**To: Robert Weissman**
**From: Peter Maybarduk**
**Date: July 20, 2007**
**Re: Envisioning a public interest response to counterfeiting and drug quality**

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Unsafe and ineffective drugs threaten patient health worldwide. As industry strengthens its efforts to combat counterfeiting, the public interest community should respond by describing the problem from the perspective of patients, more accurately and honestly than has PHrMA. Without understating the dangers of fake drugs, access advocates can note that counterfeiting is part of a larger drug quality problem. It may even be that more patients are injured by the poor quality of legitimate drugs than by counterfeits.[1] By leading a charge against counterfeits without opening a parallel front to improve its own drug quality, PHrMA opens itself to criticism. PHrMA uses images of patient suffering to combat fakes that threaten sales, but does not ultimately seek to protect patients by addressing drug quality across the board. This callousness, coupled with the public attention PHrMA brings to counterfeiting's effects on patient health, provides an opportunity for the public interest community to focus public attention on drug quality, advocating for better regulatory oversight and pressing pharmaceutical companies to improve their quality track records.

The access community's interest in industry transparency also argues for a concerted response to PHrMA's anti-counterfeiting campaign. PHrMA demands government support to stop counterfeiting, but refuses to share the data it collects. Some of the best and most quickly captured data on counterfeiting resides in the information banks of private companies and front groups, inaccessible to public health agencies except when PHrMA finds sharing to be in its interest.[2] Thus, health agencies' interest in obtaining counterfeiting and drug quality data dovetails with the access community's interest in broad pharmaceutical industry transparency. The access community and health agencies could jointly call for better counterfeiting and drug safety data disclosure.

Further, the high prices of legitimate drugs drive the market for fakes. Patent regimes provide financial incentives to innovate and to counterfeit. The access community could argue that lower prices would reduce incentives to counterfeit, and that an alternate system of funding research and development – one that separates the cost of R&D from the cost of a pill – would reward innovators while dramatically reducing the appeal of counterfeiting.

This memo identifies central policy issues in drug counterfeiting and the positions taken by influential actors. It highlights fallacious reasoning and selective observations, and suggests positions the access community might take in response.

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[1] *See* "Safety," *infra*. One long term Indian study found counterfeits constituting between 0.2% and 0.5% of the pharmaceutical supply, whereas poor quality drugs constituted 10% of the supply.

[2] *See* "Disclosure," *infra*.

Commission held a hearing on Chinese counterfeits last year.[5] Congressman Steve Israel of New York's second district has introduced legislation, called Tim Fagan's law, to enact stricter penalties against counterfeiters and require pharmaceutical companies to disclose knowledge of counterfeits of their products in the market. The Department of Justice proposed tougher trademark laws to capture more of the counterfeiting trade.[6] The Food and Drug Administration authored "Combating Counterfeit Drugs,"[7] which recommends adopting product tracking technologies, stronger laws and penalties, and better reporting practices (but does not advocate mandatory disclosure for PHrMA). Perhaps most significantly, in 2006 the World Health Organization convened an International Conference on Combating Counterfeit Medicines, yielding the Declaration of Rome and IMPACT, the International Medical Products Anti-Counterfeiting Task Force.

The access community, however, seems only peripherally involved in policy debates concerning counterfeits. Doctors Without Borders briefly mentions counterfeiting in a number of reports. This year, the BUKO Pharma-Kampagne, a member of Health Action International, published the only access community report on counterfeiting my brief search revealed. "Pharma-Brief Special: Counterfeit Medicines – what are the problems?" is about 12 pages long and covers key issues with some helpful insights. It may have been written by non-native English speakers, and appears to be largely based on a student's master's thesis research. In some cases the paper goes further than the access community probably should, devoting a paragraph to occasional health benefits of counterfeits and emphasizing that price is more important than quality. A more detailed report, reflecting the consensus of the community, recognizing the danger of counterfeits, anticipating counterarguments and employing empirical data when possible, would be useful to policymakers and hence to consumers.

***Defining the Problem: counterfeits or drug quality?***

Industry and most health agencies treat counterfeit drugs and drug quality as two separate problems. From the patient perspective, however, counterfeiting is a subset of a larger drug quality issue. We could conceptualize the concerns of industry, patients and health agencies as follows. Industry asks, "Is this product a trademark violation or other fake?" Patients and their advocates ask, "Is this product safe and effective?" (In theory, patients in difficult circumstances might accept fakes if their safety and efficacy could be proven.) Health agencies ask both questions: "Is it safe, effective, and legal, i.e., appropriately registered?"[8]

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[5] "Intellectual Property Rights Issues and Imported Counterfeit Goods," Hearing before the U.S.-China Economic and Security Review Commission, June 7-8, 2006.

[6] "United States Intensifies Fight Against Counterfeit Drugs: Tougher Trademark Laws Considered, say Justice officials," Nadine Leavitt Siak, USINFO Staff Writer, December 1, 2006.

[7] "Combating Counterfeit Drugs: A Report of the Food and Drug Administration," February 2004, available at www.fda.gov/oc/initiatives/counterfeit/report02_04.html.

[8] WHO IMPACT also cites substandard drugs as contributing to drug resistance.

***Disclosure***

Although pharmaceutical companies depend on law enforcement and public resources to locate counterfeits and maintain consumer confidence in their brands, companies do not always disclose what they know about counterfeits in the market.[13] PSI recorded 76 cases of counterfeiting in 2004, the FDA only knew of 58.[14] Though considered the world's best, PSI's database "is not accessible to the WHO, health authorities or the public."[15] Industry seems to favor general public awareness of the counterfeiting problem, which may lead to enforcement assistance, but sometimes disfavors public knowledge of specific counterfeited drugs, which could undermine confidence in industry products. Cockburn *et. al* write, "The industry's history of secrecy over data about fake drugs, and claims of commercial motivation, go back over 20 years. In 1982, a spokesperson for the Association of the British Pharmaceutical Industry said, "It is difficult to declare a [fake drug] problem without damaging legitimate business."

In 1995, GSK asked the Ghanaian government not to alert the public of the presence of fake halofantrine antimalarial syrup in the market, for the sake of the company's reputation.[16] In 1998, the Brazilian government accused Schering do Brasil of failing to disclose knowledge of counterfeit contraceptives for thirty days (a court cancelled the government's fine on appeal).[17] In 2002 in Kansas City, BMS and Eli Lilly settled for $72 million with the families of deceased victims of counterfeit drugs, seemingly to avoid the precedent that drug companies could be held liable for failing to disseminate information about counterfeits.[18]

No country, so far as we know, statutorily requires pharmaceutical companies to disclose their knowledge of counterfeits.[19] In 2003, pharmaceutical companies in the United States committed, voluntarily, to report counterfeits within five days. Most countries lack even a voluntary commitment.

Would a statutory disclosure requirement be a good idea? Cockburn *et. al* think so, and propose following the model of the United Kingdom Civil Aviation Authority for unapproved aircraft parts. Pharmaceutical companies would be required to report suspected counterfeits to the drug regulatory agency. The agency would then take responsibility for

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[13] Despite warning and reporting resources like safemedicines.org.

[14] BUKO at 5.

[15] PLoS.

[16] BUKO and PLoS. GSK also was reluctant to share information about fake syrup with the authors of the PLoS article.

[17] PLoS.

[18] PLoS. There are, of course, counterexamples. "In 2002, Johnson and Johnson issued 200,000 letters to health care professionals in the US warning them of fake Procrit…within one week of being notified of a severe counterfeit problem." PLoS.

[19] BUKO at 5.

Access advocates should point out that all sides agree the high prices of drugs drive the market for counterfeits, and that lower prices would mean less incentive to produce fakes. Cockburn *et. al* write that an effective response to counterfeits requires "provision of effective, available and inexpensive drugs." It is ironic, and arguably unfair, that pharmaceutical companies harness public resources to crack down on counterfeiting while their high prices motivate both supply and demand. There is an argument that pharmaceutical companies should pay more of the enforcement bill.

But the access community could go one step further, and make a broader point. Patent regimes create incentives both to innovate and to counterfeit. The high cost of research and development is reflected in each consumer's purchase of a bottle of brand-name pills. By contrast, James Love's proposed system, in which countries sell pills at marginal cost while separately investing in research and development, would create incentives only to innovate. Counterfeiters would be forced to compete with low-price legitimate sales reflecting only the low overhead and manufacturing costs of each pill. With the bulk of medicines' value off the private market, incentives to trade in fakes would dwindle, and perhaps all but disappear.

***The technological solution***

Nearly all recent reports proposing plans of action to combat counterfeiting cite the need to adopt "track and trace" technologies.[24] One commonly cited emerging technology is Radiofrequency Identification (RFID) tagging, presently undergoing testing for efficacy. The FDA says RFID could make counterfeiting "extremely difficult or unprofitable," and places implementation of the technology first on its list of suggested anticounterfeiting measures. Technological solutions also seem to be the WHO's present primary focus. The WHO met with twenty technology companies in March to discuss solutions to counterfeiting in developing countries.[25]

Apart from any efficacy concerns, there may be at least two reasons the access community would find an exclusively technological solution to counterfeiting suboptimal. First, it seeks to stop counterfeits without improving the quality of registered drugs. Second, BUKO suggests technological solutions advantage the larger and wealthier brand name companies. If the technologies prove very expensive, brand name companies might be able to implement them whereas smaller generics firms might not. Under such circumstances, brand name companies could use their advantage to cast further doubt on the quality of generics generally.

It is unclear whether such a scenario is at all likely. In any event, the access community should be careful when expressing concern about the limits of technological solutions. If

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[24] "Combating Counterfeit Drugs: A Report of the Food and Drug Administration," February 2004, available at www.fda.gov/oc/initiatives/counterfeit/report02_04.html.

[25] Medical News Today, in materials.

I have the impression that brand name companies have grown cautious about such statements in recent years, and that at least the better industry commentators prefer not to make claims about generics and counterfeiting that they cannot defend.

It is worth noting, however, that diminishing patient confidence due to counterfeits would probably disproportionately diminish confidence in generics, because accurately or not, many consumers interpret brand names as quality assurance.

***Industry influence in policymaking***

The pharmaceutical industry clearly exerts great influence over anti-counterfeit policymaking. Indeed, given that IMPACT, now the official international anti-counterfeiting force, was founded through a joint venture of the WHO and IFPMA, given that government agencies and press reports[28] routinely rely on industry statistics and papers, given the superiority of private counterfeit tracking databases, and given the joining of the U.S. Chamber of Commerce to CACP – all added to the preexisting extraordinary influence of the pharmaceutical industry - it is probably not a stretch to say that industry directs policy as much as government, and maybe more.

***Other enforcement tactics***

A few other anti-counterfeiting programs merit mentioning. The FDA may soon begin (if it has not already) to enforce the Prescription Drug Marketing Act (PDMA) of 1987, after many years developing implementation rules. The resultant pedigree requirement may blend paper records and track and trace technologies to verify the history of drug shipments. In 2000, Public Citizen commented that the PDMA only required unauthorized distributors to provide a paper trail, whereas all distributors should have been required to do so. I am not sure where this matter stands now, but it seems the practice of repackaging parallel drug imports – which industry groups argue creates opportunity to introduce counterfeits in international trade – would support a broad pedigree requirement.

The Department of Justice and FDA now collaborate in counterfeit enforcement. In 2006, Congress adjusted the trademark laws to make prosecuting drug counterfeiters easier. The new laws mandate prison sentences up to ten years for counterfeiting, whereas the Cosmetic Act previously mandated only three. The FDA also plans to create (or has created) a Counterfeit Alert Network, "that links together and enhances existing counterfeit notification systems[.]"[29]

Effective drug regulation and registration would help countries control their pharmaceutical supplies. According to the WHO, "At present, out of the 191 WHO Member States about 20% are known to have well-developed drug regulation. Of the remaining Member States,

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[28] See USA Today article in materials.

[29] "Combating Counterfeit Drugs: A Report of the Food and Drug Administration," February 2004, available at www.fda.gov/oc/initiatives/counterfeit/report02_04.html.

framework, could also support arguments for compulsory licensing where patent holder's refusal to license stifles public access or technological progress.

The declaration includes a section titled, "Intellectual Property Protection as the Backbone of Innovation," which in turn includes the statement, "A fully functioning intellectual property system is an essential factor for the sustainable development of the global economy through promoting innovation." The G8 also emphasizes, "the crucial importance of efficient innovation value chains that promote business commercialization of patented research results and exploit licensing as a major driver for the international transfer of technology."