Chris,

Apologies for this further email which will add to your inbox on your return to work.

However, further 'evidence' has just come to hand regarding the speculative nature of the commercial side of the above development.

I appreciate that the consultation 'deadline' of 26th December has passed but I see that you have uploaded a letter of 'support' (effectively) from CPRE dated 31st December so I trust you may allow this further objection email.

This objection to 13/05724/OUT relates to the Planning Design and Access Statement (PDAS) for planning application N/11/03816/FUL by Bath ASU for expansion of their premises at Park Lane. The statement gives seven reasons why the company cannot operate across two separate sites. The relevant part, 4.24 **Why the company will not operate over two sites**of the PDAS, shown below. Reasons, as you may see are: regulatory overheads, controlled drugs, quality control, control of starting materials, duplication of stock, environmental impact, resilience and contingency.

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**Why the company will not operate over two sites**

4.24 For regulatory reasons the company is not prepared to continue to expand the business by splitting manufacturing operations across two sites. If any starting material or finished goods or staff move across uncontrolled areas, even over short distances, then the business would be operating across two separate legal sites which will increase regulatory overheads considerably, erode competitiveness and undermine growth of the business for the reasons set out below:-

i. **Regulatory overheads**- a second site would require a separate Medicines and Healthcare products Regulatory Agency (MHRA) site licence and would give rise to additional costs associated with a separate site  e.g. site starting materials, storage, Standard Operating Procedures (SOPs) and quality management.

ii. **Controlled drugs** - the company is licensed by the Home Office for the import and manufacture of controlled drugs. Drugs such as narcotics and opiates need strict accounting and security. Transfer of such drugs between sites and outside of controlled premises would greatly increase the need for additional security and accountability measures as only authorised people can manage such transfers.

iii. **Quality control** - many of the company's products undergo 'in process' testing where samples are taken and analysed mid-process in Quality Control Labs prior to the batch continuing through to final production. This is a time critical activity that must take place at the point of production and without delays associated with transfer from one site to another. This would necessitate the provision of another QC lab which represents an unnecessary duplication of costs.

iv. **Control of starting materials** - medicines are subject to very stringent controls requiring batch number traceability for product recalls. Even short movements of stock across sites would require stock to be booked in and out adding unnecessary complexity to stock control and handling with the need for additional goods-in/goods-out functions with quarantine processes.

v. **Duplication of stock** - both sites would require access to the same starting materials. This is likely to mean that the company would need to hold duplicate stock on each site which adds to cost and ties up capital that could be employed elsewhere.

vi. **Environmental impact** - the company maintains the highest environmental and sustainability standards. Working in partnership with the carbonfund.org, it achieves a zero carbon footprint. Splitting the operation across two sites will lead to less efficient use of energy and will undermine the company's ability to achieve this, particularly as it would require duplication of temperature controlled storage of starting materials and finished product.

vii. **Resilience and contingency** - in order to maintain an optimum service to NHS customers, the company's facilities require clean (to maintain calibration of scientific instruments) and uninterruptable power (a 20 minute power cut with consequent loss of air pressure requires 40 man days of cleaning) . The company has already invested heavily in this infrastructure for the current site and is not willing to duplicate this investment to serve a second site.

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This is further evidence, if indeed any was required, of the speculative nature of the commercial side of application 13/05724/OUT. The point is that speculative development on a greenfield site will have no advantages over a brownfield development - for example the brownfield site, for sale at present, at the former RAF Rudloe No 2 site - just across Westwells Road from the present Bath ASU premises. Either development would be remote (and about equidistant) from the main Bath ASU premises and would fall foul of the stipulations for a one-site operation shown above.

Indeed, one of the maxims of carbonfund.org, Bath ASU's partner, is **reuse** - should this not apply equally to land - brownfield rather than greenfield?

Sincerely

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