**Written evidence from Mr Mike Hore**

**** Please note, this submission is intended to be viewed in conjunction with a letter and supporting documents sent by my local MP, Dame Cheryl Gillan, who has written on my behalf to the Secretary of State for Health & Social Care and the Secretary of State for International Development, to inform them of my invention of a novel male condom which has the potential to improve the overall efficacy of condoms. I requested that Dame Cheryl write to these two departments to suggest that they may find opportunities to co-operate in their respective efforts to promote correct & consistent condom use for sexual health advocacy both here domestically within the UK as well as in LMIC settings where the UK Government is supporting the Sustainable Development Goals through the financing of family planning and HIV prevention activities. I had requested for Dame Cheryl to write on my behalf prior to being made aware that the Health & Social Care Committee had launched a sexual health inquiry. ****

Condoms are a low cost and easily distributed method of dual protection against both unplanned pregnancies and the transmission of a wide range of STI’s, including HIV. As such advocacy for the ‘correct & consistent’ use of male condoms has formed a cornerstone of public health policy for many years and this is most likely to remain the case for the foreseeable future.

In recent decades there have been coordinated international efforts to improve the manufacturing and testing standards for male condoms, resulting in the development of ISO standards such as ISO4074 for latex condoms. Whilst these standards have improved the product quality and consistency as a result of improved testing and compliance, they have actually done little to improve the overall level of protection provided by the condoms. Therefore, despite condoms offering the best ‘all round’ protection available, generally
agreed to be ~98% effective with ‘perfect’ use (i.e. consistent & correct), the actual effectiveness drops to around ~85% as a result of ‘typical’ use (i.e. real world use).

This drop in the efficacy of ~13% is effectively the result of a wide range of user issues that can result in a condom not performing as intended. – It is also the opportunity that my invention was designed to address. By reducing the ‘efficacy gap’ it is possible to have a significantly positive impact on improving the sexual health outcomes for individuals and improve cost-effectiveness by addressing overlapping risks and reducing the requirement for treatments.

The reason for this ~13% ‘efficacy gap’ between ‘perfect’ and ‘typical’ condom use is in fact quite clearly illustrated in the stock photography image of the two condom wrappers that has been used by the committee to promote this very inquiry – Here we have a vital product that is intended to protect people against a range of diseases, some of which have the potential to kill you if left untreated, whilst others are becoming untreatable. We know that for this regulated Class IIB medical device to work effectively it is extremely important that it must be used both ‘CONSISTENTLY’ and ‘CORRECTLY’ – yet staggeringly, a conventionally foil wrapped condom does not possess a single product feature that will actually assist a user in achieving correct and consistent condom use.

When we examine the range of types of user errors that can typically occur when applying a condom, for example:

- Damaging the condom when opening the wrapper / removing the condom.
- Touching the wrong side against the penis then ‘flipping it over’.
- Trapping air in the tip of the condom.
- Contact transfer of bodily fluids.
- Failure to fully unroll the condom.

And the range of different reasons for errors of these types to occur, such as:

- The condom was applied in a rush.
- It was dark or low light level.
- Reduced judgment or dexterity as a result or alcohol or drugs.
- Anxiety or excitement about the sexual activity that is about to happen.

And the many different contexts of use:

- Condom use negotiation is required with a partner reluctant to use a condom.
- A sex worker who has to make the risky decision between allowing the client to apply a condom, possibly incorrectly, or applying it themselves but in doing so risking having to contact the clients unsheathed penis.
- A user who is either nervous / inexperienced or at the other end of the scale a user who’s perhaps over confident or complacent in their own condom use abilities.

The above are all factors that a conventional foil wrapped condom is unable to positively address and they contribute to the efficacy of condoms being much lower than theoretically possible.
Simply distributing large quantities of condoms via C-Card schemes on their own won’t address these user error issues, and whilst education is obviously an essential element in improving correct & consistent condom use, it is extremely difficult to recreate the range of possible contexts of condom use in either a classroom or clinical environment.

Ultimately I am convinced that we need to start offering consumers (and especially consumers of C-Card condom distribution schemes) a broader range of condom types to choose from and that these options should include condoms that come supplied in a wrapper that includes features that assist in the quick, easy and correct application of condoms, preventing a wide range of errors from being able to occur, regardless of the physical context in which the condom is being used.

This is the reason that I, as an independent inventor, have developed an innovative condom wrapper that is fully compliant with the existing ISO4074 specifications, but includes a range of features that act to promote correct & consistent condom use.

A study has been conducted by Dr Cynthia Graham from the Centre for Sexual Health Research at Southampton University and has recently been accepted for publication in the International Journal of STD & Aids (the actual publication date is not yet listed).

For brevity I shall not include details of the study here, but I can confirm that it does indicate that the proposed design would lead to both the improved consistency of condom use and significantly reduced incidents of condom use errors, and that the design achieves this through a range of design features that physically prevent a wide range of errors from being able to occur.

In the current funding climate, I’m sure that the committee will be under extreme pressure to select between two polar opposite solutions:

- Either cutting costs by reducing access or overall service provision levels.
- Or fund development of innovative, but future focused vaccines for each individual sexual health issue, some of which are still much further from deployment than others.

Whilst I would not wish to divert attention from the long-term ambition to have preventative vaccines’ available, I would urge the committee to urgently consider other technologies, such as the Temptt condom wrapper that can be made available for use and provide tangible benefits very quickly due to the fact that the design was purposefully made to already be compliant with the existing ISO specifications and as such there are a number of OEM condom manufacturers who could potentially be in production of the new condom wrapper design in relatively short notice, however in order to find such a production partner I would first need to be able to demonstrate a significant level of market demand.
Most focus now is on developing new LARC’s for family planning and new vaccine’s for STI prevention. Whilst I agree that such solutions are extremely attractive, in fact they are still often many years away from being able to achieve what we can already achieve with condoms today.

Condoms however are often overlooked – there seems to be a general regard that these are ‘old technology’ and that there’s no more progress to be made here. I have to say that I disagree most strongly with this assessment. – Even a simple glance back at the stock photograph above should be enough to convince anyone that we’re a long way yet from achieving the optimum, or ‘peak design’ for condom wrappers.

I feel that family planning, HIV Prevention and other STI’s all exist in different ‘silos’ – worse still is that education, prevention and treatment are all treated as different activities as well, undertaken by different departments or bodies and thus acting as a deterrent to innovate and try new things as any benefits achieved will be reaped ‘downstream’ in the health system and not by the body that has implemented the improvement. (i.e. better prevention = fewer treatments required. But fewer treatments required does not = more funding for better prevention).

Recommendations:

I believe that there needs to be a much more ‘holistic’ approach to sexual health than currently exists and I would urge the committee to find ways to work across government departments to simplify and coordinate the commissioning of all sexual health services and research. Where appropriate including for International Development as well.

Many large corporations now engage in ‘open innovation’ where they realise that no matter how large their own R&D activities are, they’re more likely to get a better solution if they actively engage with external and independent innovators as well. I would urge the committee to find ways to collaborate with independent innovators.

Despite the importance ascribed to the ‘correct & consistent’ use of condoms, it is astonishing that the products that are currently being distributed don’t have any features in place to actively promote and support the user in its correct & consistent use.

As mentioned earlier, since the UK Government is a significant purchaser of these condoms, both for domestic use and for international development, I had already asked my MP to write on my behalf to the SoS for DfID and the SoS for H&SC to encourage both departments to find ways to work together to improve condom efficacy by using their combined buying power to apply pressure to the OEM condom manufacturers to innovate by adopting condom wrapper designs that actually support the user in the correct and consistent use of condoms.

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