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Professor Paul Hunt
United Nations Special Rapporteur on the right to the highest attainable standard of health
Department of Law
University of Essex
Wivenhoe Park
Colchester CO4 3SQ
United Kingdom

Dear Professor Hunt,

We thank you very much for the opportunity to provide written feedback on the draft *Human Rights guidelines for Pharmaceutical Companies in relation to Access to Medicines*. We have appreciated meeting with you and your team in New York and look forward to hosting an investor consultation in London. Such meetings helped us understand the process and aims of the Guidelines.

We would like to place on record that we feel companies need to be more active and transparent on the issue of access to medicines. We have some concerns as to whether the publication of UN Guidelines is the correct mechanism for addressing this, but have approached this consultation from the perspective that if the UN is to issue Guidelines, they need to be as effective as possible.

As an active investment management firm with over £103 billion (as of 31 December 2007) under management, F&C Management has substantial holdings in the pharmaceutical industry. For many years, our firm has run a dedicated "engagement program" with pharmaceutical companies, as we try to understand and address strategic risks to companies that arise from their management of Environmental, Social & Governance (ESG) issues and their potential impact on shareholders. Such issues have included access to medicines, intellectual property, clinical trials, bribery and corruption, board structure, executive compensation and much more.

In addition, F&C often collaborates with other investors interested in ESG risks to the industry. F&C was a founding member of the Pharmaceutical Shareowners Group (PSG), and currently co-leads the Pharmaceutical Shareholders Forum (PSF). We participated in Pharma Futures and have spent considerable time with pharmaceutical company staff and executives examining different corporate responses to the ESG risks that may affect long-term shareholder value.

We hope that our investor perspective will prove useful to you and your colleagues as you consider your options for furthering the important dialogue on access to medicines and the particular responsibilities of the pharmaceutical sector.

We thought it best to organize our feedback in several sections

1. General thematic comments on the Guidelines
2. Thoughts on the consultation process and next steps
3. Specific feedback on the text

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In submitting our comments, it is worthwhile to re-iterate that our specific perspective as an institutional shareholder leads us to question where this initiative will protect or enhance shareholder value. We believe that the issue of access to medicines is material to the long-term value of some, but not all, pharmaceutical companies, and even in those cases may be strategically important but beyond the valuation horizons of a company's share price. We feel the investment case for involvement in access to medicines rests on firms maintaining their licence to operate, and the unique privileges of the international patent regime, as well as positioning companies to benefit from business opportunities in emerging markets. At the same time, it is fundamentally important for the sustainability of companies and their ability to invest in research and development, that they are able to generate adequate returns from their activities. In this context, we would like to express our concern that the Guidelines, as they stand, may not add value to shareholders. However, we do believe it would be possible to produce guidelines or principles that reconcile the requirements of both widening access to medicines and providing shareholder value.

1. The Guidelines

General: We find the effort to integrate access to health within the human rights framework to be an interesting one, but one that creates potential areas of concern for shareholders. We agree strongly that companies have not done enough to communicate on their efforts in a manner that reaches beyond anecdotal reporting to provide substantive, systematic data-driven disclosure on access to medicines strategies and outcomes. This lack of consistent, comparable data is a serious impediment for investors assessing the risks that companies face as they seek opportunities in developing markets and work to ensure their "license to operate" across all global markets. It is also an impediment to other stakeholders seeking to assess companies' progress on access to medicines.

However, we are concerned that these Guidelines are too sweeping in their reach and scope and in their assumption that all companies must be so singularly focused in guaranteeing access to medicines for all people for all diseases. We caution that both the reach and the process used to develop the Guidelines actually undermines the author's stated intention of providing a useful tool for pharmaceutical companies to use in understanding their "obligations" related to access to medicines.

Balancing Human Rights with Commercial Realities: In general, we found that the guidelines did not strike the right balance between the commercial realities that pharmaceutical companies face and the UN's mission to promote human rights. For example, nowhere do the Guidelines recognise that companies have a legally binding obligation to their shareholders. While the Guidelines consider many important stakeholders for pharmaceutical companies, they should acknowledge that publicly traded companies are required to create value for their shareholders. This is an important reality – and often a barrier – for companies taking a more proactive, but non-commercial, approach towards the access to medicines challenge. It is an essential ingredient in the mix and should be recognised.

In addition, the Guidelines suggest a long list of actions companies should take, but provide very little guidance about which companies the Guidelines apply to. From our reading, we would assume that they are focused mainly on large, global publicly traded pharmaceutical companies that have massive research and development capabilities and offer a variety of drugs for a wide range of disease management. However, it is extremely important for the Guidelines to define their target audience – do they cover small biotech companies that are working on one or two highly targeted treatments for rare cancers? What about a small company working on several targeted applications for a more common kind of cancer? Do they cover privately held

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companies or only publicly traded companies or state-owned companies? Are generic drug companies expected to follow these Guidelines or are they only for companies that produce patented drugs? Are they to be applied to companies based in developing countries?

Also, the Guidelines do not adequately lay out expectations for pharmaceutical actions in highly stratified and diversified emerging markets. The current draft applies more clearly to least developed countries, but it does not discuss what steps companies should take in middle-income markets that have a wealthy upper class, a fast-growing middle class and an impoverished under-class (e.g. BRIC countries). It is imperative that pharmaceutical companies retain their pricing power for middle and upper income individuals in developing markets, while they may need to develop a different, targeted strategy for those living in poverty. This type of practical discussion is important for grounding the Guidelines in commercial realities, and it is an operational challenge for companies in which investors are particularly interested.

Scope: We believe that the task and views of the Special Rapporteur are well articulated in the preamble to the guidelines. We understand that the majority of his focus has been on states, but that he is also considering the important role that the pharmaceutical sector plays in promoting the right to health. However, we question how these Guidelines interact with other relevant United Nations' initiatives and conventions in an integrated manner. For example, there is a relatively short discussion on standards of clinical trials, which are increasingly conducted in developing nations. How do these Guidelines dovetail with work done in other areas of the United Nation on "free prior and informed consent?" We were also interested in comments made by Calvert Group at the New York City consultation referring to the UN Convention on Biological Diversity, that the guidelines do not consider the "equitable sharing of benefits." This would be relevant to smaller, specialized companies and research institutions that are involved in bio-prospecting and may benefit from indigenous knowledge. It may be that this is outside the intended scope of the Guidelines. Also, it is difficult to understand how the Guidelines interface with the UN Global Compact, which is a UN approach to corporate responsibility that has a much different flavour than the Guidelines and that companies have been encouraged to sign.

Finally, and most important, it was unclear what classes of disease management fall under the Guidelines. One would assume that they apply to treatment for diseases such as HIV and TB as well as neglected diseases. But what about diseases that are growing in prevalence in developing nations such as heart disease, diabetes and cancer? Do all diseases fall within the scope of the Guidelines? If so, then we are concerned that the Guidelines may be too far-reaching to be effective.

Legal Status: We have noted the comments of the US government in response to the consultation, and share a concern about the intended legal status of the Guidelines. It is unclear to us whether the intention is to create voluntary guidelines or the basis for states to enact these principles in their domestic human rights legislation. Our general concern is that the combination of legalistic language, and the principle of a "rights-based" approach places an expectation on pharmaceutical companies that it is both their legal and moral duty to provide access to the drugs that they have researched, developed and manufactured. As outlined above, the shareholder perspective is inevitably that companies have such a duty when it in the interests of their shareholders although we acknowledge that some companies have demonstrated a poor understanding of the link between access and long-term shareholder value. It is possible for states to alter the framework within which companies operate – for example by incentivising or rewarding companies that offer greater access to their products and technologies – in order to promote behaviour that will enhance both access to medicines

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and shareholder value. In this case, it seems sensible to create an equal expectation within the Guidelines that companies cannot be expected to act in a vacuum and that states have the responsibility to set appropriate frameworks within which companies can act.

2. **Consultation Process and Next Steps**

Perhaps our most serious concern with the Guidelines are related to the lack of a substantive exchange with the pharmaceutical companies. In our view, the companies have made a serious error in choosing to absent themselves from this process, which we will communicate to the companies in our portfolio. However, we question if the process of developing these Guidelines was sufficiently responsive to the needs and concerns of the industry.

We cannot agree with the argument of the Special Rapporteur that a series of external standards is necessary for evaluating the performance of the companies. We believe that other initiatives and advocacy groups are already doing this. Rather, we see a real need for a pragmatic approach that works with the industry and its trade association to define appropriate levels of responsibility while focusing on realistic actions companies should take. We would like to see greater emphasis on developing consistent standards for disclosure and comparison.

Rather than finalize the Guidelines in the remaining few months of the Special Rapporteur's term, we would suggest that a more consultative process be developed that more fully reflects commercial realities of publicly traded companies and that has a greater chance of collaborative success.

The United Nations Environment Programme's Financial Initiative (UNEP-FI) is a strong model for the kind of collaboration that is needed to address the challenging issues of access to medicines. We have been impressed by the convening ability of UNEP-FI which has brought together major players for substantive work on the intersection of banking and ESG issues. This is the kind of role that should be assumed by effective trade associations, but the pharmaceutical trade associations have done a serious disservice to their companies by playing an obstructionist role rather than a productive one. As the UN has such depth of experience with social issues, as well as a strong reputation with important stakeholders, we see this as an area where it could play a unique and valuable role. From our point of view, this kind of engagement might be more valuable than a static set of guidelines.

Without a stronger track record of engagement with the companies in question, we fear that the Guidelines will lack effectiveness and be easily marginalized.

3. Specific Feedback

In order to highlight our thinking on the Guidelines we have included a series of comments within the text (attached). Our comments are indicated by ***formatting*** and, at times, refer to specific passages or phrases that are highlighted in yellow. We hope that more specific comments in the text will help to illustrate the comments we have made above.

In conclusion, we thank you for your willingness to engage with both supportive and critical stakeholders. This project has certainly opened up a new front in the dialogue regarding access to medicines and the role

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that companies play in addressing this global challenge. We very much appreciate being involved in the dialogue and we look forward to your final report.

Sincerely,

Elizabeth McGeveran
Director
F&C Management Ltd.

Robert Barrington
Director
F&C Management Ltd

cc: Rajat Khosla, Sr. Research Officer, Human Rights Centre, University of Essex

Encl: Human Rights Guidelines for Pharmaceutical Companies with F&C feedback
F&C's corporate governance policy on political donations & transparency