

# Cautionary Notes and Future Directions

# Cautionary Notes on a Global Tiered Pricing Framework for Medicines

Owain D. Williams, PhD, Gorik Ooms, PhD, and Peter S. Hill, MBBS, PhD

Recently, there has been a policy momentum toward creating a global tiered pricing framework, which would provide differentiated prices for medicines globally, based on each country's capacity to pay.

We studied the most influential proposals for a tiered pricing framework since the 1995 World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights. We synthesized 6 critical questions to be addressed for a global framework to function and explored the many challenges of implementation.

Although we acknowledge that there is the potential for an exceptional global commitment that would benefit both producers and those in developing countries in need of wider access to medicines, our greatest concern is to ensure that a global framework does not price out the poor from pharmaceutical markets nor threaten current flexibilities within the international patent regime. (*Am J Public Health.* 2015;105:1290–1293. doi:10.2105/AJPH.2015.302554)

**SINCE LATE 2013, WE HAVE** witnessed a resurgence of policy, academic, and pharmaceutical industry interest in the potential of a new politically and commercially sanctioned global tiered pricing framework that could gear prices of medicines according to different country and population incomes.[1–3] Proponents have argued that tiered pricing provides a "win–win" solution for access to medicines. The unmet demands of poorer markets would be serviced more adequately and fairly, whereas pharmaceutical firms would retain their profits through increased demand for their products. This is an equation that simultaneously suggests equitable pricing and equitable access.[4] The idea of a tiered pricing framework has gained substantial recent traction, especially since Mark Dybul, the executive director of the Global Fund to fight AIDS, Tuberculosis and Malaria (Global Fund), announced a blue ribbon taskforce in late 2013 to

> develop a framework for multiple pricing and royalty tiers for health commodities to help ensure a sustainable marketplace and maximize availability across countries of all income levels.[3(p1)]

This goal has recently been formalized as the Equitable Access Initiative working group, which was commissioned to commence its operations in December 2014, with a view to have input into the post-2015 Sustainable Development Goals agenda.[5] Seth Berkeley of the GAVI Vaccine Alliance (Geneva, Switzerland) has also lent support, claiming that a new global framework for the area of vaccines could provide a mechanism by which a "balance between fair access and fair profit levels can be struck" and possibly solve the political conflicts that have characterized the access to medicines debate for at least 2 decades.[6] Moreover, the initiative coincides with a recent upsurge in interest in tiered pricing from pharmaceutical corporations. These corporations are particularly concerned that some key emerging economies are increasingly prepared to use compulsory licenses, competition law, and tougher patent standards to facilitate generic production in therapeutic areas that are associated with patented medicines previously targeted almost exclusively at their core Western markets.[7,8] Against this present momentum, civil society groups (some of whom, such as Oxfam [Oxford, UK], have previously supported plans for a global tiered pricing framework),[9] have, in an open letter, asked the Global Fund to end this initiative.[10]

## A TIMELY CRITIQUE OF GLOBAL TIERED PRICING

Although the urgency for a global framework may have eased in late 2014, the political and economic interests that have driven it persist. Therefore, we used this opportunity to introduce what is hopefully a timely critique, analyzing the implications of the proposed systems and exploring the political interests that will seek to determine who wins and who loses under the global "deal." We first examined the key proposals to date that have supported the development of a global tiered pricing framework. In fairness, these largely positive proposals have openly documented the major technocratic, regulatory, and governance problems that could be anticipated in developing a functioning global framework.[9,11–14] We studied these issues, which in themselves raised questions whether a framework might not be able to operate sustainably or fairly, and highlighted other implications that have not been previously addressed. We then offered a critique of the political tradeoffs that low- and middle-income countries (LMIC) might be offered in return for their participation in what would be an unprecedented global

system for regulating pharmaceutical prices.

## WHAT IS REQUIRED FOR A FRAMEWORK TO FUNCTION?

Our survey of literature on tiered funding confirmed the scale and complexity of the potential problems involved in the creation of a global framework. From the academic literature and agency reports, several largely positive studies identified a number of widely accepted obstacles to forming a global tiered pricing framework and a range of counterpart solutions or necessary conditions for its success.[11–15] We identified 6 major questions that these proposals detailed, and we raised further related issues to elucidate the different potential political, legal, and economic implications of such a pricing system.

### Who Will Govern Price Setting?

The critical questions for a global tiered funding framework are about who sets the price and who regulates the system. There is more than 1 potential solution to this pressing question. The framework could involve the (market-driven) self-regulation of price tiers by firms,[11] in which firms would simply coordinate with each other to decide on prices, with possible light-touch regulation by a monitoring body. Firms might also agree to tier prices by some pre-agreed formula for calculating the ability of parties to pay, which perhaps could be decided upon in joint negotiations with a body like the Global Fund's Equitable Access Initiative. However, even such a public–private collaboration raises questions about the nature of the compromises that might be made. The effective monopoly of firms over the health technologies for which prices are being set would give them substantial leverage and advantage in price setting negotiations, compared with their countervailing public sector partner(s). Self-regulation would without doubt be most appealing to the corporations, but would also offer opportunities for anticompetitive agreements between firms. This would risk a politically sanctioned global system that reduces competition on price and facilitates the carving out of markets.[11]

In distinct contrast, the framework might see a global public body, such as the World Health Organization, tasked with setting prices[9] either in conjunction with the firms or through ultimate authority derived from a World Health Assembly resolution. Here, states would need to collectively agree to the criteria for affordable tiered prices, and couple this with the political commitment to providing necessary sanctions on offending firms to protect the poor and their governments from being priced out of markets or universal access to medicines. This option requires substantial elaboration beyond the constraints of our critique: such a framework would require the authority to ensure that companies asking unacceptable charges modify them to meet affordability criteria, or accept that compulsory licenses would be issued on behalf of the countries, and that those countries are protected from challenge by international patent regulation or by countervailing political pressure.

### Will Market Monopolies Be Perpetuated?

For such a framework to operate, participating firms must have the market power over the health technologies to which tiered pricing would be applied.[4,11,14,15] This market power, which is associated with monopoly producers of a product, is integral to tiered pricing. Without a monopoly (or close to it), the resulting competitive market would act to lower prices, undercutting those tiered prices agreed upon, thus making the framework irrelevant.

It is the lack of competition that allows prices to be set, and that lack of competition may need to be legally preserved for the framework to operate. The firms that participate in the framework will want to see that market power preserved under the framework; they are unlikely to provide meaningful voluntary discounts if these can be further undercut by generic competition. The deal that would be offered to LMICs would promise that the framework would work, effectively lowering prices without the need for generic competition. The risk is that the framework could become another international regulatory instrument that actively supports monopoly power, maintaining and even strengthening those patent-based monopolies, with price discounting only undertaken when it benefits firms.

### What Are the Constraints and Compromises for States?

As a result of the previously discussed monopolies, present government strategies such as price referencing, bilateral negation with firms, and price controls would be major impediments to the framework if prices secured by given any country were below their agreed price tier.[14,15] Resentment would lead to defection, either by firms or higher price paying states. Government sanctioned competitive generic entries would also lower prices and reduce market power by competition.

But if these policies were rendered impermissible under the global framework, it would remove important national safeguards and autonomy for countries with purchasing or generic production power, and potentially do so in instances in which medicines prices under the framework remain too high for national health needs.

### How Do We Determine Who Can Afford What?

All the reports and articles on a potential framework for tiered pricing alerted us to the need to identify different market segments in terms of their ability to pay, or price sensitivities.[13–15] Market segmentation appears necessary both across different national markets (thus prices are tiered according to some indexes that indicate the relative wealth of nations or national market segments) and within each of these different national markets (reflecting the fact that national markets are, in turn. composed of people [or intra-country market segments] with

often vastly different abilities to pay).[13–15]

The scale of identifying different market segments within countries for a global framework is particularly daunting. If the framework desires to fairly determine what each different segment of a country population could afford to pay, then it would have to develop a very granular process, possibly requiring rich data on in-country income and factors (e.g., local disease burden and rates of out-of-pocket payment) to enable calculation of ability-to-pay based on income and price sensitivity. There is no certainty yet as to what indexes would be used for such calculations, nor what would be the data and monitoring requirements to adequately ensure that the framework's prices do not prove to be regressive for the poor and progressive for the rich.

### How Do We Keep Markets for the Poor Separate?

Once these different segments have been identified, they will also need to be sealed from each other to prevent "leakage" by arbitrage, which is the arbitrage and parallel trade within or between different market segments.[11,13–15] The framework could not tolerate lower priced drugs being sold up to higher price paying markets,[13] and therefore, might require more stringent control on pharmaceutical imports and exports between countries (to prevent what could become illegal intercountry trade) despite increasing Internet-based circumvention of existing controls.

By contrast, intracountry arbitrage could also require new national laws, bureaucratic and policing powers, as well as improved price and product flow monitoring and distributional systems beyond those currently operated by firms, governments, or middle men.[14,15] Problematically, the framework would need to seal different market segments within each different country, a difficult feat when citizens of the same country can freely associate with each other or frequent the same outlets for accessing drugs. Given the scale of possible adjustments necessary to fulfill this condition for a functioning framework, will the low income countries unable to afford the cost of required changes receive support in terms of both capacity and resources, and, if so, who will pay?

### How Do We Calculate the True Cost of Medicines?

Under a potential framework, problems of transparency would need to be addressed, most specifically in terms of prices set by the framework (are they disclosed or not, and what is the political and psychological consequence of the public knowledge of those being asked to pay higher prices?).[15] However, transparency should also apply to firms' real marginal costs of production, such as when it is necessary to determine the lowest possible prices achievable for drugs or for open scrutiny of data from clinical trials. These are essential components to determine a fair structure of pricing. It is impossible to set a fair price when the manufacturer, but not the purchaser, knows the true value of the product.

## WINNERS AND LOSERS, INTERESTS AND POWER

Beyond this literature, the debates around tiered pricing and global frameworks have proved difficult to follow, and this problem is further compounded because the meaning of success with regard to the outcome of tiered pricing for medicines may be very different for different authors and readers. For some, success simply means that essential medicines would become more accessible to people who need them. For others, success would result from the redistribution of the financial burden of research and development of new medicines by means of more people either directly (by purchasing medicines privately) or indirectly (by contributing to governments purchasing medicines for them) paying more revenues to the companies that develop medicines.

For the pharmaceutical industry, the clear yardstick of a successful global framework would have to include the protection (or expansion) of profit margins and the preservation (or expansion) of market reach. Analyses of existing tiered or differential pricing indicate that the increase of profits and expansion of markets to previously unmet demand has always been the outcome of this pricing strategy.[15] Although the economic model that stresses the poor also gaining in terms of access and lower prices is no doubt appealing and theoretically coherent, there is the need to consider the underlying drivers of the resurgence of interest in global tiered pricing. As ever, in issues that touch on political economy, interests and power shape outcomes. There is a real difference between theoretical models and the potential of power politics to distort the outcomes of otherwise appealing policy initiatives.

The present momentum toward tiered pricing and the ultimate composition of the global deal is driven by the same interests that have been integral to the global political economy of pharmaceuticals for almost 2 decades. Any new framework would be expected to align with the established international regulatory environment that presently structures the production, distribution, and price of products to reflect those interests. Corporate dominance of the pharmaceutical sector and markets is dependent on that regulatory environment; it is a symbiotic relationship that has intensified since the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) came into force in 1995. The basic mix of power and interests in the push for the global tiered pricing framework will be very much akin to those that created the Trade-Related Aspects of Intellectual Property Rights Agreement, although there will be new actors lending support. This is occurring as the underlying political economy of pharmaceutical production and markets are being subjected to new competitive and political pressures.[15]

Global tiered pricing is a strategic response to recapture the international regulatory high ground, following a period when LMIC nations and generic firms

have politically and competitively challenged patent and other exclusionary rights over medicines. Pharmaceutical corporations and developed country governments have enjoyed a very successful track record of collusion in shaping (or capturing) the international regulatory architecture for their perceived interests and profit. If they are again able to achieve regulatory capture using a global tiered pricing framework and can mobilize the new multilaterals in global health to that end, then their success will ultimately depend on such a deal appearing reasonable and legitimate to LMIC nations and offering a political framework that appears to be a win–win for all parties. These key LMIC economies are also the major actual and potential producers of generic drugs, and have shown strong determination to pursue the generic and compulsory licensing route to meet their population health needs, and to fulfill national commitments to universal health coverage.[15]

In response to the challenges of extending the gains made in the Millennium Development Goals, ensuring access to medicines for all is integral to the post-2015 agenda. We share Dybul's sense of urgency in achieving equitable access. However, our greatest concern is that the political and commercial deal necessary to launch a global framework for tiered pricing should not involve any compromise under which flexibilities and competitive generic entry would disappear. If these flexibilities are effectively negotiated away, or newly constructed as somehow unfair or illegitimate practices, then the result will damage the basic established guarantees already present in international trade and Intellectual Property Rights law, and reduce the policy space that exists for countries to supply affordable generic medicines to those in need of them. In the long term, this is not a win–win situation. ■


## About the Authors

*Owain D. Williams and Peter S. Hill are with the School of Public Health, The University of Queensland, Herston, Australia. Gorik Ooms is with the Department of Public Health, Institute of Tropical Medicine, Antwerpen, Belgium.*

*Correspondence should be sent to Peter S. Hill, School of Public Health, The University of Queensland, Herston 4006, Australia (e-mail: peter.hill@sph.uq.edu.au). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.*



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## Contributors

O. D. Williams, G. Ooms, and P. S. Hill conceptualized the analysis. O. D. Williams wrote the first draft of the article. G. Ooms and P. S. Hill revised the draft of the article. All of the authors contributed to the revisions in response to the reviewers, and read and endorsed the final version of the article.

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