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**UNITAID/IDPF
An Analysis of the
International Drug Purchase Facility**

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Executive Summary

At the St. Petersburg G8 meeting in July 2006, the government of France proposed a solidarity tax on airline tickets, of which the proceeds would be used to buy drugs for AIDS, tuberculosis, and malaria patients in the developing world. The proposal wasn't adopted by the other G8 members because there was no clear rationale for a new program which is repetitive of current drug procurement schemes. Nonetheless, the governments of France, Chile, Brazil, Norway, and the United Kingdom signed a Memorandum of Understanding (MoU) at the United Nations on September 19, 2006 and agreed to collaborate in the implementation of the International Drug Purchase Facility (IDPF).

The Facility was proposed as an innovative mechanism to accelerate access to high-quality drugs and diagnostics for AIDS, tuberculosis, and malaria patients. WHO has agreed to assist UNITAID by serving as the host organization. It will provide a Secretariat, Trust Fund, administrative, fiduciary support, and facilities. UNICEF will provide procurement services.

This analysis will review the three key published documents: 1) UNITAID – The International Drug Purchase Facility, September 1, 2006; UNITAID Constitution, September 6, 2006; and 3) the MoU among the principal parties. The documents use the acronym “UNITAID” for the Facility, though the letters don't correspond to “IDPF”.

Demand, high product prices, and drug supply form barriers to access for the poor, according to these documents. These assumptions will be tested against published reports from WHO and other UN agencies, NGOs, and non-profit research firms. In sum and substance, the rationale will be shown to be without merit and expensively duplicative of current programs. For the same diseases, the IMF has expressed concern over the macroeconomic risks associated with vast resource flows now in play — including high inflation which acts like a tax on the poor. Most importantly, since UNITAID is not a legal entity, yet states that it will be administered in accordance with the WHO Constitution, this presents a specific challenge to the intent of Article 37: “The Director-General and the staff shall not seek or receive instructions from any government or from any authority external to the Organization.” By hosting UNITAID for the benefit of special interest groups, this is also contrary to Article II of the UN Charter, which maintains “the principle of sovereign equality for all its Members.”

In 2000, the WHO became a founding member of the United Nations Accelerated Access Initiative (UN/AAI), now the single largest provider of AIDS drugs in the developing world. There are two critical distinctions between its membership in this program and its hosting of UNITAID: 1) UN/AAI provides medicines of known quality, safety and efficacy as attested to by stringent regulatory authorities; 2) UNITAID will either procure medicines in which WHO has issued a Disclaimer on their safety and efficacy, or buy them from countries which permit the exportation of drugs that aren't bioequivalent to their reference products. These are substandard drugs which accelerate drug resistance.

Part I will describe UNITAID documents, and Part II will analyze them.

Part I –Descriptions of the New Entities

Introduction

The three UNITAID documents are published on mimeo formats and bear no official or recognized institutional seals. For instance, none of the five founding countries, hosting Organization, or procurement agencies are listed on the cover page of UNITAID’s Constitution. Whatever legal status UNITAID has, its registration as a “public charity”, place of legal residence, or Board of Directors—isn’t described in any of the documents. Since WHO has agreed to be the hosting agency, and UNICEF the procurement agency, each should have presented some official documentation to UNITAID which would have reflected their institutional commitments, while expressing in what legal manner they have bound their authorities to the UNITAID Constitution.

1. UNITAID: The International Drug Purchase Facility¹

This document outlines the course of events leading up to the formation of UNITAID, including the Declaration on Innovative Sources of Financing for Development, adopted on September 14, 2005 at the United Nations. Subsequently, the UNITAID Joint Declaration was issued by Brazil, Chile, France, and Norway at the United Nations on June 2, 2006. At this time, the United Kingdom was not yet a partner.

In addition to the five country partners, several international organizations have joined UNITAID, including the WHO, UNAIDS, UNICEF, various NGOs, and several private foundations (only the Clinton Foundation is mentioned by name). The specific objective is to secure predictable multi-year contributions, permitting a process to “scale up access to treatment for the poor in developing countries—through lowering the price of drugs and diagnostics and accelerating the pace at which they are made available.” UNITAID will seek “leveraged” price reductions—through more donor funds—and increased access to medicines which are “currently unaffordable for most developing countries.”

The Declaration on Innovative Sources of Financing for Development outlines the mission, key principles, and objectives of UNITAID. According to the Declaration, UNITAID is to fulfill its mission through these four principles:

- Complementing the role of existing international institutions
- Not replacing or duplicating existing institutions or mechanisms
- Following principles of solidarity and aid effectiveness
- Being adaptable, independent, transparent, and accountable

UNITAID wants to significantly intensify these efforts while ensuring that it does not add complexity to existing mechanisms. “It will use its unique sustainable, predictable and additional funding to help generate a steady demand for drugs and diagnostics, thereby significantly impacting market dynamics.”

Furthermore, UNITAID’s four principles have guided the following objectives:

- Price reduction on medicine and diagnostics
- Increased availability and supply of medicines and diagnostics
- Base price reduction strategy on *market competition*. Where intellectual property barriers hamper competition and price reductions, it will *support use by countries of compulsory licensing* under the framework of the Doha Declaration on the Trade-Related Aspects on Intellectual Property Rights (TRIPS) and Public Health, when applicable. (Emphasis UNITAID's)
- *Any other innovative solution that may overcome limitations to market diversification in developing countries will also be pursued.*
- *And, it will rely on and work closely with its partners to ensure a successful implementation up to the patient.* (Emphasis UNITAID's)

UNITAID states that the founding countries agreed to give a “green light” and initiate immediate next steps to implement programs in AIDS, TB, and malaria treatment at a cost of \$174.5 million, beginning in the fourth quarter of 2006 and running into 2007.

UNITAID's governance structure intends to transcend the divide between donor countries of the North and recipient countries of the South. Thus, developing countries will be adequately represented in the Executive Board, not only as beneficiaries but also as contributing countries. This “*is a vital guarantee that decisions taken by UNITAID will fully take into account the needs of recipient countries.*” (Emphasis UNITAID's)

The Executive Board will be composed of ten members: the five founding countries, one representative of African countries and one from Asian countries, two representatives of civil society, and one representative of the WHO. Decisions will be made by consensus. However, if a vote is called for, then a simple majority of those present will suffice. For more substantive matters, the vote of two thirds of those present will be required.

The Clinton Foundation will work with manufacturers and national governments to organize the markets of HIV/AIDS commodities to lower the prices of medicines and diagnostics. It will provide technical assistance to ensure the delivery of commodities.

In order to establish a fiduciary structure, UNITAID will contract with the WHO for the set-up period to serve as trustee for: 1) receipt, management, and disbursement of funds and return via treasury and cash management functions; 2) giving the public confidence that funds are being managed responsibly; 3) providing the funds with protection from liability or other prosecution; and 4) keeping financial records of all transactions in a transparent and auditable manner for both the Board and the public.

The implementing partner for UNITAID hasn't been identified.

2. The UNITAID Constitution²

The language and content of this section do not reflect what is normally seen in “constitutional” documents, such as those which prescribe the nature, functions, and

limits of the institution being created. Rather, it repeats many of the concepts in item 1 above, such as the need for “price reductions which currently are unaffordable for most developing countries.” A paper is attached to the Constitution which describes the provenance of “compulsory licensing” in item 1 as emanating from Act-Up Paris. It reads as follows:

Act UP-Paris and all other access-to-medicines campaigners have had to lobby the five governments insistently in order to obtain this commitment to lowest prices, competition and compulsory licensing. This commitment to back up the Doha Declaration with purchasing power should signal to global holders of HIV, tuberculosis and malaria drug patents that the time has come to open their products to competition in developing countries, for example by voluntarily creating a patent pool.

In an appended note to the Constitution, a Brazilian diplomat is quoted as saying: “All five countries have agreed to include the language on intellectual property and embrace it wholeheartedly.” The diplomat added: “countries have vowed to support UNITAID with a total of \$300 million annually ... the money has not been paid yet, but the WHO is expected to open the account after the board meeting.”

3. UNITAID Memorandum of Understanding³

The MoU is more of a “constitutional” document in content and form than the UNITAID Constitution. It sets forth in a Preamble and 12 Articles the mutual expectations and respective roles, responsibilities, and undertakings that the five signatories, in addition to the WHO, have pledged to UNITAID. Since Article 1.1 states that “in case of inconsistency between the terms of this MoU and the UNITAID Constitution and By Laws, the terms of this MoU shall govern the respective roles, responsibilities and undertakings of the Parties,” in effect, it means that MoU, not the Constitution, is the operative document for UNITAID’s governance.

Several of the MoU’s Articles are of particular importance as they pertain to how UNITAID will operate, and also illustrate several potential problems. Article 2.2 describes how the “privileges and immunities of WHO shall apply to the staff, funds, properties and assets supplied to or for the use of the Secretariat of UNITAID within the remit of this MoU.” This is a broad scale interpretation of the International Organizations Act, under which no UN body can be held to legal suit in any jurisdiction. For instance, if the Clinton Foundation purchases substandard pharmaceutical products on behalf on UNITAID, which subsequently accelerate drug resistance and mutation of the AIDS virus, the affected patients would be unable to seek redress for medical malpractice. However, if the procured drugs are distributed by a different NGO or foundation in a particular country, patients would be able to take the responsible group to court. Subsection 2.3 of this Article states that “the hosting arrangement and the operations of the Secretariat shall in all respects be administered in accordance with the WHO Constitution, WHO’s Financial and Staff Regulations and Rules, Manual provisions, and applicable policies, procedures and practices and with the terms of the MoU.”

Although WHO is only one member of ten on the Executive Board, this subsection concedes all operational authority over UNITAID to the WHO, making UNITAID a wholly owned subsidiary of the UN's health agency.

These Articles are in contravention to UNITAID's By-Laws of September 12, which contend that "the Executive Board is the decision-making body for UNITAID (except for those delegated to the Secretariat)." In this arrangement, the Executive Board is the horse and the Secretariat is the rider.

Further articles solidify the WHO's unilateral authorities. Subsection 2.4, *Modification to Rules*, states that "the WHO Rules may be updated or revised by the WHO from time to time as is necessary or appropriate and in accordance with mechanisms established by WHO for that purpose." Article 2.5 comments that "nothing in or related to the MoU shall be construed as a derogation of WHO's constitutional requirements." Article 3 explains that the WHO will employ staff to carry out the activities of UNITAID: "The Secretariat shall be subject to, and its activities shall be conducted with, the WHO Rules." Subsection 3.2, *Secretariat as WHO Staff*, further explains that "all staff assigned to the Secretariat, including WHO staff seconded to WHO for assignment to the UNITAID Secretariat, shall be staff members of WHO and will be considered by WHO as WHO officials for the purpose of the application of the privileges and immunities accorded under international law for the free exercise of these functions." The Clinton Foundation would be eligible under this article.

In this regard, "WHO will provide, or will request the United Nations to provide, the same travel and identification documents to the Secretariat staff that are provided to all WHO staff." Article 5 addresses Financial Matters through which all "contributions and other funds received by WHO for the benefit of UNITAID will be maintained and recorded within the WHO accounting system ... in accordance with the WHO Rules." Payments to defray the costs of operating the Secretariat ... will be subject to compliance with WHO Rules ... and WHO shall report all receipts and expenditures in accordance with WHO Rules."

When UNITAID described the composition of the Secretariat, it stated: "developing countries will be adequately represented ... this is a *vital guarantee that decisions taken by UNITAID will fully take into account the needs of recipient countries.* (Emphasis UNITAID's.) However, only two of the Secretariat's ten members are from developing countries. In this construct, UNITAID takes ownership of both the problem and the solution, marginalizing participation from the affected countries.

Article 6, *Fees and Costs*, details the amount of Programme Support Costs and other fees to be charged by WHO for its services, together with the method of its calculation. The reader is then directed to Annex B, which reads as follows:

- The Secretariat will receive a fee of \$425,000 per annum. This covers the administrative services for processing salaries and benefits as well as administrative costs.

- The administrative service fees do not cover: video and communication equipment; office equipment; use of conference rooms and servicing of meetings; travel and visa expenses; document reproduction services; telecommunication charges and special devices or accessories; “special” audit and “special” legal services; any costs, payment orders or awards associated with Secretariat staff complaints, appeals or grievances; and any other liabilities arising out of activities performed under the MoU.
- The fixed administrative costs do *not* (emphasis WHO’s) include the fees related to Programme Implementation work by WHO, nor the special arrangements now envisaged for the administration of the trust fund based on a new procurement model for which a percentage fee applies. Such percentages are applied to income received for programme activities at the following rates:

Table 1: Percentages of income received for WHO Programme Activities

Percentage under Joint Programming Arrangements with UNICEF	1.0%
Percentage for processing of funds for procurement by the Clinton Foundation	1.0%
Percentage for GDF managed procurement	3.0%
Percentage for Procurement of Second Line ARV Drugs based on the Proposed New Model	1.5%
Percentage for Technical Support (e.g., pre-qualification) ¹	13%

Article 7, *Procurement Practices*, states that WHO rules will permit the procurement and distribution strategies and procedures as set forth in Annex C. Generally all of these relate to WHO rules. Several examples follow:

- WHO intends to facilitate the procurement of medicines at reduced prices in a manner consistent with applicable WHO Rules, including principles such as best practices for money, international competition and compliance with international quality standards.
- Selection of beneficiary countries will be determined by disease burden; national treatment guidelines and the compliance of such national treatment guidelines with WHO guidelines.
- UNITAID funds managed and disbursed by WHO will be used to procure products that are consistent with WHO technical guidelines.

1. There is a note attached to this item, stating that a higher rate is charged for Technical Support because the activities within this type of work tend to entail more significant cost than bulk procurement.

- Selection of procurements at reduced or most competitive prices may either be undertaken by the UNITAID Secretariat or by agents designated by UNITAID in accordance with principles set out in WHO rules.
- Selection of suppliers will be in accordance with criteria to sustain competition and be consistent with WHO procurement principles.
- Procured pharmaceutical products will be in compliance with national regulatory requirements and with WHO standards.
- Procurement of single and limited-source HIV/AIDS, TB and malaria medicines will be through the quality criteria of the Global Fund to Fight HIV/AIDS, but is not limited to WHO prequalification.
- WHO/UNITAID or its authorized procurement agents may execute contracts with a supplier before the supplier reaches the relevant quality standards for the particular product to be procured.
- Procurement under National Procurement Procedures may be conducted, and in such cases the UNITAID Board and WHO would make funds available to pay suppliers on behalf of the purchasing beneficiary country.

In Subsection 7.2 of this Article, WHO comments that it is not a party to any exclusive or similar arrangements with manufacturers or other suppliers of drugs to which WHO is bound and which would be applicable to UNITAID procurement activities, such that UNITAID would be precluded from contracting with any specific party or be obliged to contract with a specific part with respect to certain procurements.

PART II –ANALYSIS

This section will review the basis for UNITAID’s contention that demand, drug supply, and price form the barriers to access of medicines for the poor. It will then address the consequences to WHO members when they permit the Organization’s institutional legitimacy to be subcontracted out to special interest groups.

1. Reports from U.N. Agencies, NGOs, and Private Research Organizations

Since March 2006, several documents released either by UNAIDS, WHO, the UN/AAI Program, the Global Fund, Médecins Sans Frontières, the International Treatment Preparedness Coalition (a global alliance of over 600 treatment activists that includes people living with HIV/AIDS (PLWHA) and their advocates), the International Monetary Fund, the Center for Global Development, or media reports and private research organizations, have all repudiated the fundamental premise for the formation of UNITAID, and raised substantial concerns over the macroeconomic impacts of extant resource flows. In turn, each of these organizations published the following comments:

- a. In August 2005, UNAIDS published “Resource Needs for an Expanded Response to AIDS in Low and Middle Income Countries.” Of the projected resource needs for 2006, 2007 and 2009 of \$62.1 billion, only \$12.3 billion, or 19 percent were for treatment and care by 2008. This component includes palliative care; provider-initiated testing; ART including nutritional support; treatment for prophylaxis for

opportunistic infections; and laboratory testing. ARV therapies are a minor part of treatment and care. In 2006, UNAIDS estimates that of the total of \$3.1 billion for this component, only \$1.6 billion is for ART and nutritional support. The UNAIDS report goes on to say that “the resource needs estimates also include the funds required for increasing the rate of scaling-up, such as investments in human resources, and, for the first time, for building additional infrastructure, e.g. capital investments in facility construction and refurbishment.”⁴

In August, UNAIDS provided its 2006 report on the global AIDS epidemic to the United Nations. It commented: “Barriers to providing widespread HIV prevention and treatment, such as the lack of infrastructure, poor transportation, or shortages of trained workers are substantial and can only be overcome through our greatest collective efforts.”⁵

- b. WHO has published several reports in the past few months, addressing the subjects of price and demand:
- In its March evaluation of “3 by 5,” the WHO commented: “universal access requires serious consideration of the *health system constraints* that are limiting service coverage; inhibiting early care-seeking; and compromising the continuous supply and durability of treatment ... there are many barriers to individuals finding out their HIV status; starting ART when indicated; and continuing to benefit from chronic therapy.” (Emphasis WHO’s)⁶
 - In March 2006, WHO published “Progress on Global Access to HIV Antiretroviral Therapy: A Report on ‘3 by 5’ and Beyond.” It commented: “Although stigma and lack of perceived benefits of treatment may slow the uptake of antiretroviral therapy, demand does not appear to have been a limiting factor in scale-up.”⁷
 - During the May 2006 World Health Assembly, WHO released a report on the price, availability, and affordability of chronic disease medicines. Through country surveys, WHO stated: “One major finding of the surveys was that taxes and duties levied on medicines, as well as mark-ups applied, frequently contribute more to the final price than the actual manufacturers’ price does.” It went on to say: “There is evidence that some governments procure medicines efficiently, but charge markedly higher prices to patients, e.g., in Indonesia’s public sector, patients paid 11 times the procurement price.”⁸ WHO released an audit report at the May WHA on expenditures for AIDS during the “3 by 5” program: It ended the 2004-2005 biennium by expending only 57 percent of its AIDS budget.
 - On July 21, 2006 the director of WHO’s HIV division was interviewed by *Reuters News Media*. He was quoted as saying: “Africa has been hardest hit by the AIDS epidemic, is short of a least a million healthcare workers

and, over the past quarter-century, infrastructure in many countries have eroded. If you work in these countries it is very obvious, very quickly, that the elephant in the room is not the current price of drugs. The real obstacle is the fragility of the health systems. You have health infrastructure that is dilapidated, a health workforce that is demoralized, labs that don't work, supply chains that don't exist and diagnostics that are missing.”⁹

- c. The United Nations/Accelerated Access Initiative (UN/AAI). This program was the first global effort to initiate AIDS treatment, beginning in May 2000. WHO is a founding member, along with seven multinational pharmaceutical companies. Heavily discounted or donated ARVs with stringent regulatory approvals from either the FDA or EMEA are made available to low and middle-income countries. In March 2006, WHO reported that at the end of 2005, the UN/AAI program was delivering ARVs to 716,000 patients, a number higher than the combined totals of PEPFAR and the Global Fund.¹⁰ When the 2006 numbers are tallied, it is expected that the UN/AAI program will have at least 825,000 AIDS patients under coverage. This demonstrates that there is demand for ARVs of proven quality, safety, and efficacy and their price isn't a barrier for procurements by low and middle-income countries. Still, UNITAID estimates that 85 percent of its total resources will be spent on low-income countries.
- d. Médecins Sans Frontières (MSF) has consistently criticized the R&D industries over the high cost of patented ARVs vs. copy drugs from India and Thailand. In May 2005, the Hudson Institute conducted a comparative study, using only the prices published by MSF in its Pricing Guide. Of the 18 drugs with comparative prices, 5 patented drugs were cheaper than the lowest copy price, and only 4 patented drugs were more expensive than the highest copy drug price. The remaining 9 patented drugs fell within the price range of their counterpart copy drugs. Thus, out of 18 comparable AIDS drugs, 14 patented drugs were either less expensive or fell within the range of copy drug prices.¹¹
- e. The Global Fund in its mid-year 2006 Results Report stated, “Initially, the drug supply was the problem. Now it is all about capacity for implementation to meet the increasing demand.” The Global Fund has experienced a 150 percent increase in AIDS patients on ARV treatment; a 140 percent increase for tuberculosis patients treated under DOTS; and a 265 percent increase in insecticide-treated bed nets distribution to combat the spread of malaria, all in the time period between June 2005 and the Report. As of October 2006, the Global Fund had disbursed \$2.8 billion of the \$6.4 billion it had in pledges.¹²
- f. The International Treatment Preparedness Coalition (ITPC), published a six country survey in November 2005. In terms of major roadblocks facing the international AIDS community, it found “in every country surveyed there were concerns about inadequate leadership at the national level and the subsequent failure to dedicate sufficient resources or mobilize governments. Scale up of treatment will not happen unless countries fulfill their responsibilities to those

living within their borders—and national governments must be the primary engine for increasing access to care.”¹³ One country in the survey was India, which had \$598 million in donor contributions for AIDS. For the 2005-2006 period, however, India’s government had committed only \$5 million to the effort. WHO reported that of the 785,000 AIDS patients needing treatment, only 12,000 were receiving it as of December 31, 2005. Yet, India is the main supplier of ARVs to poor African and Asian countries.

- g. In July 2004, the International Monetary Fund (IMF) expressed its concerns when reviewing current aid resource flows of \$8 billion for HIV/AIDS. It found:
- There are macroeconomic risks associated with large grant flows—including high inflation, which retards growth and acts like a tax on the poor
 - Real appreciation of the currency, which can hinder the rural poor from exporting commodities vital to their livelihood;
 - Rising domestic interest rates can squeeze social spending by raising public debt service payments.¹⁴
- h. In October 2005, the Center for Global Development (CGD) published “After the Big Push? Fiscal and Institutional Implications of Large Aid Increases”. If the world were to heed calls of large aid increases, as those implied in the Millennium Development Goals, the Commission for Africa, and donor pledges at the recent G8 Summit, “low income countries could witness a dramatic increase in the financial assistance they receive—making it imperative to ponder potential impact on institutions.” Five key findings for 52 low-income countries:
- Aid levels are already fairly high. Nearly half of the countries are receiving aid worth more than 50% of government expenditures and more than one-fifth are above the 75% level
 - Aid intensity would increase substantially under “Big Push” scenarios. In the average projection, two-thirds would rise above the 50% threshold and one-third above 75%
 - “Big Push” aid flows can give governments even less of a reason to go through the tedious task of building and improving tax administration if they can get more resources from donors than their own citizens
 - As donor financing of national budgets increase, the budget process becomes directed more towards satisfying donors rather than domestic preferences
 - Rapid increases in aid could be problematic if such levels are not sustainable over the long run. Tenuous fiscal situations in many of the leading donor countries suggest that the promises made may be extremely difficult to maintain.¹⁵

2. Consequences of Subcontracting Out WHO's Institutional Authorities

The legal status of UNITAID cannot be determined from any of the three documents presented in Part I. In the MoU, there is an acknowledgement that it has no such status--though UNITAID is the trigger which expends WHO's authorities and resources! The operative guidance in this matter should be WHO's Constitution. Since the initiating parties to UNITAID are NGOs and the government of France, the acceptance of UNITAID by WHO should be in accordance with Article 37 of its Constitution, wherein: "The Director-General and the staff shall not seek or receive instructions from any government or from any authority external to the Organization. Each Member of the Organization on its part undertakes to respect the exclusively international character of the Director-General and the staff and not to seek to influence them."¹⁶

Huge resource flows from particular members do serve to influence the Director-General and his staff, subjecting them to a "pay to play" program environment at the expense of non-participating members. In 1996, former Director-General Hiroshi Nakajima warned the WHO about this issue. In the Proposed Programme Budget for 1996-97, he wrote of his growing anxiety for use of the Extrabudgetary Account: "these funds are usually earmarked, the choice of activities is determined by the donor and not by the community of Member States comprising the Organization, and the management of these funds generally escapes the jurisdiction of the Executive Board and the Health Assembly."¹⁷

The WHO draws its authorities from the United Nations Charter. Article II of this Charter maintains "the principle of sovereign equality of all its Members."¹⁸ Those who framed the U.N. Charter sought to safeguard this principal against future encroachments by establishing the preeminence of the Charter over any other international obligation. In Article 103, it stipulates: "in the event of a conflict between the obligations of the Members of the United Nations and of the present Charter and their obligations under any other international agreement, their obligations under the Charter shall prevail."

The material effect of UNITAID is to advantage some members and non-members, while at the same time disadvantaging non-participating members and non-members. Given this principal in the Charter, can some members now be more sovereign than others! And if so, shouldn't the Charter be amended to reflect these new circumstances?

UNITAID is planning to allocate \$300 million to the WHO Secretariat in the first year of operations. This is a conservative figure, as France alone has promised 200 million Euros in the same time period, or \$253 million at current exchange rates. The Global Fund has declined the role as UNITAID's implementing agency. In doing so, it commented: "It has been our understanding that the initial actions of UNITAID would be for the short-term only, enabling the resources that are already being generated to have an immediate impact ... however, those developing the short-term programmes have been asked by UNITAID representatives to plan the continuation of activities until 2010 ... there have been very limited discussions to our knowledge of halting initial programmes after the first year to integrate them with existing mechanisms ... if taken forward in this way,

these programmes would, in effect, become new parallel financing mechanisms with all the associated implications at both the global and country level.”¹⁹

The rapid growth of the Extrabudgetary Account bears concern for those that support the institutional integrity of WHO. From the time former Director General Nakajima expressed his anxieties about it to the present, this account has expanded almost four times:

Table 2: WHO’s Budget: Regular and Other Sources 1996-1997

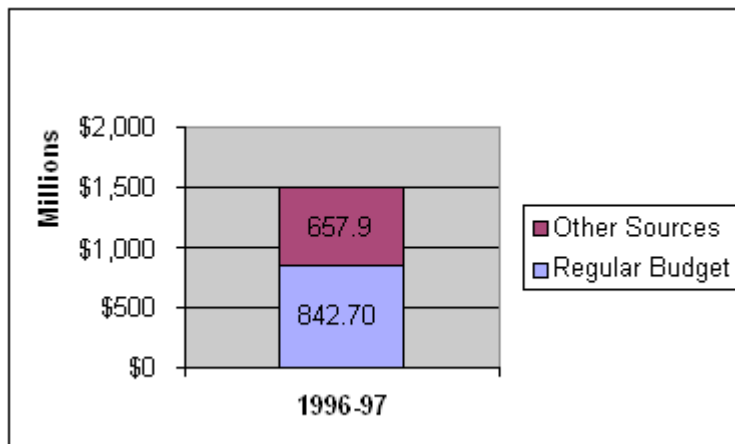
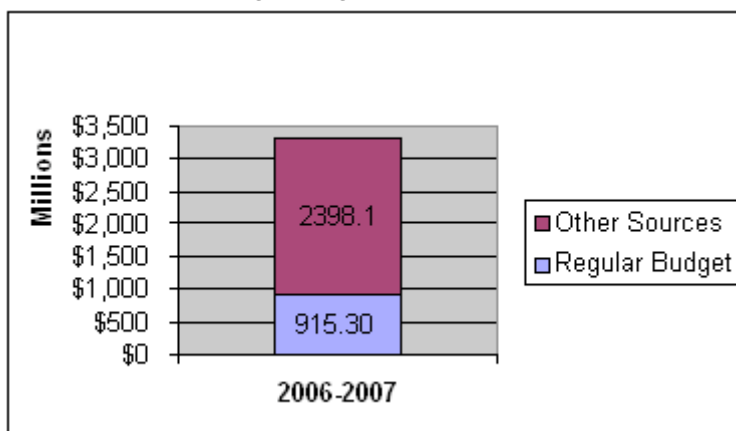


Table 3: WHO’s Budget: Regular and Other Sources 2006-2007



WHO’s Secretariat will charge processing and technical-support fees for all drugs procured by the Global Fund, UNICEF, or the Clinton Foundation, e.g., 13 percent for technical support alone. These funds will accrue to the Extrabudgetary Account, and a substantial portion will be designated by the Secretariat to WHO’s Office of Essential Drugs and Medicines Policy. Based on UNITAID’s estimate of a \$300 million annual income from airline taxes, processing fees and direct payments, this could increase the Office’s Extrabudgetary Account from \$19.4 million to \$77.4 million:

Table 4: Office of Essential Drugs and Medicines Policy Budget 2006-2007
(In Millions)

Regular Budget	\$6.3
Extrabudgetary Account	\$19.4

Table 5: Office of Essential Drugs and Medicines Policy Budget 2006-2007
UNITAID addition (In Millions)
(est.)

Regular Budget	\$6.3
Extrabudgetary Account	\$77.4

It would not be unusual for those countries that fund this account to insist on a management input. In the past, WHO’s first requirement for the composition of a Management Advisory Committee to this Office was that would-be committee members be “government representatives of those countries which contributed funding in support of its budget in the previous two years.”²⁰

In every organization, public or private, money rules. The uses of the Extrabudgetary Account external to the governance structure of the Organization have downstream consequences, particularly because they will be expended through WHO’s Office of Essential Drugs and Medicines Policy. If UNITAID is correct in its estimates, then WHO’s Regular Budget for this Office—which members vote on in Annual Assemblies—will be insignificant. This Office will be enthralled to specific member states rather than to the community of members comprising the Organization.

3. Other Constraints to UNITAID/WHO

Intellectual Property (IP)—WHO appears to have imparted a legal status to UNITAID, through the copyright notice “© World Health Organization,” but its authorities for doing so remain unstated. WHO does not explain how it will negotiate with the original holders of intellectual property over the use of their copyrights, e.g., fees for its use, etc. Nor does it discuss how another party’s IP can be applied to a substandard copy drug product. If a patient has an adverse reaction sufficient to seek legal redress, in what jurisdiction can it be adjudicated, e.g., in the legal residence of the original holder of the copyright?

Privileges and Immunities—WHO will extend these to members of its Secretariat, which can include NGOs and the Clinton Foundation. This removes the moral incentive to procure and negotiate for drugs of known quality, safety, and efficacy, as the Secretariat will be covered under the International Organizations Act, relieving inclusive parties of any liabilities, but not other parties involved in service delivery, e.g., NGOs.

National Regulatory Requirements and WHO Prequalification—As a membership organization, WHO must accept the standards of its members. According to WHO, many member countries permit the export and import of drugs that are not bioequivalent to the reference product. These are, by definition, substandard drugs which can accelerate the onset of drug resistance and cause a possible mutation of the AIDS virus. Furthermore, beginning in May of 2004, the WHO had to de-list 18 ARV drugs that it had previously pre-qualified due to a lack of proof of their bioequivalency.

UNITAID comments in its procurement criteria that “assurance of quality will be through established international standards which assure their quality, safety and efficacy ... and be consistent with WHO procurement principles.” If this is to be followed, then it would eliminate the use of drugs on WHO’s pre-qualification list. WHO clearly states that these drugs “have been found acceptable, in principle,” but does not define either the meaning of “acceptable” or “principle.” Nor does WHO ever use the term “generic” on this list. It issues a Disclaimer in every prequalification publication: “Inclusion in the list does not constitute an endorsement, or warranty of the fitness, of any product for a particular purpose, including in regard of its safety and/or efficacy in the treatment of HIV/AIDS.”²¹

It is proper for a Membership organization to respect the sovereign standards of its Members. Yet, the UN Universal Declaration of Human Rights establishes the preeminent principle of informed consent, e.g., in the present situation, patients must be given to understand which of the WHO pre-qualified drugs are substandard.

UNITAID Will Work Closely to Ensure Implementation Up to the Patient—This places the WHO Secretariat into a position of being simply a purveyor of drugs to governments or NGOs via UNICEF—but sets aside patients’ outcomes from the use of these products. It is a quantitative metric rather than a qualitative measurement of clinical progress in disease treatment. The late Director General of WHO, Dr. Jong-wook Lee, wrote passionately about the need for bedrock ethical values in meeting targets. He fixed the WHO’s core values on those found in its Constitution of 1948, commenting in *The Lancet* in 2003: “unequal development in different countries in the promotion of health and the control of disease ... is a common danger.”²² The creation of UNITAID and its hosting by WHO is only a partial application of this Constitutional provision.

UNITAID comments often in the three documents that it is adopting the WHO “public health” approach to treatment, e.g., providing treatment to as many as possible, as quickly as possible, and as cheaply as possible. The continuation of this policy ignores the recommendation of the evaluation team on WHO’s “3 by 5” program: An area which merited further assessment by WHO was to evaluate “the evidence for the public health approach to scaling up HIV treatment, prevention and implementation.”²³

Selection of Suppliers—Although the MoU states that “all eligible suppliers should have fair access to whatever procurement approach UNITAID adopts,” it then goes on to temper this statement by commenting that it should be “consistent with WHO procurement guidelines.” These guidelines have been imperfectly hidden non-tariff barriers to open and free international competition. They deprive many people in member

states of the opportunity to manage their disease burdens through informed, rational choice between therapeutic alternatives that are fiscally sound and clinically prudent.

Exclusivity Arrangements—WHO states that it is not a party to any exclusive or similar arrangement with manufacturers or suppliers. However, the WHO procurement guidelines limit competition by pre-qualifying only those manufactures who agree to be inspected by teams it designates, by choosing bids based on lowest price rather than value to patients, and by favoring the procurement of copy drugs of indeterminate quality vs. those of known quality, safety and efficacy. For instance, most of the drugs on its pre-qualification list are made in India, which permits the export of non-bioequivalent drugs.

Clinton Foundation—This is an IRS tax exempt 501(c) 3 organization, registered in the state of Arkansas. One of the few limitations to its operations is to establish that a substantial portion of its financial support is from the “public.” What that means is that it cannot receive, for example, \$1.9 million of a \$2 million budget from one organization consistently over time.

The Foundation does need to initiate a discussion with the IRS and clear the way for it to be materially involved in mercantile activities with an international organization that is copyrighting products already covered by copyright; that it will work on behalf of an organization which has no legal status (UNITAID); that WHO may cover the foundation under provisions of the International Organizations Act, thus shielding it from U.S. laws; that it will remit to UNITAID’s Secretariat a 1 percent fee for processing of funds from its negotiations; and that it will “work with manufacturers and national governments to organize the markets for HIV/AIDS commodities.” These aren’t considered “charitable” or “educational” activities; they can jeopardize the foundation’s standing with the IRS.

Conflict of Interest—WHO is establishing the normative standards by which drugs can be procured, and through the Secretariat, procuring these same products and then financially benefiting from commissions generated through procurements. Neither the EMEA nor the FDA can place themselves in a similar conflict of interest position.

Cost Benefit Analysis—WHO assumes that the UNITAID program will be able to lower the price of drugs from manufacturers. Yet, it has offered no cost benefit analysis to prove that this will lower downstream **prices to patients**. WHO did establish in its May 2006 pricing report that taxes, duties, tariffs, and in-country distribution costs contributed more to the final price to patients than did the manufacturers’ original price. Now, it is adding to those prices the fees described on Table 1. These fees do not include the transaction costs of its implementing partner, the Clinton Foundation, or UNICEF. WHO is putting itself into a position of being another middleman or distributor between the price charged by manufacturers and the cost to patients.

Taxation without Representation—The United States government is not a party to UNITAID, but it may well have to pay in any regard. The Global Fund has stated that it will not serve as the implementing agency for UNITAID. However, this doesn’t mean that a future role has been ruled out. In a letter to the UNITAID Core Group, the

Executive Director of the Global Fund said: “we believe that the most effective partnership between the Global Fund and UNITAID is through the proposal round system ... through the use of new proposal Rounds, UNITAID would be able to have a significant impact on access to essential medicines ... while effectively realizing its core principles of complementarity and additionality.”²⁴

The U. S. Congress limits fiscal support to no more than one third of any year’s disbursements. When the Global Fund receives the anticipated \$300 million per annum from airline taxes, this would raise the bar. For instance, if the Global Fund would have disbursed \$1 billion before the air line tax levies, the U.S. contribution would be \$330 million. However, if an added \$300 million comes in to support new Rounds, raising Fund disbursements to \$1.3 billion, then the share from the U. S. would automatically rise to \$429 million. Since the government of France is actively working to include China India and the UK in UNITAID, vast new resources may raise the US bar.

Solidarity Taxes as ODA – In the debt forgiveness programs now underway for the poorest countries, many activists were concerned that rich countries would consider their payments as a component of Official Development Assistance rather than as additive to that component. This concern proved all too real, as key OECD countries simply reduced ODA by the amount of their debt forgiveness. Solidarity taxes are likely to be treated in a similar manner by participating countries, resulting in no substantial resource increases but added transaction costs to the benefit of WHO—and product prices to patients.

Country Participation—The five founding countries have agreed to give a “green light” to UNITAID so next steps can be initiated. These include: providing pediatric ARVs for up to 100,000 children in 2007 across 30 countries beginning in the fourth quarter of 2006 at a cost of \$26.6 million; committing funds for scale up of second-line ARVs to 100,000 patients in 16 countries at a cost between \$60 - \$80 million in 2007; scaling up Artemisinin combination therapies at a cost of \$28.3 million in eight countries by end of 2006; providing pediatric TB treatment for up to 150,000 children in 2007 at a cost of \$8.5 million in 2006-2007; and funding \$7 million to WHO’s pre-qualification program.

UNITAID makes no mention of how its “green light” activities will be coordinated with the ongoing grant activities of the Global Fund. Its Executive Director has expressed concern to UNITAID that if these activities aren’t integrated with existing mechanisms after the first year, “these programmes would, in effect, become new parallel financing mechanisms with all the associated implications at both the global and country level.”²⁵

Creation of a Monopsony Power—What does it mean when UNITAID says it intends to “organize the market” or promote “market competition” or “overcome limitations to market diversification?” The combination of WHO standards tied to pharmaceutical procurements may represent initiatives that reduce social welfare in the long-run. The policy would bestow “Most Favored Nation” (MFN) status on a set of WHO-approved products. Manufacturers must sell the approved products to “approved” buyers at the lowest bid price offered to any buyer. Expanding the set of approved buyers at MFN prices greatly expands the volume of sales tied to the MFN prices. If demand for

pharmaceutical products is steered to a limited set of MFN products, the results may be: 1) reduced demand for newer products; 2) increased risk associated with R&D expenditures, and 3) higher prices for drugs not achieving MFN designation.

The implementation of UNITAID policy serves to create monopsony power for WHO and the countries that participate. There are adverse social welfare effects linked to creation of monopsony power. A monopsonist is able to reduce prices below the competitive level and purchase less product than would have been sold under competitive conditions. The monopsonist captures some of the surplus. Sellers must either sell at the requested price or leave the market.

Price concessions from restrictive lists of drugs come at the cost of reduced welfare by ignoring the preferences of consumers. Furthermore, bid prices reflect a range of factors other than either cost of production or even R&D. They also reflect the liability laws faced by manufacturers and the regulatory environment in the manufacturer's host countries. Forcing manufacturers to sell at MFN prices would redistribute income to WHO-approved buyer countries. Such a policy outcome has no clear or fair rationale.²⁶

Drug Resistance—In UNITAID's "green light" initiative, it states that it will treat 100,000 AIDS patients in need of second-line therapies at between \$60 – 80 million. However, if 2 million are under treatment by the end of 2006, it is more than likely that at least 20 percent, or 400,000, will be in need of second-line therapies. Still, taken at the mid point of \$70 million, this would mean a per patient per year price for ARVs of \$700—for product costs. UNITAID makes no estimate for ongoing medical care costs. But UNAIDS does, saying that in middle-income countries, the annual cost for AIDS treatment and care for those needing second-line therapies would be \$4,115 per year.²⁷

UNITAID's and WHO's policy is to take drugs "up to the patient" and thereafter to leave the consequences and recurrent costs of drug choice to someone else. There can be no doubt that sustaining life and hope for AIDS patients as long as possible is of the highest moral imperative. Still, by promoting a policy of merely purveying drugs up to patients, WHO isn't educating donors on the future unfunded liabilities for patient care. The price of these drugs may be seen as the undersea tremor: societal medical care cost, especially due to drug resistance, is the oncoming tsunami. The failure by WHO to sound this alarm has enormous populist appeal—for now.

Compulsory Licensing—At several points in all three documents, the term "compulsory licensing" is used. For emphasis, the term is in bold print. In the UNITAID Constitution, it states that "where intellectual property barriers hamper competition and price reductions, it will support the use by countries of compulsory licensing under the framework of the Doha declaration ... where applicable."

On October 12, the head of the World Trade Organization reported that his group "had not received a single notification of a developing country issuing a compulsory license."²⁸ The reason for this may well be due to several factors: discounts offered by innovative companies in developing countries, continued supplies of legal generic copies by Indian

and other generic suppliers, and the fact that voluntary licensing to South Africa, Kenya, Russia, and India has removed this issue as a problem in access to medicines.

Member States more than WHO may be exhibiting adherence to Articles 17, 27 and 30 of the UN's Universal Declaration of Human Rights and its provisions which state: "no one shall be arbitrarily deprived of his property ... and to enjoy the right of protection of the material interests resulting from any scientific production ... nothing in this Declaration may be interpreted as implying from any State, group or person any right to engage in any activity aimed at the destruction of any of the rights and freedoms set forth herein."

Winners & Losers—By subordinating its own Constitution to that of the special interest groups underwriting UNITAID, it is not obvious what WHO gains, except commissions on procurements and other direct payments. The global health community, though, loses a leader it had been able to depend upon since WHO's inception in 1948.

Lost Opportunity—Rather than leading the way forward, UNITAID and WHO are following past remedies: pour in money and stir. In an entire galaxy of opportunity, they found a world of yesterday's problems in which solutions are found only through the application of more money. The international health community is in desperate need of leadership, one that will champion patient care and hold all parties to the Collaborative Statement by the UN, the Red Cross and MSF: "there should be no double standards in quality." By lowering standards in drug procurements, UNITAID/WHO are procuring drugs for patients because they are poor rather than because they are sick.

The Market—Since 1989, the R&D industries have produced and marketed 89 different therapies which extend the life of AIDS patients. These are widely available in all countries. UNITAID/WHO now wants to "organize the market." Neither of the parties can explain how they will sustain a market dependent upon the continuing sanctioned expropriation of intellectual property; provide incentives for the promotion of innovation; manage the market in sovereign member states; maintain a steady flow of subsidies; support a price structure for drugs which comprise perhaps 1 percent of the total global pharmaceutical market; or continue to deny consumers' choice in favor of a distant, centralized organization which purports "to know better" what poor patients need.

Duplication of Effort—The Global Fund sponsored a study by McKinsey&Company in August to determine what position it should adopt relative to "market dynamics.", a term which appears frequently in UNITAID documents. An appropriate approach recommended by this firm is one that should be designed in such a way as to avoid a number of potential concerns raised by some stakeholders. "This means, for example, adopting a role that respects the limits of the Global Fund's mandate as a financial institution, and not duplicating initiatives already undertaken effectively by other organizations."²⁹ Fortunately, the Global Fund's Executive Director has taken this recommendation to heart. It is not known, though, whether the new Executive Director in 2007 will share this view. Nor does UNITAID make any comment as to how its operations will be coordinated with those of PEPFAR, the World Bank, the EU, etc.

Conclusion

The rationale behind the formation of UNITAID is at best weak, duplicative of current programs, adds to the macroeconomic imbalances now in play in poor countries, and is in contravention to Article 37 of the WHO Constitution, and Article II of the UN Charter. Issues of price, demand and drug supply were yesterday's problems, which UNITAID today boldly steps forward to address. The largest provider of AIDS therapies to patients is the UN/AAI program, of which WHO is a founding member. UNITAID's activities run parallel to that effort, as well as to multiple programs of numerous organizations.

There is a delicate bond between those charged with managing the daily affairs of WHO and the stewards charged with maintaining fidelity to the time-honored Constitutional provisions of WHO. At times compulsion must be applied to maintain the bond.

This is such a time. UNITAID is an undertaking that begins to remove WHO from its institutional legitimacy as an organization dedicated to "health as a state of complete physical, mental and social well-being." Acting as the hosting agent for the delivery of drugs to patients in return for commissions, then abandoning all clinical aspects of care, is a prescription for WHO to forfeit its role as "the legitimate inter-governmental authority on global health matters." Either WHO is a membership organization in which "the principle of sovereign equality of all its Members" is sustained, or it is a "pay to play" mercantile enterprise.

In 1947, when WHO's Constitution was going through the process of being approved by the U. S. Senate, the Foreign Relations Committee listed a number of benefits if WHO membership was approved. One such benefit was that "the international markets for low standard drugs [would be] generally eliminated."³⁰

How would the Committee vote today when informed by WHO that its procurement policies permit the use of known substandard drugs for the poor? Or that WHO would serve as the hosting agent for special interest groups which would purvey drugs at higher prices to those most disproportionately affected than any other element of society: poor patients. Or that its Extrabudgetary Account would consist of funds wherein "the choice of activities is determined by [specific donors] and not by the community of Member States comprising the Organization"³¹ Or that its Constitutional legitimacy could be hijacked by special interest groups, offering in return commissions for services rendered?

WHO managers must return the Organization to the core ethical values of its Constitution and put the interest of patients first. There is no need for WHO to serve as another commercial distributor for drugs of indeterminate quality in the absence of its adherence to provisions of informed consent in the UN Universal Declaration of Human Rights. If WHO doesn't have sufficient funds in its Regular Budget to meet mission objectives, then Member States need to step up to the realities of global health needs in the 21st Century—and provide the Organization with resource flows ample enough to sustain its institutional principles without the current stewards having to auction them off to the highest bidder.

End Notes

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