

THE WORLD BANK, PHARMACEUTICAL POLICIES, AND HEALTH REFORMS IN LATIN AMERICA

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Health care systems spend a relatively high percentage of their resources on the purchase of medicines, and the poor spend a disproportionate amount of their income on pharmaceuticals. There is ample evidence in the literature that drugs are very poorly used. World Bank–led health reforms aim at improving equity, efficiency, quality, and users’ satisfaction, and it will be difficult to achieve these goals without making medicines accessible and affordable. The purpose of this article is to examine the adequacy of World Bank pharmaceutical policies, as recommended in various Bank documents, for Latin America and to examine the implementation of the policy recommendations. The authors found that the World Bank identified and recommended a set of pharmaceutical policies that matched the needs of the region. But, as revealed through fieldwork and a review of the literature, the recommended pharmaceutical interventions were left out of the health reforms, and most of the loans that included pharmaceutical interventions allocated funds only to the purchase of drugs. The authors formulate four hypotheses that may explain the lack of congruence between the recommended policies and the strategies financed by World Bank health reform loans to the Latin American region.

For the past 20 years, World Bank–led health reforms, often referred to in the literature as neoliberal reforms, have been an important component of reforming the state in Latin America. In almost all countries of the region, the health reforms included three basic policies: decentralization of services, downsizing of the public sector through privatization and outsourcing, and the offering of minimum health service packages to the indigent populations at no cost. According to the framers of the reforms, these policies would make the health sectors more equitable and efficient, and the quality of the services and users’ satisfaction would increase.

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Other aspects of public health and medical care were given less consideration or were left out of the reforms. We consider it useful to identify policies not included in the reform blueprints that could have had a positive impact on its stated objectives, and to understand the reasons that led to their exclusion.

Our field studies of Latin American health reforms (Bolivia, Colombia, Costa Rica, Dominican Republic, El Salvador, Honduras, and Mexico) and a survey of the literature in these and other countries indicate that among the policies left out from the World Bank–led reforms were those related to pharmaceuticals. This is not to say that in some countries policymakers have not approved pharmaceutical-related policies, but when this has occurred, the policies were not part of the health reforms. Some examples of country initiatives to improve the accessibility, affordability, and use of medicines include the PROMESE plan to import low-cost generic drugs and distribute them through community pharmacies in the Dominican Republic; the free distribution of 46 essential drugs in public clinics through Plan Remediar in Argentina; the program to treat and reduce the transmission of HIV/AIDS in Brazil; and the enactment of laws requiring prescribers to use international nonproprietary names in most countries of the region.

It is difficult to explain the exclusion of pharmaceutical policies from health reforms that aim at improving efficiency and equity. In 2003, worldwide drug sales amounted to almost \$500 billion (all dollar amounts in U.S. dollars) (1), and three-fourths of the expenditures occurred in the private market. The poor spend a large percentage of their income on medications, and a substantial percentage of public health sector expenditures is allocated to drugs. It is well established that the utilization of public primary care in developing countries (used mostly by the poor) depends to some extent on the availability of affordable drugs.

In Latin America, total drug expenditures in 2003 amounted to about \$19 billion (1). Countries in the region spend between 7 and 16 percent of their public health sector budgets on pharmaceuticals: 16 percent in Argentina, 7.7 percent in Costa Rica, 8.3 percent in Honduras, 15.2 percent in Venezuela (2), and, excluding the social security institute, 9.4 percent in the Dominican Republic (3). As in other parts of the world, the cost of medicines is increasing at a faster rate than other health services (4, 5), and pharmaceuticals are the highest out-of-pocket health expenditure for the poor (6–10). The poor spend a disproportionate share of their income on medications; the lowest income decile spends up to twice as much as the highest (11). A survey of seven Latin American countries documented that the lowest income quintile allocated 52 percent of all health expenditures to drugs; for the highest income quintile, drugs represented 30 percent of their health expenditures (12). In Argentina, the lowest income quintile spends 8 percent of total income and 80 percent of health expenditures on medicines; for the highest income quintile the percentages are 3 and 30 percent, respectively (13). In the Dominican Republic, about 62 percent of all ambulatory care expenditures are for the purchase of medicines (3).

The utilization of public health services depends on the availability of medicines. The Latin American poor are not willing or are unable to pay the indirect costs of accessing “free” health services (transportation costs, unpaid sick leave, time) and co-payments, unless they know they can obtain free or affordable medicines (13–15). Rightly or wrongly, they believe that the resolution of their health problems depends on the medication. For these reasons, improving health equity needs to start by enacting policies that provide free or affordable medicines to low-income classes.

This article is organized in three sections. First, we analyze the adequacy of World Bank pharmaceutical policies as presented in the 1993 World Development Report (16), prepared in part to support the rationale of its health reform policies, and in subsequent documents. Second, we show that the World Bank’s pharmaceutical policy recommendations were not supported and financed by the loans that the Bank sold to Latin American countries. Finally, we advance four hypotheses that attempt to explain why the World Bank failed to support the implementation of its own pharmaceutical recommendations in Latin America.

THE ADEQUACY FOR LATIN AMERICA OF THE WORLD BANK’S PHARMACEUTICAL POLICIES

The 1993 World Development Report (16) was critically analyzed soon after its publication (17, 18), and our intention here is not to contribute to this discussion but to examine the adequacy of its pharmaceutical recommendations in the Latin American context and the support they received from World Bank loans to the region. Subsequently, the Bank has published other pharmaceutical documents, but the 1993 report continues to guide health policy interventions and has not been superseded by more recent papers. In 1994, the World Bank published two papers that reiterated all the key recommendations made the previous year (19, 20). Surprisingly, three years later, an official strategy document for the Health, Nutrition, and Population sector made no reference to the pharmaceutical sector (21). Conversely, a more recent World Bank discussion paper (22) encouraged the Bank to support the pharmaceutical reforms that had been voiced earlier, such as strengthening the regulatory capabilities of developing countries and encouraging the use of essential drug lists.

The inclusion of pharmaceutical policies in the 1993 report is well justified by the large amount of resources spent on drugs. Except for a few references in the overview section of the report, the pharmaceutical policy recommendations are found in pages 144 through 148. According to the report, substantial reductions in waste and inefficiency in public health programs could be obtained through the implementation of better drug policies: “countries pay too much for drugs of low efficacy, and drugs and supplies are stolen or go to waste in government warehouses and hospitals” (16, p. 12). The report considered pharmaceutical policies to be “the most promising area [in the health sector] for efficiency gains in

the short run” (16, p. 159). Table 1 summarizes the report’s drug policy recommendations, and we examine their adequacy in the Latin American context.

Essential Drug Lists

Since 1977, the World Health Organization (WHO) has prepared and periodically updated, with the technical assistance of a highly regarded group of experts, a list of essential drugs. The WHO recommends that countries adapt the list to their own health needs. The most recent revision (2003) included 310 drugs that are considered sufficient to treat the vast majority of health problems. The World Bank report, following the WHO’s advice, strongly recommended all countries to issue a list of essential drugs to guide acquisitions, and acknowledged that many countries do have a list but do not use it. The report went even further than the WHO recommendations and suggested that the list be used to guide the registration of drugs, and it offered the example of developing countries (Bangladesh and Sudan) and Norway to show the benefits of such a policy. The World Bank report mentions that international competitive bidding enables countries to purchase essential drugs at low prices and asserts that large savings can be obtained through economies of scale if drug procurement is centralized.

On the advice of the WHO, all countries in Latin America have had an essential drug list for some time, but, at best, only the ministries of health use them. Most social security institutes use formularies that contain many more drugs than those

Table 1

Pharmaceutical policy recommendations included in the 1993 World Development Report and their appropriateness for Latin America

Policies	Appropriateness for Latin America		Incorporated in the World Bank health sector reforms	
	Yes	No	Yes	No
Use of essential drug lists	✓			✓
Use of generic drugs ^a	✓			✓
Improving procurement and distribution	✓		✓	
Strengthening regulatory capabilities	✓			✓
Improving adequate use	✓			✓
Cost recovery fees and revolving funds		✓	✓	
Discouraging national production of drugs		✓		✓

^aThe recently approved (February 2004) World Bank procurement documents specify strategies that countries can use to benefit from cheaper generic anti-retroviral drugs.

in the essential drug lists, and the institutes spend much more on pharmaceuticals than do the ministries of health. Within the health ministries, hospitals and health centers purchase drugs not included on the list directly from wholesalers and retailers. As a result, the benefits obtained from the use of these lists have been limited.

Essential drug lists have not been used in Latin America for the registration of drugs, and for this reason the pharmaceutical markets have more products than needed. For example, in Chile the national formulary includes 326 active principles and 426 products, but there are more than 1,200 different active principles and more than 5,000 drugs on the market (23); Ecuador has 8,800 drugs (24); Colombia, 8,300 (25); Mexico, about 7,000 drugs available in 19,000 different forms (26); Bolivia, 8,293 legally registered drugs and 5,518 on the market; Costa Rica, 5,000 drugs; the Dominican Republic, 14,182; Honduras, 15,000; Nicaragua, 12,000; and Peru, 11,241 (2). In 1998, Peru registered 1,672 new products; only 50 percent of them contained active ingredients included in the WHO list of essential drugs, and only 49 new chemical entities were added in 119 formulations (27). In Peru the drug proliferation speed is accelerating: in the late 1980s it registered about 80 drugs per year; in the 1990s the number was above 1,000; and one year it authorized 2,000 products (28).

Generic Drugs

The World Bank report considers that patents create monopolies that drive prices up, and it indicates that large savings can be accrued by purchasing generic drugs.¹ (In 1993 all drugs in the WHO's essential drug list were off patent.) Cost effectiveness should guide the selection of generic drugs within the same therapeutic group—that is, the selection between drugs that are therapeutically equivalent should be based on cost.

The following are examples of the drastic reduction of prices that has been attributed to the use of generic drugs in the region. In Mexico, as a result of the introduction of generic drugs in 1999, there was a 30 percent decline in prices (26). In Brazil, generic products cost on average 40 percent less than brand-name products (2). In Chile, the average price per pharmaceutical unit is \$3.4, while the unit price of a generic drug is \$0.88 (2). Within months of the approval of the generic prescription law in Argentina, the prices of the most commonly prescribed pharmaceuticals decreased by 8 percent, and some by 45 percent (29). Peru, through the program PACFARM (Joint Pharmacy Administration Program), distributed generic drugs through its public health network, and their prices were 50 to 80 percent lower than the original drugs purchased in retail pharmacies (30).

¹ The term *generic* is confusing; in this context we refer to multisource drugs, which include generic drugs and copies (in Latin America frequently identified as “similar drugs”). See discussion by Homedes and Ugalde (109).

Brazil lowered the yearly cost of anti-retrovirals from \$4,860 per person in 1997 to about \$1,000 in 2003 by using generic drugs and threatening the multinational industry with issuing compulsory licenses and beginning the local production of generic versions of patented drugs if it did not lower its prices (31, 32). Researchers in a public general hospital in Corrientes, Argentina, estimated that the yearly savings of using the lower-priced drugs of the 67 most commonly used medicines could add to about \$150 million (33).

Unfortunately, countries that have enacted legislation requiring prescribers to use the international nonproprietary names (INN) or other nonproprietary names have faced the opposition of the innovative industry and other pressure groups, and in most countries the policy is not enforced. In Argentina, the ministry of health took a very strong position and mandated the use of generic names on all prescriptions. Several months after enactment of the law, only 57.7 percent of the prescriptions complied with the directive (34). Many physicians opposed the requirement to use the INN; they considered that such an obligation was an infringement of their professional autonomy and joined efforts with the pharmaceutical industry to oppose policies to promote the use of generic drugs (35).

In Costa Rica, Roche and the medical association maintained that the social security fund's replacement of a brand-name drug (Viracept [nelfinavir]) with a less expensive generic produced by a national laboratory, which was compliant with Good Manufacturing Practices (GMP) and was certified by the U.S. Food and Drug Administration, placed the health of beneficiaries at risk, and Roche sued the fund (36).

Procurement and Distribution

The World Bank report highlighted the benefits of centralized, competitive, and transparent procurement practices and offered examples of savings through adequate selection and good procurement: countries that prepared competitive bids had savings ranging from 40 to 60 percent of pharmaceutical expenditures (16, p. 12). We can add the cases of Chile and Guatemala. The Chilean hospitals saved about \$4 million by using an open electronic reverse auction bidding system, a project developed in part with World Bank funds (37). It is estimated that each hospital saved between 5 and 7 percent of the pharmaceutical budget. In 1997, in Guatemala, the ministry of health, the social security institute, and the armed forces centralized drug procurement, resulting in savings of 65 percent for the ministry and 23 percent for the social security institute (2). The 1993 report also recommends, when feasible, the purchase of drugs through international nonprofit organizations such as UNICEF and the International Dispensary Association.

The World Bank has financed the purchase of pharmaceuticals in Latin America and, to guarantee the transparency of the process and the quality of the drugs, has developed drug procurement guides and conducted training workshops.

For large purchases, the Bank recommends the use of international competitive bidding. The Bank's technical recommendations are easily available, in several languages, on its website. The most recent document was approved in February 2004 for the purchase of anti-retrovirals. This document can be used by countries that want to benefit fully from the flexibilities included in the TRIPS (Trade Related Intellectual Property Rights) agreement to gain access to generic anti-retrovirals (38).

The impact of technical assistance on drug procurement provided by the World Bank has not been clearly established. Rovira (39) found that, between 1999 and 2002, 50 countries purchased 99 percent of their pharmaceuticals and medical products from 22 countries. He also indicated that, in Nicaragua and a few other countries outside Latin America, all such products were purchased from one national supplier.

Appropriately, the 1993 World Bank report emphasizes the importance of accurately estimating drug needs. Excess can lead to waste if consumption does not take place before the expiration date, and shortages adversely affect quality of care and the utilization of health services.

The report also points out the need for improving storage conditions and distribution systems to reduce waste, and recognizes that something should be done about custom agencies that in many countries are notorious for corruption, delays, spoilage, and waste due to poor storage facilities. We have found very few estimates of the value of losses due to drug wastage, but media reports indicate that they could be very high. For example, in Paraguay, the National Comptroller's Office discovered in 2002 that medicines valued at approximately \$16,000 had expired and had to be withdrawn from public health clinics (40).

Strengthening Regulatory Capabilities

Prescribers and users cannot review all available information on pharmaceuticals, the World Bank report argues, and thus the government has a role in regulating the pharmaceutical market and ensuring that the information that reaches prescribers and consumers is accurate. The authors of the pharmaceutical recommendations added that "governments are also responsible for carrying out regulatory functions to ensure that all drugs on the market are of acceptable quality, safety and efficacy." They were well aware that "building up a national regulatory authority requires the creation of a core group of trained staff, the enactment of supporting legislation, and the establishment of quality assurance laboratories" (16, p. 145).

The limited capability of Latin American governments in this area is reflected in the number of unsafe products on the market (41). It is claimed that as many as 50 percent of the drugs sold in Argentina are useless, unsafe, or irrational combinations of active principles (42, 43). In some Latin American countries the consumer can purchase drugs that are banned in industrial nations, some of which are produced by local subsidiaries of foreign companies headquartered

in the industrial nations where the drugs have been banned (44, 45). The presence of drugs of questionable safety on the Colombian market has been documented (46, p. 299); and in Ecuador, international standards of GMP to assure safety are not enforced, and only eight manufacturing plants are inspected per year. It is well known that prescription-only drugs can be purchased over the counter in many countries of the region, and a study of drug dispensing in Mexico and Guatemala demonstrated that no mechanisms were in place to enforce pharmaceutical laws and regulations (47).

Equally important is that weak regulatory powers are unable to control the behavior of interest groups. The pharmaceutical industry frequently violates established ethical codes by providing gifts and other perks to physicians, providing inaccurate and even false information, and using questionable tactics to derail efforts to use low-cost generic drugs.

The increasing availability of counterfeit drugs suggests the need to strengthen regulatory and enforcement functions. In Peru, for example, the General Directorate of Medicines, Supplies and Drugs has indicated that 80 percent of the medicines distributed through the informal market in Lima do not have a registration label, are falsified, or are spoiled (48). In Bolivia, the Pan American Health Organization (PAHO) has estimated that 20 percent of the drugs are smuggled (22). It has been estimated that, in Mexico, up to 13 percent of drugs sold in pharmacies and open markets are counterfeit, and in the Dominican Republic counterfeit drugs are imported from eastern countries and marketed nationally with the knowledge of the customs authorities (49). Similar practices have been reported in Central America.

Adequate Use

The World Bank report recommends interventions to improve the appropriate use of drugs and proposes behavioral changes for patients, prescribers, dispensers, and the industry. The interventions suggested are aimed at educating consumers, reducing self-medication and unnecessary requests for injections (given the risks of this form of administration), increasing the number of and strengthening continuous education programs on clinical pharmacology for prescribers and dispensers, and enforcing the use of formularies by physicians and pharmacists.

As in many other parts of the world, in Latin America physician prescription patterns are often inadequate and poorly understood by patients, who frequently do not adhere to the prescribed regimen (50–60). Physicians do not clearly explain the various components of the administration of pharmaceutical therapies, and patients fail to request clarifications. Written instructions are seldom provided, either by the physician or at the pharmacy. The physician-patient contact lasts only a few minutes, and patients rarely ask questions. In a study of 404 consultations in Costa Rica, Ugalde and Homedes (61) found that the average duration of the encounter was 4 minutes and 45 seconds, and of 1,028 medications

prescribed, the patients asked for clarification for just 10 of them. This study also found that physicians very seldom discussed nonpharmaceutical therapies, even when those would have been the most appropriate form of treatment.

Studies in Colombia identified high levels of irrational prescribing, and half of the prescriptions for the treatment of high blood pressure and urinary infections and the ambulatory treatment of pneumonia were considered inappropriate (62–65).

As noted above, prescription-only drugs are frequently sold over the counter, leading to excessive self-medication, especially among the poor (66). According to a recent study by the Ecuadorian Federation of Pharmacists, 85 percent of the population self-medicates (67). It has been estimated that 9 percent of antibiotics and 30 percent of other prescription-only drugs are self-prescribed in Latin America (68). Even more troubling is the fact that those who dispense drugs are pharmacy clerks with no professional or vocational training. The Ecuadorian study found that only 12 percent of the pharmacies have professional pharmacists on duty (68), and in Mexico and Guatemala researchers have found that most drug recommendations made at the pharmacies were inappropriate (46), a finding similar to those reported in Peru (69), Colombia (70), and Mexico (14).

A good part of the poor prescribing practices is due to the inadequate pharmacological training of physicians and the aggressive and costly marketing strategies used by the industry. As acknowledged by the World Bank report, the promotional and marketing tactics of the industry influence physicians' prescribing behavior, a reality that has been amply documented worldwide in recent years (71, 72). Studies in Brazil (73), Argentina (74), Chile (75, 76), and Peru have shown the unethical and frequently unlawful promotional tactics of the industry. In Colombia, the industry is pressing to change the status of a number of prescription-only drugs to over-the-counter (25), following the United States and more recently the United Kingdom's example. It is expected that this change will increase sales and decrease the pharmaceutical expenditures of social security schemes, which often do not cover the cost of over-the-counter medicines. All of the above suggest that patients are at risk of inappropriately using very powerful chemicals.

The processes of prescribing, dispensing, and using medicines are very deficient in Latin America, and improving them is a complex and challenging task. Strong regulatory bodies and strengthened law-enforcement capabilities could deter the pharmaceutical industry from continuing to commit abuses through the drug promotion system.

Cost Recovery Fees and Revolving Funds

Based on the Bamako initiative, the World Bank recommended the use of cost recovery fees to finance drugs in low-income countries. In spite of having

expressed some reservations about the sustainability of the revolving funds, the World Bank 1993 report claimed that the achievements of the Bamako initiative were impressive and it wholeheartedly endorsed them. In Latin America, only Haiti and Honduras are classified as low-income countries, and therefore this recommendation is not generally applicable to the region. However, most countries were using recovery fees for many years before the World Bank–led reforms were implemented. Today, there is ample evidence that recovery fees do not engage the communities as previously expected, are inequitable, and do not promote the rational use of drugs (77). Nevertheless, Bank loans to Ecuador and Nicaragua required the organization of revolving funds.

Production of Pharmaceuticals

The authors of the pharmaceutical recommendations of the 1993 World Bank report raised questions about the public and private production of pharmaceuticals in most developing countries. In their judgment, the survival of local production requires subsidies or import tariffs to protect the national industry. With the exception of the very large countries (in Latin America, Brazil, Mexico, and Argentina were singled out), the report argued—following literally the advice published in a 1986 World Bank publication (78)—that local production would drive up prices and it strongly discouraged it. We should note that the author of the 1986 publication did not have expertise in pharmaceuticals. In a recent document available at the World Bank website (79, p. 49), the authors take a more cautious position: “Can other, ‘smaller’ countries, repeat the success of India and Brazil? That nobody has an answer to this question should . . . not be surprising.” In a presentation at a conference on generic drugs sponsored by the World Bank, Kaplan (80) identified important reasons for the interest of developing-country industry in local drug manufacturing, and Barton (81) discusses the reasons that the governments of these countries may want to manufacture drugs. Chile offers a good example of why some advocate for the strengthening of public production of drugs: the Chilean president authorized the ministry of health to import drugs manufactured by the Brazilian government if private industry would not lower anti-retroviral prices. The threat had the desired results, and prices were lowered by 50 to 70 percent (82). The recent successful intervention by the French government to avert the purchase of Aventis by Swiss Novartis indicates that political action to protect local pharmaceutical production is justified in the name of defending national interests, regardless of the financial consequences.

Our data suggest that Latin America has a thriving private industry of generic drugs, and large and small countries are producing a relatively large quantity of pharmaceuticals at competitive prices. Brazil has shown that public production

of drugs can have a strategic function within a global cost-containment policy (31). The capacity to produce its own drugs has also been the key factor in making a credible threat of overcoming patent monopolies by issuing compulsory licenses. Argentina has 280 laboratories and produces 85 percent of its national consumption; Chile has 40 national laboratories, which supply 56 percent of the market value and 79 percent of the pharmaceutical units; in the Dominican Republic, 30 percent of the consumption is manufactured locally; Guatemala has 87 laboratories; Mexico's 150 companies export and satisfy 95 percent of the national needs; Peru has 46 laboratories; and the national production in Venezuela covers 45 percent of the country's total needs (2). Ecuador has 36 laboratories, which satisfy 20 percent of the market; and Uruguay has 40 national laboratories and 20 multinational producers (83). Almost 80 percent of the drugs used in Cuba are manufactured locally (84), and Cuba exports \$70 million in drugs (85), a quantity that suggests its pharmaceutical industry is competitive. Argentina's public sector has a relatively large and idle capacity to manufacture generic drugs, and it still supplies 7 percent of the country's needs (13); some public provincial and municipal laboratories are producing quality drugs at very competitive prices. According to Cavallone (86), the Chilean pharmaceutical market is highly competitive and has relatively low prices. The public production of vaccines in the region is very large, and Cuba is the only country in the world that produces an effective vaccine against meningitis B (84). One can infer that small Latin American countries can competitively produce drugs from the disbursement of a \$7 million loan from the International Finance Corporation, an affiliate of the World Bank Group, to Gutis, a family-owned Costa Rican pharmaceutical company in 2003. Costa Rica is one of the smallest countries in the region, with a small industrial base, and if the World Bank had followed its own 1993 recommendations, Gutis would have been unlikely to receive the loan.

Latin America has three regional markets that are in the process of consolidation: Mercosur, Andean, and the Central American market. From the information presented above, we can conclude that, as the regional markets integrate, the Latin American pharmaceutical industry has the potential to become highly competitive.

With the exceptions of the recommended use of recovery fees and the discouragement of local production, the policies advanced in the 1993 World Bank report (16) and in the 1994 policy working paper (20) are quite appropriate for Latin America (see Table 1). They comprise an ambitious package that would have increased equity and efficiency and improved the quality of care in the health systems—the defined goals of the health reforms. The recommendations advanced in these two documents could have been included in the Latin American reforms promoted, supported, and financed by the World Bank.

WORLD BANK SUPPORT FOR CHANGES IN THE
PHARMACEUTICAL SECTOR

Gutiérrez Arriola's review (87) of PAHO's Health Sector Reform Observatory² indicates that, with a few exceptions, the reforms do not include pharmaceutical interventions. Her in-depth analysis of the Mexican health reform confirms the absence of pharmaceutical policies. The only reference to pharmaceuticals is a vague statement indicating that some resources should be directed to supply medicines, meaning that health centers should be stocked.

Our review of the health reform documents of El Salvador yields similar findings. The documents that outlined the health reform (88, 89) do not make any reference to pharmaceutical policies. Programmatic goals included nutrition and environmental interventions, but the words "drug," "medicine," and "pharmaceutical" do not appear anywhere in the documents. The case of Colombia offers a similar scenario; the only reference to pharmaceuticals is the number of drugs to be included in the subsidized insurance plan (90).

It could be argued that some health reform policies or their implementation contain pharmaceutical interventions or have consequences for the pharmaceutical sector. In Mexico, three health reform policies have been implemented. The first is decentralization from the federal health secretariat to the state health secretariats and, in some states, to the next administrative level, or *jurisdicciones*. The second policy is the delivery of a package of 14 basic interventions free of charge to the entire indigent population. The third is the Seguro Popular, a federal health insurance scheme for the poor that began in 2003.

Case studies of the decentralization of the Mexican health secretariat in several states indicate that decentralization had some indirect positive and some negative consequences for the pharmaceutical sector. On the one hand, transferring some decision-making to the states and in some states to jurisdictions has improved the stocks of medicines in the health centers and increased the utilization of the centers (91), although in other states it has reduced the availability of drugs (92). On the other hand, the fragmentation caused by decentralization has made the procurement of medicines more expensive. The decentralized units cannot achieve the economies of scale that a larger buyer authority could.

² PAHO: Políticas nacionales sobre reform del sector salud en América Latina. Iniciativa de Reforma del Sector Salud, Casos revisados de Bolivia (a octubre de 1997), Brasil (a marzo de 1998), Colombia (a 10 de abril de 1998), Chile (a junio de 1998), Ecuador (a marzo de 1998), Guatemala (a 30 de marzo de 1998), Haití (a 30 de octubre de 1997), Honduras (a 30 de marzo de 1998), Jamaica (a 30 de octubre de 1997), México (a 2 de abril de 1998), Nicaragua (a 30 de marzo de 1998), Panamá (a 30 de abril de 1998), Paraguay (a 18 de marzo de 1988), Perú (a 30 de marzo de 1998), El Salvador (a 30 de marzo de 1998), Internet, 1998a. PAHO: Información de país sobre reformas del sector salud en América Latina. Perfil de los sistemas de servicios de salud en 1998. Casos de Argentina, Brasil, Costa Rica, Guatemala, El Salvador, México, Nicaragua, Panamá, Rep. Dominicana y Trinidad y Tobago. Iniciativa de Reforma del Sector Salud, Internet, 1998b. Both cited by Gutiérrez Arriola (87).

The states do not have the technical expertise to prepare international or national tenders. Many buy medicines from wholesalers or retailers at high prices. In the state of Nuevo Leon, one of the wealthiest states of the federation and with one of the best health care systems in the country, the purchases from wholesalers and retailers amount to 40 percent of all drug expenditures (93).

The only pharmaceutical intervention included in a World Bank loan to Mexico is the free distribution of the drugs needed to deliver the basic package of health services to hard-to-reach areas, and continuation of this program after the period covered by the loan is uncertain. One key feature of the Seguro Popular is the provision of free medications to those insured. If the Seguro were to be fully implemented to cover the 40 million or more Mexicans entitled to the insurance, it would go a long way to meeting the pharmaceutical needs of the population. Unfortunately, assessments of the Seguro indicate that the federal government does not have the resources to finance the scheme and that the logistic and organizational problems are formidable.³

The decentralization of health services in other Latin American countries has faced problems similar to those observed in Mexico: decentralized units are too small to justify the preparation of complex national or international tenders, and administrators do not have the training to make accurate estimates of need. Even the solution found by some Colombian autonomous hospitals to organize a cooperative to purchase drugs may not be sufficient to obtain full advantage of the economies of scale. For this and other reasons, Colombian hospitals are bankrupt and the quality of care has deteriorated to the point that the lives of patients are at risk (94). In El Salvador, an experiment to privatize the primary care clinics of the social security institute failed due to financial insolvency. The autonomous directors of the clinics decided to purchase brand-name drugs from wholesalers and retailers instead of generic drugs that they could have purchased at a lower price from the social security institute (95). The additional costs incurred in the purchase of medicines contributed to the inability of the clinics to meet their financial obligations.

We do not have the space here to present data from health reform documents in other Latin American countries that confirm how drug policies are, as suggested by the information in PAHO's Health Sector Reform Observatory, more the exception than the rule. A complementary way to document the characteristics of pharmaceutical interventions within the World Bank-led health reforms is to examine the Bank's health loans to Latin America.

³ Personal interviews with officers of Mexico's Federal Health Secretariat and the National Institute of Public Health (names withheld to maintain confidentiality), March 2001, September 2003, February 2004.

Latin American World Bank Health Loans with Pharmaceutical Components

Three studies by World Bank staff or consultants have examined loans with pharmaceutical components and analyzed their content and the amounts allocated to pharmaceuticals for human use (96–98). The lending period and the methodologies of the three studies are different; the first study covers loans from 1989 to 1995; the second, 1983 to 1999; and the last, 1991 to 2002.

While their methodologies vary, the three studies examined loans of the Health, Nutrition, and Population sector and reviewed related documents, mostly staff appraisal reports, project appraisal documents, and, for projects already completed, the implementation completion reports. Sabaté and coauthors (97) also reviewed development loans from outside the sector that had pharmaceutical components, and Tapalova and Rovira (98) included loans from the International Finance Corporation, a member institution of the World Bank that lends to the private sector. The authors of the three studies are aware of the limitations of the data and state that the conclusions are tentative. Perhaps the most serious constraint is that the standardized accounting system of the World Bank did not allow the authors to break down expenditures in the categories needed for the analysis. For instance, the data recorded at the Business Warehouse, the main database for Bank projects and contracts, do not separate pharmaceuticals from other medical products and cannot quantify the value of the drugs purchased by the borrowing countries with World Bank loans. These limitations add difficulty to the analysis. The differences in study methodologies do not allow for comparing results, but as we will show, all three reached similar findings in our main area of concern.

We decided to analyze in some detail the World Bank loans included in the most recent study (98). The document identified 37 Health, Nutrition, and Population projects that received funding for pharmaceutical interventions. In addition to staff appraisal reports, this study reviewed memorandums and recommendation reports and project information documents. As an analysis of these documents showed, most projects were for maternal and child health care programs and for the control of HIV/AIDS and other sexually transmitted diseases, and the funding was to support the logistics of the interventions and the procurement of medicines. The medications financed by these projects were mostly oral rehydration salts, vitamins for pregnant women, anti-retrovirals, antibiotics, vaccines, birth control pills and condoms, and some anti-malaria and anti-TB drugs. A few loans financed activities to improve drug management, such as improving procurement processes, training personnel, estimating the costs of pharmaceutical treatments in hospitals (in preparation for the privatization of hospitals in Colombia), and improving the efficiency of managing pharmaceuticals (see Table 2). Two loans required the organization of revolving funds, but the loan description did not indicate how much, if any, of these funds would be allocated for the organization

Table 2
World Bank loans with pharmaceutical components, 1991–2002

	No. of loans	Procurement ^a	Management ^b	Improving drug quality control	Safe disposal of drugs	Organizing revolving funds
Argentina	7	7	1 loan includes MDs' training in treatment of HIV/AIDS and sexually transmitted diseases			
Bolivia	2	2				
Brazil	6	4		1	1	
Chile	2		2	1		
Colombia	1		1			
Dominican Rep.	3	3				1
Ecuador	3	3				
Mexico	4	4	1			
Nicaragua	1	1	1	1		1
Panama	2	1		1		
Paraguay	1	1				
Peru	2	2	1 loan includes training of auxiliary personnel in use of contraceptives			
Uruguay	1	1				
Venezuela	2	2				
				1 loan includes studies on drug toxicity (onchocerciasis)		
				1 loan includes improvements of storage and purchase of refrigeration units		
Total	37	31	7	6	1	2

Source: Prepared from information presented by Tapalova and Rovira (98).

Note: Numbers in rows may sum to more than the total number of loans because some loans contain more than one category.

^aIncludes purchase of vaccines, vitamins, medicines, and condoms.

^bIncludes training of physicians and auxiliary personnel, development of data systems (cost controls; improvements in management efficiency, supply, procurement, distribution, and storage).

of the revolving funds. Table 2 provides a summary of World Bank loans with pharmaceutical components by country and type of intervention.

Only the loan to Nicaragua can be considered to satisfy the requirements of a comprehensive pharmaceutical program to improve access, utilization, and efficiency. This loan allocates resources to conduct studies and provide technical assistance in improving policy and regulation, financing medicines (including operating a pilot private pharmacy within the ministry of health), procurement, supply, distribution, inventory management, rehabilitation of storage areas, and assessing the nature and level of irrational use of pharmaceuticals and starting to reduce its incidence. Among the objectives of the loan were the completion of studies that would facilitate the enactment of a new pharmaceutical law, and improvement of the procurement system to better respond to the needs of the decentralized entities.

As indicated above, the World Bank requires transparency and competitiveness in all procurement processes that require Bank financing. The Bank trains nationals in the preparation of tenders, but the accounting system does not permit us to estimate the amount of effort allocated to this end. Similarly, it is difficult to assess the effectiveness and long-term impact of these efforts. Recent news from Brazil, the country that has received by far the highest amount of World Bank lending for pharmaceutical interventions, raises questions in this regard. It has been alleged that, during the past decade, pharmaceutical companies, lobbyists, and public health officials rigged government contracts and embezzled funds in the amount of \$637 million. The alleged crimes are currently under investigation by the public prosecutor's office, which has placed 14 suspects under temporary detention (99).

Tapalova and Rovira's estimates (98) of the allocation of World Bank loans are as follows: about 44 percent of the funds are for drug procurement, including vitamins and pharmacy materials; about 33 percent for condom procurement and promotion; 14 percent for vaccinations; 8 percent for rational use of drugs, drug regulation, and policy studies as part of health system reform; and 1 percent for pharmaceutical waste management. In other words, 91 percent of the funds are allocated to acquisitions. The authors do not cite the absolute amounts from which these percentages were calculated.

Falkenberg and Tomson (96) calculated that 17 percent of the lending for Health, Nutrition, and Population projects was dedicated to pharmaceuticals. Using their data we have calculated that, for all regions of the world, the percentage allocated to what the authors call "hardware"—a category that includes reconstruction/repair of warehouses and pharmacies, and purchase of drugs and equipment—amounts to 93.3 percent (\$972 million) of the pharmaceutical components of the loans for the fiscal years 1989 to 1995. The rest (\$70 million) was spent on "software," a category that includes "education, information, legislation and regulation monitoring, continuing education . . . management training and development, training of inspectors, quality control agents and pharmacists . . .

technical assistance governing procurement . . . cost recovery, introduction of the Essential Drugs concept and Rational Use of Drugs in medical curricula, continuing education of providers, consumer information and pricing policy” (96, p. 53). In sum, the percentage of funds allocated to improving the use of drugs is almost negligible.

Sabaté and colleagues’ study (97) estimated that 82.12 percent of pharmaceutical expenditures were allocated to procurement, though they clarified that this percentage could be lower because they generally classified expenses for institutional strengthening under the “non-defined health category” that was not included in this percentage. The report acknowledges that procurement takes place without assessing the pharmaceutical systems and “in the absence of a policy framework for pharmaceuticals, or without appropriate linkages with the broader health care system in the country” (97, p. 7).

In sum, regardless of which of these estimates is closest to the correct allocation of funds, we can conclude that they confirm our review of the literature and our fieldwork: the reforms financed by the World Bank have not given sufficient consideration and funds to the pharmaceutical policy recommendations advanced in the 1993 World Bank report. The lack of support is surprising because, during the 1990s and even earlier, the WHO detailed important pharmaceutical strategies and invested a share of its meager resources in promoting the adequate use of pharmaceuticals (100–103).

UNDERSTANDING THE WORLD BANK’S FAILURE TO SUPPORT ITS OWN RECOMMENDATIONS

To advance an understanding of and ability to influence pharmaceutical policies, it is useful to explore the reasons why the World Bank failed to support its own pharmaceutical policy recommendations through its lending program. As discussed previously, the Bank’s recommendations would have facilitated the goals of the reforms: they would have increased equity and productivity, lowered costs, improved quality of care, and increased user satisfaction. Here we present four hypotheses to help foster debate and future research on this topic.

First Hypothesis: Lack of Pharmaceutical Experts with Influence at the World Bank

As a first hypothesis we could suggest that the World Bank staff who prepared the section on pharmaceutical policies for the 1993 World Development Report had little influence within the upper echelons of the Bank. A similar comment has been made about the World Bank environmental unit in an attempt to explain this unit’s inability to stop the funding of projects with adverse environmental effects (104). A comprehensive health report could not ignore that countries invest a large amount of their health resources in drugs, and the 1993 report had to

include some recommendations on this topic, even if the pharmaceutical sector, like the environmental sector, is given a low priority at the World Bank. This hypothesis also explains how few pharmaceutical experts are employed by the Bank. Govindaraj and coauthors (22) were aware of the World Bank's weakness in the pharmaceutical field and recommended strengthening the professional staff in this area. The study by Falkenberg and Tomson (96) also attributed the high percentage of expenditures allocated to hardware areas to the lack of pharmaceutical expertise. They found that 31 of the 56 projects analyzed were prepared without the input of pharmaceutical experts. The situation today is even worse. The World Bank has no staff specialized in clinical or social pharmacology. It is clear that, if an institution does not have experts in a particular area, it is most likely that programs in this area will not be developed. Experts in other areas will seize the available funds to promote their own programs.

Second Hypothesis: The World Bank's Tendency to Exclude Interventions That Do Not Fall within the Hardware Category

The World Bank's preference is to lend for capital investments such as infrastructure construction, institutional development, and the purchase of equipment. In the health sector, the favored interventions are hospital and clinic construction, the purchase of equipment and drugs, and some basic training to prepare personnel for management of the newly decentralized/privatized hospitals.

All World Bank project documents have to include monitoring and impact indicators, but those that we have examined do not have indicators to assess the impact of the pharmaceutical interventions. Geyndt (105) pointed out that evaluations of health programs by World Bank staff only took into consideration the quality of investments in infrastructure and in procurement. In his view, the inability to incorporate other, more important indicators explained the excessive emphasis on these two dimensions. This also seems to be the case for pharmaceutical interventions, where funds are allocated almost exclusively (about 90 percent) to the purchase of drugs. Evaluating the impact of interventions to improve the adequate use of pharmaceuticals is very complex, and the World Bank does not have the expertise to do it. In addition, it is probably easier to reach agreement with a government on the terms and conditions of lending for purchasing drugs than for funding behavioral and policy changes.

Drugs, including birth control pills and vaccines, are tangible goods and their impact can be measured through health status and demographic indicators (morbidity, mortality, and population growth). The difficulties of World Bank staff in handling other pharmaceutical interventions can also be understood by considering the very nature of the Bank. As a development agency, it demands fiscal responsibility from its borrowers and is reluctant to finance recurrent expenditures such as those on drugs, except in the case of emergencies. For World Bank staff, it has been easier to find loopholes to justify the purchase of medicines

(106) than to develop interventions to improve the rational use of drugs and finance the implementation of needed pharmaceutical policies.

Third Hypothesis: Countries' Opposition to the Financing of Pharmaceutical Interventions

The World Bank has to negotiate its lending programs with recipient countries, and during the negotiations countries can modify the terms of the loan. Therefore, it is possible that the absence of loans for pharmaceutical policies responds to refusals by Latin American countries to accept the World Bank's proposals. In the health sector, several Latin American countries have opposed and delayed the implementation of Bank-led health sector reforms with a strong privatization and/or decentralization component (107); however, we have been unable to locate reports documenting similar situations with regard to pharmaceutical policies. Two of the authors of this article worked in health projects at the World Bank between 1992 and 1997 and between 2001 and 2004, and despite our interest in pharmaceuticals we did not witness or become aware of any situation where countries refused to follow the Bank's pharmaceutical advice. From our experience, it would be more accurate to suggest that the staff at the World Bank was not encouraged and had limited resources to influence pharmaceutical policies in Latin America.

Fourth Hypothesis: The Neoliberal Ideology of World Bank Decision-Makers

If the first hypothesis is correct, the question is: why doesn't the World Bank have experts in the pharmaceutical sector? A possible explanation can be formulated in the following terms. As is well established, the neoliberal ideology that permeates the higher echelons of the World Bank promotes the downsizing of the public sector and advances the interests of the private sector. In the pharmaceutical sector, transnational corporations play the dominant role. These corporations are mostly headquartered in the United States, Germany, United Kingdom, France, and Japan, which together with a few other industrial nations control the Bank's decision-making process (108). The United States, as the major stockholder, has a dominant role and appoints the Bank's director. These nations protect their industries, and the industries have a formidable lobbying influence on their governments. Most policies recommended by the 1993 report—such as using essential drug lists to control the registration and procurement of drugs, using generic drugs, strengthening the regulatory role of government, improving the rational use of drugs, and controlling the marketing techniques of the industry—would, if implemented in all the developing countries, have adverse financial consequences for transnational corporations.

To influence World Bank pharmaceutical policies, the innovative pharmaceutical industry created some years ago a fellowship to finance an internship at Bank headquarters. The World Bank chooses the person from a three-name slate

proposed by the industry. The person has an office in the Bank, has ample direct access to health strategy discussions, and functions de facto as an adviser/lobbyist for the industry.

The recent interest of the World Bank in endorsing the purchase of anti-retroviral generic drugs as manifested in its technical guide (38) is a welcome change from its previous position, which required the procurement of brand-name anti-retrovirals. This change can be attributed to the intense pressure from many nongovernmental organizations and foundations, the legal failures of research-based pharmaceutical firms to stop the procurement of generic anti-retrovirals, and the tragic reality of sub-Saharan Africa.

Additional support for this fourth hypothesis comes from the silence maintained by the World Bank during the debate at the 2002 Doha meeting of the World Trade Organization regarding the agreement on TRIPS and the discussions that followed. The TRIPS agreement establishes a drug patent monopoly of 20 years and defines when compulsory licenses can be issued and parallel importing permitted. Objections by the United States left the signing of the agreement pending, and the discussions that ensued were not settled until the 2003 Cancun meeting. During this time, the World Bank avoided any comments on the topic and maintained its silence on bilateral free trade agreements between the United States and developing countries that have included clauses more restrictive than those established by TRIPS. Bilateral free trade agreements have extended the patent monopoly beyond the 20-year period and restricted the use of compulsory licenses and parallel imports beyond the conditions established by TRIPS. In Latin America, Colombia, Peru, and Ecuador are in the process of signing the Andean Free Trade Agreement, and the Central American countries and Dominican Republic have signed the Central American Free Trade Agreement.

Most observers agree that the modification of TRIPS imposed by the United States in the bilateral trade agreements makes access to drugs more difficult for the poor in developing countries, and many will suffer and die as a result. One might have expected that an agency whose aim is to assist the poor of the world would have taken a position on an issue that directly affects the quality of life and survival of hundreds of millions, but the World Bank decided to remain aloof from the debate. According to our fourth hypothesis, it would have been difficult for the agency to take a position against its principal shareholders.

CONCLUSIONS

In 1993, the World Bank's World Development Report offered a comprehensive set of pharmaceutical recommendations that fit well with the needs of Latin America at the time the health reforms were being implemented, but the Bank failed to support and finance them. We have offered four hypotheses to explain the lack of congruence between the World Bank's own pharmaceutical recommendations and its funding priorities. The hypotheses are not exclusive—that is,

the Bank may lack staff with expertise, the staff may lack the methodologies to measure the impact of software interventions, *and* the Bank may fail to generate policies that go against the interests of its principal stockholders. Obviously, if the fourth hypothesis is correct, it is of little consequence to add staff with expertise or to develop evaluation methodologies. Given the lack of transparency of the World Bank, it is difficult for outsiders to verify the validity of the hypotheses. We may have to wait until insiders occupying high positions decide to confirm one or more of them, or offer alternative satisfactory explanations.

If the fourth hypothesis is correct, then, it will be difficult for the World Bank to engage in pharmaceutical interventions that will help achieve the goals of health reform (equity, efficiency, quality, and satisfaction). Most Latin American countries have sufficient resources to purchase essential generic drugs, and the use of World Bank loans for recurrent expenditures may be fiscally irresponsible, except in the case of extreme situations (pandemics, natural disasters, and economic depressions).

As discussed in this article, the pharmaceutical needs of the Latin American health systems correspond closely to the policies expressed in the 1993 World Bank report—namely, to rationalize the use of drugs, a concept that includes improvements in production, prescription, dispensing, and consumption, and the regulation of the industry. It is in these areas that technical assistance is needed. The WHO's pharmaceutical technical assistance in this area is praiseworthy, but its resources are very limited. World Bank loans could be used to complement the WHO's work.

Providing more drugs without attending to the rationality of their use is counterproductive, and if the purchase of the additional drugs is through loans at commercial interest rates, as is the case for most World Bank loans to Latin America, the only certain result is an increase of the countries' indebtedness. The use of drugs does not guarantee health improvements: their adequate use does. If the first or second hypotheses, or both, explain the World Bank's indifference to supporting sound pharmaceutical policies, it will be necessary to recruit staff with pharmaceutical expertise in positions of influence within the agency and to find ways to assess the effects of pharmaceutical policies on the quality of life among the poor.

Also, the World Bank must reconcile health reform and pharmaceutical policies. As we have indicated, economies of scale achieved through centralized procurement may be incompatible with the privatization and decentralization of services. In theory it may be possible to downsize government and at the same time strengthen its regulatory capabilities, but in practice it may not. For the pharmaceutical sector, the need to strengthen the regulatory powers of the public sector is paramount. As we have seen, this has not happened since reforms began in Latin America. Whether this is due to privatization or to other factors is at present unclear, but in Colombia, the country implementing a health reform that conforms most closely to the World Bank blueprints, INVIMA, the drug regulatory agency, is under threat of being dismantled.

There are pharmaceutical interventions that the World Bank can carry out at minimal cost. Its support and promotion in international forums of policies to enhance the accessibility of affordable drugs for the poor majority would not require large outlays of funds. The timid attempts that the Bank has made thus far are hardly enough to have an impact. However, the Bank's support of some policies (as in the case of the use of anti-retroviral generics) and opposition to others (as should be the case for TRIPS+) could make a valuable contribution to the health of the poor. Whether the World Bank has the freedom to decide on the merits of the issues, independent of the interests of its main stockholders, is something that needs to be clarified.

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