, undermining pharmaceutical profits and ultimately, pharmaceutical R&D. In fact, this form of dysfunctional pharmaceutical arbitrage is rarely observed. A much greater threat to both pharmaceutical profits and public health is the production and sale of counterfeit drugs. The proposed R&D Treaty would eliminate the threat of dysfunctional arbitrage and dramatically reduce incentives to counterfeit.

### **I. Dysfunctional Pharmaceutical Arbitrage of AIDS Drugs**

#### **A. Dysfunctional Arbitrage is Rarely Observed**

International pharmaceutical arbitrage (or parallel trade) seems to pose a plausible risk to pharmaceutical companies and essential access programs for high-cost drugs. The consumer retail price of a kilogram of the active ingredients in Combivir<sup>1</sup> is about \$20,000 in the U.S., but sells for as little as \$612 in Hyderabad and sub-Saharan Africa.<sup>2</sup> This price differential is equal to about twenty-five times the average per capita income in the lowest income countries. Neo-classical economic theory predicts that entrepreneurs<sup>3</sup> will divert these drugs from the poor and export them to wealthy countries where they will fetch higher prices. Domestic arbitrage occurs within the U.S. at much lower thresholds. Much smaller price differentials have instigated significant arbitrage within the US market,<sup>4</sup> a billion dollar trade flow from Canada to the US,<sup>5</sup> and a multi-

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<sup>1</sup> Combivir is GlaxoSmithKline's best selling ARV drug, and the company holds a forty-five percent global market share in HIV/AIDS drugs. See Gautam Naik, *Glaxo's HIV Drugs Come Under Pressure: Competition, Calls for Price Cuts Weakens Company's Dominance of Maturing Market*, WALL ST. J., Sept. 22, 2003, at B3; GLAXOSMITHKLINE PLC, 2003 ANNUAL REPORT, Form 20-F, at 63 (total of all HIV sales), available at <http://www.sec.gov/edgar/searchedgar/companysearch.html>.

<sup>2</sup> The active ingredients in Combivir total 450 mg per tablet. A kilogram of active ingredients will create approximately 2222 tablets. The retail price of 2222 tablets of Combivir in the U.S. retail market exceeds \$20,000. See <http://www.drugstore.com> (visited July 9, 2004).

<sup>3</sup> Or smugglers, depending upon your perspective.

<sup>4</sup> Jackie Judd, Senior Fellow with the Kaiser Family Foundation Speaks with Gilbert M. Gaul and Mary Pat Flaherty, Washington Post Staff Writers on a Five-Day Special Report Called "Pharmaceutical Roulette," that Focuses on Prescription Drug Safety Issues in the United States, (Kaiser Family Foundation transcript, Oct. 24, 2003), <http://www.kff.org> (describing significant arbitrage diversion within the U.S. market taking advantage of relatively modest price differentials).

<sup>5</sup> Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation In International Pharmaceutical Markets*, 5 Yale J. Health Policy, Law & Ethics, at §VII (pending, 2004).

billion euro parallel trade in Europe.<sup>6</sup> Since the great majority of the world's AIDS patients are in poorer countries, if only a small percentage was diverted, significant volumes of ARVs could flow into high income country markets.<sup>7</sup>

Further, criminal organizations might be attracted to the profits to be found in dysfunctional pharmaceutical arbitrage. The pricing ratios operating in the illegal cocaine market are broadly similar to ARV pricing ratios. The U.S. wholesale price of a kilogram of cocaine ranges from \$13,000 to \$25,000,<sup>8</sup> comparable to the U.S. retail value of a kilogram of the active ingredients in Combivir.<sup>9</sup> The U.S. retail price of a gram of cocaine is about \$100.<sup>10</sup> The retail price of cocaine in Columbia is between three dollars and five dollars per gram,<sup>11</sup> yielding a ratio of about 25:1.<sup>12</sup> Since ARV arbitrage offers potentially higher profits than cocaine trafficking, one might expect criminal enterprises to enter the ARV business, especially since the risk of apprehension and punishment are so severe for cocaine trafficking, but relatively modest for prescription drug counterfeiting.<sup>13</sup>

Given these facts, it would be striking if dysfunctional ARV arbitrage did not occur. And yet reality appears to depart from the neo-classical economic model, for there is quite limited evidence of dysfunctional arbitrage. It is notable that generic drugs have been produced in India for decades without apparently infiltrating or undermining Western markets.<sup>14</sup> As of April 2002, both the European Commission and the

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<sup>6</sup> PETER WEST & JAMES MAHON, BENEFITS TO PAYERS AND PATIENTS FROM PARALLEL TRADE (York Health Economics Consortium Working Paper, May 2003); *see also* PANOS KANAVOS ET AL., THE ECONOMIC IMPACT OF PHARMACEUTICAL PARALLEL TRADE: A STAKEHOLDER ANALYSIS 15-16 (Special Research Paper, London School of Economics and Political Science, Jan. 2004) *available at* <http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/documents/otherpaperseries.htm>.

<sup>7</sup> The United States is a likely target market. The EU may not be as vulnerable to diversion because most of its citizens are covered by a third party prescription drug benefit, and may not as price sensitive. *See, e.g.,* DG TRADE, EUROPEAN UNION, TIERED PRICING FOR MEDICINES EXPORTED TO DEVELOPING COUNTRIES, MEASURES TO PREVENT THEIR RE-IMPORTATION INTO THE EC MARKET AND TARIFFS IN DEVELOPING COUNTRIES (EU Working Document, Apr. 22, 2002), at §3.3. This conclusion might be true for ultimate consumers, but European intermediaries such as parallel traders could seek arbitrage earnings from this trade. The available evidence suggests that European parallel traders are closely scrutinized and do not knowingly participate in illegal diversions. *See, e.g.,* Glaxo Group Ltd v. Dowelhurst Ltd, [2004] E.T.M.R. 39 (July 31, 2003) *available at* 2003 WL 21729286.

<sup>8</sup> U.S. Drug Enforcement Administration, Drug Trafficking in the United States, Sept. 2001, *available at* <http://www.usdoj.gov/dea/pubs/intel/01020/index.html> (visited July 7, 2004) (2000 data). Retail prices per gram are significantly higher, particularly for smaller quantities.

<sup>9</sup> *See supra* note 2.

<sup>10</sup> OFFICE OF NATIONAL DRUG CONTROL POLICY, TRENDS IN COCAINE PRICES (1981-2000) (price per gram for purchase of 1 to 10 grams). The UK price for a gram in similar lots is around £ 50. Independent Drug Monitoring Unit Ltd., UK Drug Prices 2002, <http://www.idmu.co.uk/prices02.htm>.

<sup>11</sup> From a hopelessly anecdotal source, a travel journal of an American using drugs in Columbia. David Ashley, Cocaine in Columbia, <http://www.erowid.org/experiences/exp.php?ID=1796> (last visited—the website, not Columbia—July 9, 2004).

<sup>12</sup> The numerator is \$100 per gram and the denominator is \$4 per gram.

<sup>13</sup> Alliance Against Counterfeiting & Piracy, Proving the Connection: Links Between Intellectual Property Theft and Organised Crime 7-8 (circa 2002) *available at* [www.a-cg.com](http://www.a-cg.com) (visited Oct. 7, 2004).

<sup>14</sup> One would expect some significant reported court cases over the past 20 years on illegal imports of Indian and other unlicensed generics if the problem was widespread. Andrew Farlow of Oxford finds little

pharmaceutical companies acknowledged that pharmaceutical arbitrage from poor countries into high income countries was “still largely theoretical.”<sup>15</sup> Only six months later, GlaxoSmithKline, the patent holder for several important AIDS drugs, brought the sensational charge that 36000 packages of HIV/AIDS medicines worth approximately US\$18 million were found to have been diverted from West Africa to the EU.<sup>16</sup> GlaxoSmithKline sued several participants in the transactions, including a legal parallel trader in pharmaceuticals, Dowelhurst Ltd, for trademark infringement.<sup>17</sup>

The Dowelhurst case unearthed several remarkable facts which undercut the public relations spin that Glaxo had put on the case. First, 99% of the packages handled by Dowelhurst were not part of Glaxo’s charitable access initiative for Africa, but were ordinary commercial sales to Africa, at prices approximating EU prices.<sup>18</sup> The Deputy Judge expressed keen displeasure upon finally understanding this point, as he had been led to believe that all of the packages were destined for charitable access programs.<sup>19</sup> Second, 99% of the packages had been sold within Europe, to addresses in France, and probably never made the trip to Africa.<sup>20</sup> The alleged diversions occurred in Europe, not in Africa. I say alleged diversions, because the case clearly says that the resale of the drugs was not proscribed by contract.<sup>21</sup> Third, by placing the packages into commerce within Europe, Glaxo exhausted its IP rights within Europe.<sup>22</sup> Finally, Glaxo sold the packages without any attempt to label them as ineligible for sale or re-importation into the EU. They were packaged in French, with EMEA license codes and nothing was done to indicate they were destined for a charitable access program.<sup>23</sup> Legal European parallel traders were led to believe the drugs had been lawfully placed into European commerce. Indeed, the defendant suggested that Glaxo did so deliberately in order to generate the

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evidence of diversion, Andrew Farlow, Costs of Monopoly Pricing Under Patent Protection, Presentation at Columbia University, Dec. 4, 2003, slide 19.

<sup>15</sup> DG Trade, *supra* note 7, at §3.3.

<sup>16</sup> A sample of media reports from three continents in October 2002 include: Gautam Naik, *Profiteers Divert to Europe AIDS Drugs Meant for Africa*, Asian Wall St. J., Oct. 7, 2002, at A9; Sarah Boseley & Rory Carroll, *Profiteers Resell Africa’s Cheap Aids Drugs*, The Guardian, Oct. 4, 2002, at P1; *HIV Drugs For Africa Diverted to Europe; Probe Targets Wholesalers*, Wash. Post, Oct. 3, 2002, at A10. See also Graham Dukes, Interim Report of Task Force 5 WORKING GROUP ON ACCESS TO ESSENTIAL MEDICINES 32 (UN Millennium Project, Feb. 1, 2004), at 50, n.1.

<sup>17</sup> *Glaxo Group Ltd v. Dowelhurst Ltd*, [2004] E.T.M.R. 39 (July 31, 2003) available at 2003 WL 21729286.

<sup>18</sup> *Id.* at ¶36.

<sup>19</sup> *Id.* at ¶46. The Deputy Judge imposed over 90% of the litigation costs on Glaxo, in part because he felt misled. *Glaxo Group Limited v. Dowelhurst Limited*, [2003] E.W.H.C. 3060 (High Court, Ch. Div. 2003) available at 2003 WL 23014797, at ¶¶ 10, 17.

<sup>20</sup> *Glaxo Group Ltd v. Dowelhurst Ltd*, [2004] E.T.M.R. 39 (July 31, 2003) available at 2003 WL 21729286, at ¶¶ 66-76. Only 1% of the packages had actually been sold to a buyer in Africa, namely the packages involved in the access program.

<sup>21</sup> *Id.* at ¶ 39.

<sup>22</sup> *Id.* at ¶¶ 66-76. On appeal, the Court of Appeal upheld the Deputy Judge’s rulings on summary judgment, permitting the trial to proceed on the question of compliance with EU rules for pharmaceutical parallel trade. *Glaxo Group Limited v. Dowelhurst Limited*, [2004] E.W.C.A. Civ. 290 (Court of Appeal, Civ. Div., 2004) available at 2004 WL 412961. Specifically, the Court of Appeals upheld the exhaustion rule on 100% of the packages rather than just 99%. *Id.* at ¶¶ 30-40.

<sup>23</sup> *Glaxo Group Ltd v. Dowelhurst Ltd*, [2004] E.T.M.R. 39 (July 31, 2003) available at 2003 WL 21729286, at ¶¶ 46-50.

resulting publicity.<sup>24</sup> Within three weeks of the Glaxo diversion story, the European Commission announced plans to issue a regulation to curb such diversions.<sup>25</sup> The 2003 Council Regulation promptly required many modifications to packages and pills destined for essential access programs.<sup>26</sup>

The only other major media report of diversion of essential access drugs was in *Forbes* in April 2004, noting diversions in Indonesia, Chile and Lebanon.<sup>27</sup> This story parroted PhRMA's spin on the 2002 Glaxo case in Europe, but failed to mention any of the facts from the Dowelhurst case discussed above. The source of the report in Indonesia was a survey in Jakarta by a respected local health group, which found many donated drugs being either sold on the black market in Jakarta or available in the public health clinics for a price in excess of the statutory maximum.<sup>28</sup> This is a simple case of local corruption, and there is no evidence that the drugs are leaving the immediate market. This situation might be regrettable, but it is not dysfunctional arbitrage; it does not replace commercial markets in the high income countries. Similar local diversions occur in the United States.<sup>29</sup> The reports from Chile and Lebanon are sourced exclusively from local affiliates of PhRMA. Neither report was substantiated; nor do they suggest dysfunctional arbitrage as opposed to local movement of drugs within low or medium income countries. In sum, empirical evidence to date does not indicate a sizable arbitrage market in ARVs from low income markets into the high income countries.

## **B. Effective Measures to Hinder Dysfunctional Arbitrage**

Possible reasons for the dearth of empirical evidence of dysfunctional pharmaceutical arbitrage include moral and legal sanctions within high income market countries. The impact of these norms is significant in pharmaceutical arbitrage markets. When pharmaceutical arbitrage is unmistakably legal, it flourishes, even at low differential pricing ratios. For example, the EU follows the "community exhaustion" rule, permitting parallel trade in patented and trademarked products within the European Economic Area. Differential pricing ratios of less than 2:1 have been sufficient to create a multi-billion euro legal arbitrage market within the EU,<sup>30</sup> subject to complex rules on repackaging and trademark infringement devised by the European Commission and the

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<sup>24</sup> *Id.* at ¶¶51-53.

<sup>25</sup> *EU/WTO – Plan to Curb Illicit Medicines Trade*, Eur. Rep. Oct. 26, 2002 (no page number available) available at 2002 WL 13768322.

<sup>26</sup> At present, the EU Council Regulation only applies to "tiered price" pharmaceutical exports to 76 listed developing and least-developed countries and to "HIV/AIDS, malaria, tuberculosis and related opportunistic diseases," (a limitation which should be amended following Cancun). The EU defines a "tiered price" pharmaceutical as being offered to the poor for either direct manufacturing cost plus no more than 15% or at less than 25% of the OECD weighted average ex-factory price. Council Regulation 953/2003 to avoid trade diversion into the European Union of certain key medicines, art. 7, 2003 O.J. (L135/6) art. 3(a).

<sup>27</sup> Richard C. Morais, "Pssst ... Wanna Buy Some Augmentin?" *Forbes* 2000, April 12, 2004 available at [http://forbes.com/forbes/2004/0412/112\\_print.html](http://forbes.com/forbes/2004/0412/112_print.html).

<sup>28</sup> *Id.*

<sup>29</sup> Judd, *supra* note 4.

<sup>30</sup> WEST & MAHON, *supra* note 6; KANAVOS ET AL., *supra* note 6, at 15-16.

European Court of Justice.<sup>31</sup> As described above, illegal pharmaceutical arbitrage is rarely observed in the EU.<sup>32</sup>

Canada provides a contrasting example. Pharmaceutical arbitrage from Canada to the U.S. operated for years under legal ambiguity. Proponents occupied the moral high ground of enhanced consumer access. The pricing differential is less than 2:1, but the arbitrage market now is in the range of \$600 million to \$1.1 billion a year.<sup>33</sup>

So the first imperative is to prevent any legal or moral uncertainty concerning dysfunctional arbitrage. At a minimum, diversion to high income country markets of drugs intended for the poor should be clearly illegal. The EU, for example, promptly moved in this direction following media reports of the Glaxo diversion.<sup>34</sup> The US should follow suit.

The second task is to modify the product to resist substitutability. The pharmaceutical manufacturing process could be altered to create multiple versions of any prescription drug, distinguished by radically different colors, shapes, names, sizes and packaging. Markets must be segmented into commercial and charitable markets, and never the twain shall meet. The Cancun General Council Decision addresses this issue: exporting countries must clearly identify the products through labeling or marking and through special coloring or shaping.<sup>35</sup> The EU Council Regulation follows this tact.<sup>36</sup> GlaxoSmithKline and others are complying, altering both the packaging and the color of the product.<sup>37</sup> These steps will eliminate the flow of improperly diverted essential access medicines through legal distribution channels such as parallel traders and distribution companies.

Third, consumers in high income markets can be persuaded to resist substitution. Advertising could be directed to commercial market consumers, warning them never to take the red pills with labels in Swahili. This should not be an implicit safety warning: "those pills may not be safe," since Africans will be told exactly the opposite: "the red pills are safe and effective."<sup>38</sup> Advertising should describe diversion as a moral and legal issue: high income patients who take pills intended for impoverished Africans are

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<sup>31</sup> For a recent discussion, see *Boehringer Ingelheim KG v. Swingward Ltd*, [2004] E.T.M.R. 65 (Mar. 5, 2004) available at 2004 WL 343819, at ¶¶ 3-17.

<sup>32</sup> See *supra* Section I.A.

<sup>33</sup> Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation In International Pharmaceutical Markets*, 5 *Yale J. Health Policy, Law & Ethics*, at §VII (pending, 2004). The higher range estimate comes from IMS.

<sup>34</sup> See Council Regulation 953/2003 to avoid trade diversion into the European Union of certain key medicines, art. 7, 2003 O.J. (L135/6) art. 3(a).

<sup>35</sup> World Trade Organization, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 ¶11 (Decision of the General Council of 30 August 2003), at ¶ 2(b).

<sup>36</sup> Council Regulation 953/2003 to avoid trade diversion into the European Union of certain key medicines, art. 7, 2003 O.J. (L135/5) ¶10. While the Council Regulation addresses importation in luggage for personal use, similar to the U.S. personal importation rule, it does not address (but probably covers) internet sales. *Id.* at ¶13, art. 10. Seized product may be used for humanitarian purposes. *Id.* at ¶14.

<sup>37</sup> GLAXOSMITHKLINE PLC, 2003 ANNUAL REPORT, Form 20-F, at 29.

<sup>38</sup> Vertical product differentiation based on quality is common in some products (regular v. premium gasoline), but is probably untenable in pharmaceuticals.

stealing from the poor.<sup>39</sup> Under the EU Council Regulation, all covered pharmaceuticals exported from the EU will bear a special logo identifying the product as destined for the poor.<sup>40</sup> In addition, domestic law within the high income countries should criminalize the practice.

The final front for anti-diversion measures are the borders of the high income countries. Pharmaceutical arbitrage may become dysfunctional only when diversion occurs from low or middle income markets to high income markets. Trade among or between low and middle income markets is not dysfunctional.<sup>41</sup> Thus, the key moment to control dysfunctional arbitrage is at the border of high income countries, not at the border of the exporting country. These protections can be put into place immediately by high income countries, and do not depend upon reaching a multilateral agreement at the WTO. Furthermore, the high income countries possess the resources and infrastructure to make interdiction a reality. Indeed, the absence of observed dysfunctional arbitrage may well be a result of the border controls over the entry of drugs that many high income countries enjoy.

### **C. High Income Markets Should Bear the Burden of Anti-Diversion Measures**

The most striking aspect of these anti-diversion measures is that the responsibility for all of them logically rests upon the manufacturers and high income markets. All four measures do not require expenditure by low or medium income countries. Nevertheless, when PhRMA companies finally agreed to significant differential pricing of ARVs in low income countries, they insisted on strong anti-diversion protections and burden-sharing by the recipient countries.<sup>42</sup> The Cancun General Council Decision requires importing countries to implement reasonable measures to prevent diversion and re-exportation. “Reasonable” measures must be “within their means” and “proportionate to their administrative capacities and the risk of trade diversion.”<sup>43</sup> Under Cancun, developing and least developed countries inappropriately bear these costs even if global patent rents are supra-optimal.<sup>44</sup>

Minor diversions at the clinic or patient level should not be an international enforcement focus. Given the difficulty in setting up a source collection system, it is unlikely that small batches or individual blister packs without packaging will filter back

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<sup>39</sup> If the arbitrated drugs were voluntarily sold rather than stolen, then the moral claim weakens.

<sup>40</sup> Council Regulation 953/2003 to avoid trade diversion into the European Union of certain key medicines, art. 7, 2003 O.J. (L135/7). The logo is found in Annex V of the regulation.

<sup>41</sup> Trade amongst individuals who could not afford pharmaceuticals at OECD prices is not dysfunctional since it does not reduce pharmaceutical patent rents. For a detailed explanation of this position, see Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation In International Pharmaceutical Markets*, 5 Yale J. Health Policy, Law & Ethics, at §V.D.2 (pending, 2004).

<sup>42</sup> Paul Blustein & Barton Gellman, *HIV Drug Prices Cut for Poorer Countries; Other Firms May Follow Merck's Lead*, WASH. POST, Mar. 8, 2001, at A1.

<sup>43</sup> World Trade Organization, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 ¶11 (Decision of the General Council of 30 August 2003), at ¶ 4.

<sup>44</sup> If global patent rents are supra-optimal, these costs could be borne by the PhRMA companies without harming innovation. Placing the burden on countries with annual per capita health budgets of \$100 or less is exceedingly unfair.

to high income country markets in significant quantities. Minor local diversions are likely to remain in the region, and may well be re-sold to other poor patients outside of the current distribution system.<sup>45</sup> This is not a best-case result, but certainly is not an enforcement priority. The priority should be on weaknesses in the supply chain where large batches could be diverted in a single transaction. The risk may be greatest while the product is still outside of the recipient country.<sup>46</sup>

Finally, some level of dysfunctional arbitrage may be tolerable from an innovation point of view. So long as commercial markets are not replaced, the practice will not harm innovation. Modest leakage from commercial markets may reduce patent rents, but will not harm innovation if patent rents are supra-optimal.<sup>47</sup>

## II. Counterfeit Drugs

In the debates over essential medicines, care must be taken to distinguish arbitrage from counterfeiting. For example, a August 10, 2004 article on Internet drug purchases in the Wall Street Journal used the words “fake” or “counterfeit” many times, before mentioning that FDA lab tests “showed that most of the drugs contained too much active ingredient, making the fakes potentially harmful.”<sup>48</sup> These drugs may be poorly produced, or too strong by U.S. standards, but they should not be called counterfeits.<sup>49</sup> In copyright and patent practice, a ‘counterfeit’ or ‘pirated’ copy is one that was manufactured by an unlicensed source, but it might well be as functional as the genuine article.<sup>50</sup> In pharmaceuticals, the term ‘counterfeit’ should be reserved for a drug which does not contain the proper active ingredient.<sup>51</sup> A safe and effective pill which is produced without a patent license should be called an ‘unlicensed’ product.

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<sup>45</sup> This appears to be the case in Jakarta. Richard C. Morais, “Pssst ... Wanna Buy Some Augmentin?” *Forbes* 2000, April 12, 2004 available at [http://forbes.com/forbes/2004/0412/112\\_print.html](http://forbes.com/forbes/2004/0412/112_print.html).

<sup>46</sup> Both conditions were present in the Glaxo case.

<sup>47</sup> A detailed discussion of pharmaceutical patent rent optimality may be found in Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation In International Pharmaceutical Markets*, 5 *Yale J. Health Policy, Law & Ethics*, at §V (pending, 2004).

<sup>48</sup> Heather Won Tesoriero, *Fake-Drug Sites Keep a Step Ahead*, *Wall St. J.*, Aug. 10, 2004, at D4. See also Mark McClellan, Testimony before the Senate Committee on Commerce, Science & Transportation, March 11, 2004 (discussing “unapproved, imported pharmaceuticals” and “unsafe and illegal drugs” with “ineffective, counterfeit” drugs) (McClellan was at the time the Commissioner of the Food and Drug Administration; he currently heads the Centers for Medicare and Medicaid Services).

<sup>49</sup> The trade association of European pharmaceutical research companies and the WHO use the broader definition. EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS, *INTERNATIONAL EXHAUSTION OF TRADE MARK RIGHTS* 5 (April 2001). My point is not to argue who’s definition is ‘right,’ but to demonstrate the analysis which is possible when using a narrower definition.

<sup>50</sup> A counterfeit Gucci purse might nevertheless be a fully functional and stylish purse. A counterfeit music CD contains authentic, but unlicensed, recordings. Pharmaceuticals may contain sub-therapeutic doses of the active ingredients; be improperly packaged, labeled, or stored; or may contain improper contaminants. These drugs are substandard rather than being counterfeit.

<sup>51</sup> The FDA definition is broader, including drugs with improper dosages, sub-potent or super-potent ingredients, or contamination. U.S. Food & Drug Admin., FDA’s Counterfeit Drug Task Force Interim Report 5 (Oct. 2003) available at [http://www.fda.gov/oc/initiatives/counterfeit/report/interim\\_report.html](http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html) (visited Oct. 1, 2004). This improperly conflates counterfeits with poorly manufactured or stored product.

Empirical evidence suggests that virtually all of the internationally arbitrated drugs arriving in the US are not counterfeits by this definition.<sup>52</sup> These drugs might violate restrictions on parallel importation, FDA approval or labeling, or other laws, but they are not counterfeit. Most of the counterfeit drugs in the U.S. have domestic origins or domestic networks,<sup>53</sup> but the FDA still considers it a relatively rare practice,<sup>54</sup> which is nevertheless growing rapidly.<sup>55</sup> In 2000, the estimated value of EU pharmaceutical counterfeiting was Euro 1.554 billion. The UK-based Anti-Counterfeiting Group estimated in 2003 that 5.8% of pharmaceutical company annual revenue is lost due to counterfeiting.<sup>56</sup> If true, counterfeiting is a major threat not only to public health, but also to innovation, far outstripping the limited potential damage from dysfunctional pharmaceutical arbitrage.

Criminal enterprises are currently involved in pharmaceutical counterfeiting.<sup>57</sup> Counterfeiting opportunities may explain the absence of criminal ARV arbitrage. In the illegal, nonprescription drug market, counterfeiting is a difficult practice: If users do not get high, the product will not sell, particularly in sales between repeat players.<sup>58</sup> In prescription drugs, however, the opportunity for counterfeiting is much greater. Patients are often unable to know whether a counterfeit pill contains the correct active ingredients. It may take weeks or months to notice that therapy is failing, and the cause of failure may not be linked with the counterfeits. Counterfeits may be introduced into legitimate supply chains, diluting therapy but making the counterfeiting more difficult to observe and trace. These information characteristics enable the criminal seller of counterfeit prescription drugs to act as if the transactions were discrete, rather than repeating.

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<sup>52</sup> In the FDA seizures of imported drugs, no counterfeit drugs were found, FDA Press Release, Recent FDA/U.S. Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments (Jan. 27, 2004) (mentioning many categories of unapproved drugs but never indicating that any of them contained no active ingredient).

<sup>53</sup> Mary Pat Flaherty, *US Prescription Drug System Under Attack: Multibillion-Dollar Shadow Market is Growing Stronger*, WASH. POST, Oct. 19, 2003, at A1.

<sup>54</sup> FDA, Counterfeit Drug Task Force Interim Report 3 (Oct. 2003).

<sup>55</sup> The FDA estimates that pharmaceutical counterfeiting has increased four fold in the past few years. See *The Washington Post* series of articles on counterfeit drugs which ran in Fall 2003 by Mary Pat Flaherty and Gilbert M. Gaul. See, e.g., Mary Pat Flaherty & Gilbert M. Gaul, *Anti-Counterfeit Steps Drugmakers Sought; Legislators' Goal Is to Halt Illegal Sales*, WASH. POST, Jan. 17, 2004, at A11; Mary Pat Flaherty & Gilbert M. Gaul, *Miami Man Charged With Selling Counterfeit Lipitor*, WASH. POST, Dec. 6, 2003, at E1; Mary Pat Flaherty & Gilbert M. Gaul, *Lax System Allows Criminals To Invade the Supply Chain*, WASH. POST, Oct. 22, 2003, at A1. The Wall Street Journal has also covered the story. Anna Wilde Mathews and Heather Won Tesoriero, *Murky Channels: Bogus Medicines Put Spotlight On World of Drug Distributors*, WALL ST. J., Sept. 29, 2003, at A1.

<sup>56</sup> The Anti-Counterfeiting Group, *Why You Should Care About Counterfeiting 14* (circa 2003) available at [www.a-cg.com](http://www.a-cg.com) (visited Oct. 7, 2004).

<sup>57</sup> Alliance Against Counterfeiting & Piracy, *Proving the Connection: Links Between Intellectual Property Theft and Organised Crime 2* (circa 2002) available at [www.a-cg.com](http://www.a-cg.com) (visited Oct. 7, 2004) (“This document provides clear and unambiguous evidence of organised crime controlling, exploiting and benefiting from intellectual property fraud. It is on the increase.”).

<sup>58</sup> The business plan of the Cali drug cartel probably includes a quality assurance mechanism. See the interesting (and merely conjectural) marketing plan for the Cali Cartel by Matthew Kwan, completed during his MBA studies at the Melbourne Business School, <http://www.darkside.com/au/mba/cali.html> (visited July 8, 2004).

While obtaining arbitrated ARVs might be possible, obtaining them in sufficient quantities would require a procurement team in the field (sub-Saharan Africa), with multiple diversions against an alerted supply chains, followed by repackaging and a reverse supply chain back to high income country markets. Counterfeits could be appropriately labeled and packaged, rather than having pills in the wrong color and packaging labeled for essential medicine programs. These characteristics enable counterfeits to be introduced into high income country supply chains directly, and much easier than diverted pills from Africa. Counterfeiting dispenses with many costs. The per pill cost to produce a placebo without active ingredients may be far cheaper than covert diversion and procurement, re-coloration, repackaging, and transportation. Finally, it is unlikely that anyone would bother to counterfeit a cheap generic drug. Expensive, patented drugs are the targets of counterfeiters; cheap generics are not.<sup>59</sup> A criminal is unlikely to counterfeit a pill and sell it as aspirin or Triomune, when it could be sold as Lipitor or Fuzeon. When low-cost unlicensed generics are widely available, the public health threat of counterfeits recedes.

Additional anti-counterfeit measures in high income countries should include a pedigree system of tracing drugs from the manufacturer to the consumer. A pedigree system (or the European system of parallel traders giving notice of intent to trade) would also hinder arbitrage by making product movement transparent to the manufacturer. Most importantly, routine market sampling for counterfeits must be introduced, and sources of counterfeit drugs aggressively traced by law enforcement.<sup>60</sup>

### III. The Hubbard-Love R&D Treaty Resolves Both Issues

Free trade in goods and services is the default position for most international economists. In patented pharmaceuticals, free trade has been blocked largely on innovation grounds: parallel trade hinders pharmaceutical profits, and thus, pharmaceutical R&D. The Hubbard-Love R&D Treaty<sup>61</sup> proposes to take all R&D cost recovery out of the price system, and to fund R&D as a global public good. Doing so removes all of the innovation arguments restricting pharmaceutical trade.

Counterfeits, not dysfunctional arbitrage, are the more immanent danger to both public health and PhRMA innovation. Counterfeiting will remain an issue so long as the actual product has a high value relative to the cost of manufacturing a plausible placebo. Current ratios of marginal cost to sales price exceed 30:1, attracting criminal enterprises

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<sup>59</sup> The examples of counterfeits in most media and FDA reports are of expensive patented drugs such as Lipitor, Epogen, Zyprexa and Serostim. See Leila Abboud, Anna Wilde Mathews & Heather Won Tesoriero, *Fakes in the Medicine Chest; As Drug Counterfeiting Rises, FDA May Propose Changes in Sales, Distribution Network*, WALL ST. J., Sept. 22, 2003, at B1.

<sup>60</sup> Some steps towards an anti-counterfeiting policy are being taken by the FDA Task Force. FDA, Counterfeit Drug Task Force Interim Report 18-22 (Oct. 2003) available at [http://www.fda.gov/oc/initiatives/counterfeit/report/interim\\_report.html](http://www.fda.gov/oc/initiatives/counterfeit/report/interim_report.html).

<sup>61</sup> See, e.g., TIM HUBBARD, ALTERNATIVES TO THE PRICE SYSTEM (Presentation at Columbia University, Dec. 4, 2003) available at [http://www.earthinstitute.columbia.edu/cgsd/accesstomedicines\\_papers.html](http://www.earthinstitute.columbia.edu/cgsd/accesstomedicines_papers.html); JAMES LOVE, A NEW TRADE FRAMEWORK FOR GLOBAL HEALTHCARE R&D (Presentation at Columbia University, Dec. 4, 2003) available at [http://www.earthinstitute.columbia.edu/cgsd/accesstomedicines\\_papers.html](http://www.earthinstitute.columbia.edu/cgsd/accesstomedicines_papers.html)

to the counterfeit drug market. By removing R&D costs from the retail pricing system, the R&D Treaty will greatly reduce counterfeiting pressure. If the ratio drops to 1:1, no incentive remains to counterfeit.