

29 September 2006

REF :13172

APPEAL AGAINST WEST LINCOLNSHIRE PCT DECISION TO GRANT WESTLEE LTD APPLICATION FOR PRELIMINARY CONSENT FOR INCLUSION IN THE PHARMACEUTICAL LIST AT HIGH STREET, NAVENBY

REF : 13173

APPEAL AGAINST WEST LINCOLNSHIRE PCT DECISION TO REFUSE SPC DARTOS SERVICES LTD APPLICATION FOR INCLUSION IN THE PHARMACEUTICAL LIST IN THE VICINITY OF GRANTHAM ROAD (PROPOSED NEW SURGERY SITE), NAVENBY

1 The Applications

By application dated 30 March 2005, WestLee Ltd applied to West Lincolnshire Primary Care Trust ("the PCT") for preliminary consent for inclusion in the pharmaceutical list at High Street, Navenby. In support of the application it was stated:

- 1.1 Navenby is a distinct community or neighbourhood and would benefit from a pharmacy in its centre in order to provide a broader range of access to medicines including OTC and Pharmacy Only Medicines, elastic hosiery, stoma appliances and trusses. This in turn will offer improved choice to the patient and in many instances, where the cost of OTC medicine is less than the prescription charge, better value for the patient when obtaining necessary medicines.
- 1.2 The presence of a pharmacy would allow the option of pharmacist advice to the patient at the point of dispensing of medicines making for a potentially safer and value-added interaction with the patient.
- 1.3 The pharmacy would be able to provide a range of pharmacy only and over the counter medicines not currently available in the cliff villages, often reducing the need for the patient to request a doctor's appointment and thus improving access to the GP for conditions that need the GP's particular expertise.
- 1.4 The proposal increases the range of services available to patients in the locality. If commissioned by the PCT the pharmacy will offer a range of services to patients not currently provided in the locality including pharmacy based smoking cessation, minor ailment scheme, advisory service to care homes, emergency hormonal contraception, needle exchange service, supervised administration scheme and prescription intervention scheme, anti-coagulant monitoring, pharmacist supplementary prescribing.
- 1.5 The pharmacy will increase the capacity of medicine management services in the locality which will support the effective use of medicines, reduce wastage, potentially reduce prescribing costs and help prevent inappropriate admissions to hospital.
- 1.6 The proposal allows choice for patients in the delivery of pharmaceutical services and very much supports the principal of a patient centred rather than professional centred approach to the provision of NHS services.

- 1.7 While not directly linked to the proposal WestLee Ltd are also planning to deliver a wider range of health services from the same premises in Navenby including an optometrist and, if commissioned by the PCT, NHS dentistry.

By application dated 21 June 2005, SPC Dartos Services Ltd applied to the PCT for inclusion in the pharmaceutical list In the Vicinity of Grantham Road (proposed new surgery site), Navenby. In support of the application it was stated:

- 1.8 The pharmacy would be sited within Navenby and serve primarily the residents of Navenby, Wellingore and Boothby Graffoe.
- 1.9 There are presently no pharmaceutical services within Navenby and its immediate neighbouring villages.
- 1.10 The nearest pharmacy is 6 miles away.

2 The PCT Decisions

The PCT's joint decision letter dated 26 May 2006 states:

- 2.1 At a meeting of the Executive Board held on Tuesday 24 May 2006 at West Lincolnshire PCT, consideration was given to the recommendation made by North Lincolnshire PCT in respect of two applications to establish pharmacies in the village of Navenby.
- 2.2 The applications had been submitted by WestLee Ltd and SPC Dartos Services Ltd.
- 2.3 The applications had been considered by North Lincolnshire PCT under the NHS (Pharmaceutical Services) Regulations 1992 for WestLee Ltd, and under the NHS (Pharmaceutical Services) Regulations 2005 for SPC Dartos Services Ltd.
- 2.4 After careful consideration, the West Lincolnshire PCT Board decided to endorse the recommendations made by North Lincolnshire PCT in respect of the questions of prejudice to general medical and pharmaceutical services in any area, and whether it was necessary and/or desirable to grant either application in order to secure, in the neighbourhood, the adequate provision of services or some of the services specified in the applications. The recommendations were to approve the application from Westlee Ltd, but not to approve the application submitted by SPC Dartos Services Ltd for the following reasons :
- 2.4.1 Neighbourhood defined as the settlements of Navenby, Wellingore and Boothby Graffoe.
- 2.4.2 No evidence was received to demonstrate that the existing provision of general medical or pharmaceutical services would be prejudiced by the opening of a pharmacy.
- 2.4.3 North Lincolnshire PCT was satisfied that it was both necessary and desirable to recommend approval of the application from WestLee Ltd to open a pharmacy in order to secure in Navenby the adequate provision of pharmaceutical services by persons included on the pharmaceutical list.
- 2.4.4 The application by SPC Dartos Services Ltd was not recommended for approval because an earlier application had been submitted and supported for approval, and
- 2.4.5 The patient population of the defined neighbourhood did not support the need for two pharmacies.

3 The Appeals

The Family Health Services Appeal Unit of the NHS Litigation Authority (“the Appeal Unit”), received two letters of appeal against the PCT’s decision. The respective grounds of appeal are:

SPC Dartos Services Ltd (letter dated 19/6/06)

- 3.1 SPC Dartos Services Ltd write to appeal against the decision made to allow the application by WestLee Ltd and refuse that of SPC Dartos Services Ltd as notified by PCT letter of the 26 May 2006.
- 3.2 SPC Dartos Services Ltd think the decision vitiated by errors of procedure. The West Lincolnshire PCT purported to delegate the decision to North Lincolnshire PCT, possibly as a consequence of concerns aired in solicitors' correspondence that earlier decisions may have been tainted by conflicts of interest in connexion with the management and ownership of WestLee. SPC Dartos Services Ltd do not know the authority for such delegation. SPC Dartos Services Ltd also consider that the language of the decision letter of 26 May suggests that such endorsement as West Lincolnshire gave to the North Lincolnshire decision was purely nominal.
- 3.3 In elaboration of this last point, and standing as well as one of substance, is the letter's statement at paragraph (b) that "No evidence was received to demonstrate that the existing provision of general medical or pharmaceutical services would be prejudiced". However extensive evidence was provided both by the LMC and Cliff Villages Medical Practice in correspondence. The representations of both appear to have been ignored.
- 3.4 Similarly, no evidence has been adduced as to the inadequacy of current pharmaceutical provision in Navenby. While clearly as an applicant company we hold this to be self evident, proper procedure would require the matter to be demonstrated.
- 3.5 Most significant of all was the procedure adopted by North Lincolnshire in deciding upon the application of WestLee before addressing that of SPC Dartos Services Ltd. This was in breach of the intimation expressed in the West Lincolnshire letter of 10 February 2006 where it was said: "It is our understanding that the applications will be considered in date order, which as we are sure you are aware, does not necessarily mean that one application is more likely to be granted than the other". Indeed, the procedure adopted was in direct breach of the representation made in the letter of Mr Curd of West Lincolnshire of 24 October 2005 that the procedure adopted would "not in any way be prejudicial" the applications of either party. The procedure however was highly prejudicial, in that having first approved the application of WestLee, the deciding body considered that there was no place for a further application.
- 3.6 The decision concluded (without referring to evidence) that the population of the neighbourhood (which it did not define) "did not support the need for two pharmacies", but SPC Dartos Services Ltd do not think by this summary conclusion that the decision complied with the requirement to consider matters arising under Regulation 12(2) of the current Regulations.
- 3.7 SPC Dartos Services Ltd view is that their application, which was proposed to be sited more conveniently for the local population and which would benefit far more from local support, is far more in conformity with the pharmaceutical needs of the community and should be favoured over that of WestLee.
- 3.8 SPC Dartos Services Ltd ask for their appeal to be allowed, if necessary with a hearing at which the procedural defects set out above can be remedied and in which the advantages either of both the applications or by comparing one with the other can be properly considered.

Cliff Villages Medical Practice (Dr L J Broughton & Partners – letter dated 19/6/06)

- 3.9 Cliff Villages Medical Practice consider that this application (WestLee Ltd) will be highly prejudicial to the proper provision of medical services, on the following grounds:
- 3.10 Astonishingly, the letter (PCT decision letter of 26/5/06) says (at paragraph (b) "No evidence was received to demonstrate that the existing provision of general medical or pharmaceutical services would be prejudiced". In Cliff Villages Medical Practice letter of 20 March 2006 they set out their concerns as to the highly detrimental consequences for medical services in the light of a prospective loss of 80 per cent of their dispensing income. These included immediate reduction in services and a considerable threat to the viability of the practice all in the medium term - say after 18 months or so.
- 3.11 In elaboration of these representations, Cliff Villages Medical Practice are now able to say, as a result of recent calculation, that, following upon the loss of dispensing facilities at Waddington (October 2005), they anticipate if the application at Navenby is allowed a total annual fall in income of approximately £930,000. Cliff Villages Medical Practice think it self evident that very serious consequences for current provision of medical services would follow such a change.
- 3.12 These could include substantial staff reductions, a very sharp curtailment in surgeries offered at Navenby, and the renegotiation of a number of the services Cliff Villages Medical Practice currently are contractually required to provide in view of the fact that these are often not fully reimbursed under the current regime.
- 3.13 Cliff Villages Medical Practice think it clear that a reduction in medical services could not immediately be taken up by any others in the primary care sector of the neighbourhood.
- 3.14 In addition, with one of Cliff Villages Medical Practice three principals planning retirement probably within the next two years or so, and given the difficulties of the general practitioner market (and Cliff Villages Medical Practice recent unsuccessful experience in seeking to make an appointment), Cliff Villages Medical Practice much diminished practice, even if continuing, would have very substantial long term problems.
- 3.15 Cliff Villages Medical Practice would be pleased to submit detailed financial information and costings in any oral hearing if that is thought appropriate.

4 **Summary of Representations**

This is a summary of representations received on the appeals. A summary of those representations made to the PCT are only included in so far as they are relevant and add to those received on the appeal.

Beachcroft LLP (on behalf of the West Lincolnshire PCT)

- 4.1 The Respondent makes these representations in respect of the Appeals submitted by the First and Second Appellant and respectfully requests that they be taken as the formal representations in respect of both Notices of Appeal.
- 4.2 In these submissions reference is made to the NHS (Pharmaceutical Services) Regulations 1992 (referred to as "the 1992 Regulations"); the NHS (Pharmaceutical Services) Regulations 2005 (referred to as "the 2005 Regulations"); and the Department of Health's Control of Entry Guidance (referred to as "the Guidance").
- 4.3 The First and Second Appellants were notified of the Respondent's decision to approve the Application made for the inclusion on to its Pharmaceutical List in Navenby to WestLee Limited (WLL) by letter dated 26 May 2006 (a copy of which is attached and marked "APPI") and not to approve that made by SPC Dartos Services Ltd (the Second Appellant). The Respondent's reasons for not approving the

Application submitted by the Second Appellant were set out within the letter of 26 May 2006 as follows:

- 4.3.1 Neighbourhood defined as the settlements of Navenby, Wellingore and Boothby Graffoe;
 - 4.3.2 No evidence was received to demonstrate that the existing provision of general medical or pharmaceutical services would be prejudiced by the opening of a pharmacy;
 - 4.3.3 North Lincolnshire PCT were satisfied that it was both necessary and desirable to secure in Navenby the adequate provision of pharmaceutical services by "person" included on the pharmaceutical list;
 - 4.3.4 The application by SPC Dartos Services Ltd was not recommended for approval because an earlier application had been submitted and supported for approval; and
 - 4.3.5 The patient population of the defined neighbourhood did not support the need for two pharmacies.
- 4.4 The First and Second Appellants in their respective Notices of Appeal dated 19 June 2006 are appealing the decision of the Respondent as outlined in its letter of 26 May 2006 referred to above. The First and Second Appellants appeal on the following grounds:
- 4.4.1 The Respondent's decision to grant the application for the provision of pharmaceutical services in Navenby to WLL is prejudicial to the provision of general medical or pharmaceutical services;
 - 4.4.2 The procedure adopted in the consideration and determination of the Applications for provision of pharmaceutical services within the Navenby area was not undertaken in accordance with the 2005 Regulations and consequently, the decision made by the Respondent was vitiated by errors of procedure as follows:
 - 4.4.2.1 the order in which the applications for provision of pharmaceutical services in Navenby were considered;
 - 4.4.2.2 the decision made by the Respondent to delegate the consideration of the applications to North Lincolnshire PCT;
 - 4.4.3 The decision relating to the Application made by the Second Appellant concluded erroneously (without referring to the evidence available) that the population of the neighbourhood (which it is stated was not defined) did not support the need for two pharmacies and as a result, the decision made by the Respondent failed to comply with the requirements of Regulations 12(2) of the 2005 Regulations.

Prejudice to the proper provision of services

- 4.5 The First and Second Appellants submit that the Respondent's decision to approve the Application for the provision of pharmaceutical services in Navenby to WLL is prejudicial to the provision of general medical or pharmaceutical services.
- 4.6 The First Appellant refers to its letter dated 20 March 2006 (a copy of which was provided and marked APP2) which it submits demonstrates sufficiently a prejudicial effect on the provision of general medical and pharmaceutical services that it provides and submits also that it is the dispensing profits that sustain such personal medical services (by way of background, services are provided by the First Appellant through

a Personal Medical Services contract with the Respondent). The Second Appellant asserts that this correspondence provides “extensive evidence” of prejudice.

- 4.7 The Second Appellant refers to the correspondence from the Local Medical Committee as being further evidence of the prejudicial effect on the provision of general medical and pharmaceutical services (a copy of correspondence from the LMC dated 3 April 2006 was provided and marked, APP3).
- 4.8 The First Appellant, in its Notice of Appeal, submits that it is “now” able to say, as a result of “recent calculations” that following upon the loss of dispensing facilities at their Waddington surgery in October 2005, it anticipates a fall of income in the Navenby practice of approximately £930,000.
- 4.9 Regulation 18(2)(a) of the 2005 Regulations provide that a Primary Care Trust:
“shall refuse an application to the extent that it is of the opinion that to grant it would prejudice the proper provision of primary medical services, dispensing services, local pharmaceutical services or pharmaceutical services in any locality”
- 4.10 A Primary Care Trust therefore has the power to refuse an application relating to a controlled locality to the extent that granting it would “prejudice” the proper provision of primary medical services, pharmaceutical services or local pharmaceutical services in an area. Whilst the 2005 Regulations do not provide any further definition of the concept of “prejudice”, the Guidance provides at Annex C that in general “prejudice” means that nothing must be done which would have the result of preventing *people* (our emphasis) (as opposed to financial prejudice to a practice) in any controlled locality from having access to those primary medical and pharmaceutical services at the level of service which is provided for by National Health Service contractual arrangements.
- 4.11 The Guidance also provides at Annex C that a mere reduction in the total level of service provided by either a pharmacist or a doctor is not of itself “prejudice”; prejudice arises where the service provided under the terms of service laid down by the National Health Service has in some respect to cease or otherwise be curtailed or withdrawn without proper substitution in the area. Annex C further clarifies that the burden of proof is on the First and Second Appellants who allege that prejudice will occur.
- 4.12 In response to this part of both Appellants Appeals, the Respondent disputes this ground and submits that having duly considered and applied the criteria detailed in Regulation 18 of the 2005 Regulations there was (and currently is) no evidence submitted by either the First or Second Appellant or other interested parties sufficient to satisfy the requirements of Regulation 18 of the 2005 Regulations.
- 4.13 The FHSAU is referred to paragraph 1(v) of North Lincolnshire PCT’s recommendation to the Respondent in relation to the application of WLL (a copy of which was provided and marked APP4) which confirms that reference was made to the First Appellant’s patient list size and that the submissions from the First Appellant and the LMC were taken into account. The Respondent considers that the information provided and submissions made were insufficient to indicate the effect on the viability of the surgeries should the pharmacy open and how this could in turn cause a reduction in the level of services to patients in Navenby.
- 4.14 The Respondent further contends that, as stated above, the burden of proof lies with the First and Second Appellants to establish “prejudice” and that they have failed to do so. The Respondent has a duty to consider whether a grant of an application will result in a prejudicial effect to services currently provided to the *public*, and not financial prejudice to the First Applicant. There is therefore a distinction to be made between there being a prejudice to services as a result of financial prejudice and merely financial prejudice to the surgery. Even if it is found that there is no such

distinction to be made, it is the Respondent's case that on the evidence available to it at the time, it was not satisfied, having regard to all the evidence, that there was 'prejudice' to the provision of services.

- 4.15 The Respondent disputes that correspondence received from the First Appellant on 20 March 2006 is sufficient evidence to satisfy the test within Regulation 18(2)(a) of the 2005 Regulations. The Respondent submits that this letter does no more than merely restate the submissions made in the respective Appeal Notices and does not provide any further evidence to demonstrate prejudice. It is the Respondent's position that further evidence would need to include the submission of management accounts certified by a professional accountant showing the income and expenditure at Navenby attributable separately to the two services (i.e. dispensing and medical).
- 4.16 The Respondent disputes that the correspondence received from the Local Medical Committee (LMC) dated 3 April 2006 to Katrina Egar (a copy of which was provided and marked APP3 – and referred to above) is sufficient evidence to satisfy the test within Regulation 18(2)(a) of the 2005 Regulations. The letter states that "the maintenance of a second surgery site in Navenby after the loss of dispensing services is on the very limits of viability and there remains a considerable risk that the surgery would have to close altogether". There is no financial evidence appended to this letter to support this view or to demonstrate that closure is a real possibility.
- 4.17 The Respondent submits that for the First Appellant to succeed in arguing financial prejudice (and the Respondent notes that no other form of prejudice has been argued) it would be necessary to demonstrate that dispensing profits cross subsidise medical services to the extent that without this support, the medical services at Navenby would be financially prejudiced. It is the Respondent's position that it would be very difficult to argue that earnings of, at or above the average (e.g. the Interim Average Superannuable figure for 2006/7 of £95,335) would result in the practice being unable to deliver medical services to standard necessary. To be prejudicial in accordance with Regulation 18(2)(a), it would be necessary, the Respondent submits, to demonstrate that the removal of dispensing from Navenby would reduce earnings to at least below this level. The Respondent has no evidence before it which shows that the profits from dispensing at Navenby have cross subsidised medical services and that the removal of any such subsidy would result in the practice being unable to deliver medical services at the necessary standard.
- 4.18 Additionally, the Respondent submits that the First Appellant's letter of 20 March 2006 in which it is stated that the practice wishes to proceed in the very near future to relocate to a new, far larger surgery in Navenby (the site from which the Second Appellant seeks to dispense pharmaceutical services, the Second Appellant being a Company owned by the First Applicant) is in direct conflict with its position that the Respondent's decision to grant the application to WWL is prejudicial in accordance with Regulation 18(2)(a) of the 2005 Regulations.
- 4.19 The First Appellant has not provided evidence to support the point it makes that the loss of dispensing would be sufficiently prejudicial to alter its proposal. Indeed, up until now, it has been the Respondent's understanding that the First Appellant wishes to proceed in advance of the finalisation of the dispensing issue on the basis that the eventual decision on dispensing will not alter the size of new surgery required. However, the First Applicant has been asked to further confirm this and the Respondent awaits confirmation.
- 4.20 In summary, the Respondent submits that the evidence presented to date by both the First and Second Appellants together with that submitted by other interested parties fails to establish that the opening of a pharmacy in Navenby would be prejudicial to the future provision of Personal Medical Services in accordance with Regulation 18 of the 2005 Regulations.

Procedure adopted in the consideration and determination of the applications for provision of pharmaceutical services within Navenby area

The order in which the applications were considered

- 4.21 The Second Appellant submits that the procedure adopted by the Respondent in the consideration and determination of the Applications for provision of pharmaceutical services within the Navenby area was not undertaken in accordance with the provisions of the 2005 Regulations and that consequently, the decision was vitiated by errors of procedure.
- 4.22 In accordance with Regulation 24(1) of the 2005 Regulations, a Primary Care Trust may determine an application in such manner as it thinks fit and may, if it considers that oral representations are unnecessary, determine the application without hearing any oral representations.
- 4.23 The Respondent disputes that the procedure adopted in deciding upon the application of WLL before considering that of the Second Appellant erred in proper procedure and relies upon the Regulation 24(1) of the 2005 Regulations in this regard.
- 4.24 Further, the FHSAU will note that the application from WLL was submitted under the 1992 Regulations whereas the application from the Second Appellant was submitted under 2005 Regulations.
- 4.25 Whilst the Department of Health's Guidance at Paragraph 2.17 provides that applications can be considered together, the Guidance envisages the situation where more than one application is received under the 2005 Regulations. This is to be distinguished from the situation where two applications are received simultaneously but pursuant to different Regulations. In an email dated 7 October 2005 (a copy of which was provided and marked APP5) Mr Peter Dunlevy at the Department of Health indicated that whilst the applications could be dealt with at the same meeting, the application received under the 1992 Regulations should be dealt with before moving on to the second application submitted under the 2005 Regulations.
- 4.26 To that end, the Respondent (and subsequently North Lincolnshire PCT) acting on the advice from the Department of Health, sought to consider the applications in the order recommended and therefore disputes the submission made by the Second Appellant that North Lincolnshire PCT erred in the procedure adopted in view of the advice obtained from the Department of Health and moreover, submits that the applications were considered on their merits alone in any event.

The decision made by the respondent to delegate the consideration of the applications to North Lincolnshire PCT

- 4.27 The Second Appellant submits that the Respondent's decision to delegate the consideration of the applications to North Lincolnshire PCT led to the decision to approve the application of WLL to be vitiated by errors of procedure.
- 4.28 As cited above, in accordance with Regulation 24(1) of the 2005 Regulations a Primary Care Trust may determine an application in such manner as it thinks fit.
- 4.29 The Guidance also requires at paragraphs 3.115 - 3.132, whether a hearing is held or the application is dealt with solely based on the papers submitted, the process for making the determination to be in accordance with the fundamental principles of administrative law which are that the decision-taker must not be "biased", and that the procedure must be fair. Bias in this context means that no decision-taker must have a personal or financial interest in the outcome of the hearing. Whilst the boundaries of this principle are not always clear, where a decision-taker is related to, is a personal friend or a business associate of an applicant they should not be involved in any decision-making process.

- 4.30 The Respondent submits that in accordance with Regulation 24(1) of the 2005 Regulations, it was entitled to process, consider and determine the applications for pharmaceutical services in Navenby in the form that it did. There is no provision within the 2005 Regulations which prevents delegation of the consideration of the applications to a third party.
- 4.31 The Respondent further submits that in delegating the consideration of the applications to North Lincolnshire PCT it was seeking to ensure that due and proper regard was being made to the principles of administrative law in ensuring that the process of deliberation was free from bias and the procedure fair.
- 4.32 It is of relevance that a number of the Partners at Cliff Villages Medical Practice (the First Appellant) are either shareholders and/or Directors of SPC Dartos Services Ltd (the Second Appellant). It is of further note that two Officers from within West Lincolnshire PCT (the Respondent) at the time of the consideration and/or determination of the decision had direct or indirect financial interests in WLL.
- 4.33 The FHSAs are referred to correspondence received by the Respondent from Hempsons solicitors on 3 November 2005 and 2 February 2006 (copies of which were provided and marked APP6 and APP7). The FHSAs will note that both letters detail concerns in relation to a possible conflict of interest leading to a risk of bias in the consideration and determination of the applications arising from the direct and indirect involvement of two Officers of the Respondent PCT with WLL. The FHSAs are also referred to the Respondent's responses to this correspondence (copies of which were provided marked APP8 and APP9).
- 4.34 The Respondent therefore submits that its decision to delegate the consideration of the applications to North Lincolnshire PCT did not err in procedure vitiating the decision reached but instead sought to address the concerns raised by Hempsons solicitors on behalf of the First Appellant and further, sought to meet the requirements and provisions of paragraph 3.115 - 3.132 of the Guidance (with particular emphasis on paragraphs 3.115 to 3.117).
- 4.35 Whilst neither of the Officers concerned had any role to play in either the consideration or determination of the Applications, given the extent to which both Officers were known within the Respondent PCT (on both a personal and professional basis), in order to ensure that the process of deliberating both applications was fair, objective and free from bias, a decision was taken by the Respondent to delegate this part of the decision making process to North Lincolnshire PCT.
- 4.36 The Respondent considers that its actions were driven primarily with the desire to ensure that it acted with "the utmost probity" (paragraph 3.122 of the Guidance) when making decisions on both of the applications and remains of the view that the decision to delegate consideration of the Applications was the most appropriate means of securing objective assessment of the merits of both applications.
- 4.37 The decision to delegate the consideration of the applications to North Lincolnshire PCT was therefore taken in the interests of all parties concerned and the Respondent can see no evidence to suggest that the First or Second Appellants were disadvantaged in any way given that ultimately, the process of deciding the applications did not differ from that which would have been adopted had the Respondent PCT's Committee deliberated the applications.
- 4.38 The Respondent therefore refutes the statement made by the Second Appellant that as a result of the delegation to North Lincolnshire PCT the decision made by the Respondent PCT's Board was purely nominal. The Respondent PCT's Board met and were privy to the information considered by North Lincolnshire and having considered its reasoning and deliberations, made the decision to adopt the recommendation of North Lincolnshire PCT that the application be granted to WLL.

“Consideration v Determination”

- 4.39 The Respondent does, however, acknowledge that initial representations made to both the First and Second Appellants were to the effect that the consideration and determination of the application would be by North Lincolnshire PCT.
- 4.40 However, guidance received from the LMC and subsequently confirmed by the Department of Health at a later date clarified that technically, whilst the 2005 Regulations were not clear, a favoured interpretation of these Regulations was that the formal “grant” of an application would need to be made by the Respondent PCT as only the PCT managing the list in question has the power to include a pharmacy provider onto its list. Clarification was also given that where, for example, a potential for a conflict of interest has arisen, the processing of the applications, the consideration of the merits of applications and the making of recommendations to a PCT Board can be delegated to a third party, as was in this instance.

The “necessary and desirable test” Regulations 12(2) 2005 Regulations

- 4.41 The Second Appellant submits at paragraph 5 of its Notice of Appeal that North Lincolnshire PCT failed to properly consider and apply Regulation 12 (2) of the 2005 Regulations in that the “decision” states that the population of the neighbourhood “*did not support the need for two pharmacies*” and that further, this was not supported with evidence.
- 4.42 The Second Appellant also states that “neighbourhood” was not defined during the consideration its application. In response to this aspect of the Second Appellants appeal, the Respondent submits that North Lincolnshire PCT did not fail in its application of Regulation 12(2) of the 2005 Regulations.
- 4.43 Regulation 12(2) of the 2005 Regulations requires a Primary Care Trust to take account of certain particular factors. These include but are not limited to:
- 4.43.1 whether any of the services proposed are already provided within the neighbourhood;
- 4.43.2 whether the recipients of pharmaceutical services already have a reasonable choice regarding the services or the range of persons already on the pharmaceutical list in the neighbourhood;
- 4.43.3 other information the Primary Care Trust considers relevant;
- 4.43.4 any representations received from those invited to give views.
- 4.44 The Respondent submits that the criteria within Regulation 12(2) 2005 Regulations was taken into account and duly applied when consideration was given to the application made by the Second Appellant. The FHS AU are referred to paragraphs 3(iv), 3(vii) and 5 of the recommendations made by North Lincolnshire PCT in respect of this application (a copy of this document was provided and marked APP10). The FHS AU will note that paragraph 3(iv) does define “neighbourhood” and moreover, the recommendation considers the adequacy of provisions of services in the Navenby area having regard to the recommendation to grant WLL's application and the patient population of the defined neighbourhood and concludes that there is no need for two pharmacies in the area.
- 4.45 Furthermore, the FHS AU is referred to the numerous references throughout the recommendations made by North Lincolnshire PCT detailing the responses received through the consultation process, all of which were considered as part of its

deliberations. The Respondent does not accept that this process not comply with the provisions of Regulation 12(2) of the 2005 Regulations relating to “neighbourhood” and “adequacy” of provision of services. It is evident from the detail available that consideration was given to all the evidence available at the time, including the responses received, as well as to the criteria to be applied pursuant to the 2005 Regulations.

In Summary

In summary, the Respondent submits:

- 4.46 There is no evidence to suggest that the decision made by the Respondent to approve WLL's application will have a prejudicial effect on the provision of medical and pharmaceutical services provided by the First Appellant. The Respondent disputes that any of the evidence submitted to date relating to the issue of prejudice establishes a prejudicial effect for the reasons set out above at paragraphs 4.5 to 4.20;
- 4.47 The procedure adopted by the Respondent (by delegation of the consideration of the applications to North Lincolnshire PCT) as to the order in which the applications were considered was not driven by any desire to disadvantage the Second Appellant but arose from an anomaly within the transitional arrangements in place following the coming in to force of the 2005 Regulations;
- 4.48 Following persistent pressure from the solicitors representing the First Appellant in relation to concerns regarding a possible conflict of interest, the Respondent sought to exercise its discretion under 24(1) of the 2005 Regulations to delegate its responsibilities to a third party so to ensure there was no risk of bias in terms of how the applications were considered and believes that it acted in utmost probity in doing so;
- 4.49 The Respondent had due regard to Regulation 12(2) of 2005 Regulations and duly applied “the necessary and desirable” test to the specific circumstances of the Second Applicants application.
- 4.50 The Respondent therefore respectfully requests, for the reasons set out above, that the Appeals lodged by the First and Second Appellants be dismissed.

WestLee Ltd (Applicant)

- 4.51 WestLee Ltd would like to make the following representations with relation to the appeal against the decision of West Lincolnshire PCT to include WestLee Ltd on the pharmaceutical list: Navenby, Lincolnshire.

Timing of application

- 4.52 WestLee Ltd's application was made 16 months ago under the 1992 regulations. WestLee Ltd supported the decision to hear the applications separately and in date of application order as our application was made under the old regulations and was submitted several months prior to the SPC Dartos application which, at the time of the application, had no superintendent pharmacist (WestLee Ltd are not sure if this circumstance has changed).

Prejudice

- 4.53 WestLee Ltd would contest the suggestion that the provision of general medical services in Navenby would be prejudiced by the opening of a pharmacy in Navenby. The practice has a significantly above average list size per partner (2500 patients) and will be receiving a significantly above average remuneration for the provision of general medical services compared to the average non-dispensing GP (the average

list size per GP in England is approx 1800 patients and the average remuneration is £100k approx). In addition to this they will still be receiving dispensing income for 20% of their patients unlike their non-dispensing GP colleagues. It is therefore difficult to see how, in still receiving very significantly higher income than the average non-dispensing GP in England who provides a full range of general medical services, one could support the notion that services would have to be cut.

- 4.54 There has been no evidence submitted as to what specific services over and above those required to be provided under the new General Medical Services (GMS) contract would have to be cut and why that would be necessary given the higher than average level of continuing non-dispensing funding that would still be available to the practice. Nor has there been any evidence given that any diminution of services would not be in breach of the terms of the practices GMS contract.
- 4.55 It is suggested that operating at both the Waddington and Navenby sites would become unviable, even with the significantly increased income being received by the doctors, and that there would be a considerable risk that the Navenby surgery would have to close altogether. This seems somewhat disingenuous as it is public knowledge that the Cliff Villages Practice have advanced plans to build a new, larger surgery in the village of Navenby which would become the main surgery site.
- 4.56 As stated previously the level of NHS funding to the practice, despite the loss of dispensing to the Navenby/Wellingore location, would remain higher than the average funding to a non-dispensing practice (due to the higher than average list size and continuing dispensing to a proportion of the list size) and one cannot envisage why the services that could be provided by the practice should be any less than that provided by all other non-dispensing practices in Lincolnshire or indeed England. In terms of operating services on more than one site i.e Waddington and Navenby there are several examples of this being performed by non-dispensing practices in Lincolnshire including 3 practices in Lincoln City.

Necessary or desirable

- 4.57 WestLee Ltd's application outlined additional pharmaceutical services that would allow patients access to additional capacity of certain services over and above that which the patients were entitled to or receiving under general medical services in Navenby, Wellingore and Boothby Graffoe. These include additional minor ailment, smoking cessation, emergency hormonal contraception and, particularly, medicines management services. They would also allow patients access to services not currently available to the population of Navenby, Wellingore or Boothby Graffoe.
- 4.58 These would include Over The Counter and Pharmacy Only Medicines that currently cannot be supplied by the practice dispensary along with Medicines Use Reviews, an advanced service within the new pharmacy contract which promotes better use of medicines. This is intended to promote self-care and reduce the burden on GP time. The patients would also have professional advice from a pharmacist at the point of dispensing of all medicines including prescription only medicines which they are currently not able to enjoy.
- 4.59 The services currently provided by the practice are those that the practice, like any other non-dispensing practice, are funded to provide under general medical services.

Letters outlining reasons for appeal from Cliff Villages practice and SPC Dartos Ltd

Cliff Villages Practice

- 4.60 The sum of £930,000 described as the level of fall in income to the practice following the loss of dispensing to Waddington and Navenby is very likely to be the gross figure including the costs of all the drugs and appliances dispensed. The net loss of income to the practice is likely to be 20- 30% of this sum. This figure includes loss of gross

income from the loss of dispensing in the Waddington area which is not pertinent to this application. There would be no impact on the practices core GMS essential, additional and enhanced income.

- 4.61 For the reasons described earlier in this letter WestLee Ltd cannot see why, other than dispensing staff, the level of staffing of doctors, receptionists or nurses should be any lower than any other practice.
- 4.62 The practice must continue to provide all essential and additional medical services to all patients registered with it and, like any other practice, can opt in or out of providing any enhanced medical services.
- 4.63 The difficulties in recruiting GPs to Lincolnshire have not been evidenced. WestLee Ltd are not aware of significant unfilled vacancies for GPs in the county in fact despite there being over 400 GP posts in Lincolnshire there have been no adverts for full partnerships in the BMJ or free GP magazines for the last two months and only one vacancy for a salaried GP in inner city Lincoln. WestLee Ltd are not aware as to how extensively the Cliff Villages practice advertised nor when and whether they were advertising for a profit sharing partner or a less attractive (to the applicant) salaried post. Several practices in West Lincolnshire, both dispensing and non-dispensing, have successfully recruited partners over the last 3 years. WestLee Ltd are sure evidence of this can easily be obtained from the PCT's performers list.
- 4.64 Indeed there is supporting evidence of this in the recently published "GP Practices Vacancy Survey 2006 England and Wales" carried out by the NHS Information Centre and available through the DoH website. This evidences that across the whole of Trent region (including some of the most deprived areas of Nottingham, Mansfield and the former Nottinghamshire coalfields) there are only 0.9 vacancies per 100,000 patients (i.e 1 vacancy for every 62 GP posts) and that even in the most remote rural practices in England and Wales there are only 1.5 GP vacancies per 100,000 population suggesting that recruitment, at present, is not a significant problem across general practice in the UK. It is therefore somewhat surprising that recruitment to an above average list size dispensing practice in one of the most sought after residential villages in Lincolnshire is proving so difficult.

SPC Dartos Services Ltd

- 4.65 The registered address of SPC Dartos Ltd is that of the Cliff Villages surgery in Navenby (4 North Lane, Navenby). The named director of SPC Dartos Ltd is J G McLoughlin, one of the GP partners of the Cliff Villages Medical Practice.
- 4.66 The application in June 05 from SPC Dartos Ltd to provide pharmaceutical services for Navenby did not contain the name of any superintendent pharmacist and therefore contained no evidence related to any such pharmacist's experience or suitability to manage a pharmacy contract. WestLee Ltd have not been provided with any information since to suggest that any pharmacist is involved with or employed by SPC Dartos Ltd.
- 4.67 In point 3 of the letter appealing the PCT's decision Dr McLoughlin, director of SPC Dartos and partner in the Cliff Villages Medical Practice, states that he holds as self-evident the inadequacy of current pharmaceutical provision in Navenby. WestLee Ltd cannot see how then that SPC Dartos and the Cliff Villages Practice, who are clearly inter-related, can appeal the decision on the grounds of either prejudicing medical services or the necessary or desirable test.
- 4.68 The suggestion that both applications should be approved if the WestLee application was successful is somewhat disingenuous. The WestLee application was submitted under the old regulations 3 months before the application from SPC Dartos under the new regulations and, WestLee Ltd believe quite rightly, was therefore considered before the SPC Dartos application. A pharmacy may only be viable with 2700 patients.

The opening of two pharmacies in this neighbourhood would leave both as unviable. This would clearly be in the interests of The Cliff Villages Practice and, by association, SPC Dartos Ltd.

Lincolnshire Local Pharmaceutical Committee

- 4.69 The process taken by the West Lincolnshire PCT in determining these applications was not in line with the procedures normally followed. Having previously established the area to be wholly rural in character, on 11 October 2005 West Lincolnshire PCT wrote to interested parties to submit representations regarding prejudice. However, the Pharmaceutical Services Panel at West Lincolnshire PCT never did consider prejudice relating to these applications and on 20 December 2005 the LPC was informed that a decision had been taken by WLPCT Board to delegate authority of the consideration and determination of these applications to North Lincolnshire PCT.
- 4.70 The LPC entered into correspondence with West Lincolnshire PCT relating to the fact that whilst the pharmaceutical regulations allowed for the delegation of the process of notification, processing applications, considering the merits and recommending whether the application should be granted, the PCT is not able to delegate the actual determination. The LPC were satisfied, however, that due process was followed in that the executive board of West Lincolnshire PCT did give consideration to the recommendations made by North Lincolnshire PCT and decided to endorse them.
- 4.71 In the LPC's correspondence to WLPCT and later to NLPCT the LPC stated their belief that the establishment of a pharmacy in Navenby would not prejudice the proper provision of medical or pharmaceutical services in the area. The LPC's letter to NLPCT on the consideration of necessary and desirable goes on to state that Navenby had been identified many years previously as being amongst the areas in Lincolnshire which would benefit from a pharmacy, and therefore the LPC held the view that the establishment of a pharmacy in Navenby was necessary and desirable.
- 4.72 The two applications being considered were submitted under different regulations, the WestLee application being submitted on 30 March 2005 was to be considered under the 1992 regulations, the SPC Dartos application being submitted under the 2005 regulations. The LPC believe that North Lincolnshire PCT acted correctly in considering the WestLee application before the SPC Dartos one. The LPC did have cause for concern relating to the time taken to process these applications, however, since this has not been raised by either of the applicants it is not relevant at this time.

Lincolnshire Co-operative Ltd

- 4.73 The Cliff Villages practice states its astonishment that the PCT indicated "no evidence was received to demonstrate that the existing provision of general medical or pharmaceutical services would be prejudiced". As the Appeal Unit will be well aware, the burden of proof in such a case falls on those alleging the prejudice, in this case the providers of general medical services. The prejudice must be to baseline services required by NHS terms of service and not to additional or enhanced services. The Appeal Unit will also be aware that the provision of medical services should not be underpinned by pharmaceutical services.
- 4.74 The Cliff Villages practice also mentions the loss of dispensing income at Waddington (October 2005) and adds this to the proposed loss of income at Navenby. The Waddington situation is a completely separate matter and should not be a factor when considering the applications within Navenby.
- 4.75 The West Lincolnshire PCT decision quite correctly indicated that the patient population and defined neighbourhood would not support the need for two pharmacies and that the Westlee Ltd application was submitted first.

- 4.76 The SPC Dartos appeal letter states that they propose to site their pharmacy “highly conveniently for the local population”. Their identified edge of village location for the surgery and proposed pharmacy will clearly not be convenient for all patients and a central location for pharmaceutical services would be more appropriate. There does not appear to be any evidence for the SPC Dartos claim that their pharmacy “would benefit far more from local support”.

Lincolnshire Local Medical Committee

- 4.77 The LMC was surprised by the decision of West Lincs PCT (taken in fact by North Lincs PCT) that there was no prejudice to the proper provision of medical services in these applications. If either application were to be granted, the consequent reduction in practice income, coming as it does on the back of the reduction already suffered last year through the loss of dispensing services at Waddington will seriously threaten the provision of medical services in Navenby.
- 4.78 Despite the Department of Health's intention that dispensing should not subsidise rural practice, small rural practices with split sites, such as Dr Broughton and Partners, are still reliant on the income generated by dispensing to provide the basics of general medical services.
- 4.79 The LMC is seriously concerned that, despite the declared intention of the practice to continue providing a much reduced service at Navenby, it will prove to be financially non-viable to do so and the service will have to be withdrawn altogether. The population of Navenby has grown, but is still at or below the limit of viability as far as a pharmacy is concerned and the prospect of further population growth is, the LMC understand, now limited.
- 4.80 It is the LMC's contention that there will be prejudice to the proper provision of medical services and the applications should be rejected.

Unsolicited comments were received from Mrs J O'Conner

- 4.81 Mrs O'Conner has heard from fellow neighbours of the outcome concerning the pharmacy which it been had hoped would be in the new surgery that is to be built on the outskirts of Navenby. As a W.I. member Mrs O'Conner and many of her colleges had made it quite clear for various reasons why the pharmacy should be retained not just for the elderly but also for the young mothers taking a sick child to the surgery only to find they have to go down into the village and wait for a prescription to be issued when it would be much easier to pick it up as they come from seeing the GP in the surgery.
- 4.82 There will now be added unnecessary stress to a child as mothers will have to make a further journey back into the village. Mrs O'Conner has heard from members that the Waddington Pharmacy isn't going down too well with the community as half the time things are not in and they have to make another journey at some point in the day or the next depending on what is required. Mrs O'Conner herself went to purchase some extra strong soluble aspro only to find they could get them in the evening and she was to return at 6pm. Why when something is working so well one has to change things. This meeting was done behind closed doors and patients had no say in the matter. Mrs O'Conner thinks a grave mistake has been made here and hopes at some point it will prove itself in the not too distant future.

Further comments

D R Sceats (on behalf of SPC Dartos Ltd (Applicant/Appellant))

- 4.83 D R Sceats refer to the detailed submissions of Messrs Beachcroft on behalf of West Lincolnshire PCT Ltd, identifying the relevant numbered paragraphs in brackets. Many other items, some in the letter of WestLee enclosed by the Appeal Unit, are

contested, but for the sake of brevity D R Sceats will restrict themselves to a few points.

- 4.84 Concerning the procedure adopted by the West Lincolnshire Primary Care Trust for considering the matter, a number of difficulties arise. It cannot be the case that “the applications were considered on their merits alone”. It seems inescapable that by deciding first upon the application of WestLee rather than considering the two applications together and comparing them, the deciding body was precluded from considering the merits of the application of SPC Dartos Ltd, as it was at once considered that there would be insufficient business for the two applications to be allowed.
- 4.85 It is not accepted that the application of the 1992 and the 2005 Regulations precluded the two applications being considered together, and by failing to consider itself - as opposed to relying upon a direction from the Department of Health - as to whether it should consider the two together in the interests of the community to be served, the deciding body did not consider the matter properly or fully.
- 4.86 Had the deciding body been prepared to consider the two applications together, factors such as the centrality of D R Sceats client's proposed site for the relevant neighbourhood and the voiced interests of the population could have been in issue, to the enhancement of the decision taking process.
- 4.87 It is not accepted that it was lawful for the West Lincolnshire PCT to delegate the decision in this matter to another. Messrs Beachcroft say that there is no provision in the Regulations (they say the 2005 Regulations but presumably they wish to refer as well to those of 1992) precluding delegation but D R Sceats say this is not the law (the starting principle being 'delegatus non potest delegare'), and that in the absence of authority for delegation, the decision at first instance was fundamentally flawed.
- 4.88 Further, the extent of such delegation is obscure. Mssrs Beachcroft appear to say that the decision making was split between the two PCTs although they also refer to delegation. It is submitted however that in effect there was full delegation, the decision of the North Lincolnshire PCT being summarily accepted.
- 4.89 There are numerous other aspects of the decision making process at first instance giving cause for concern. Correspondence from patients to the West Lincolnshire PCT was disregarded on the purported ground that it was addressed to the wrong deciding body and the procedures adopted in other ways prevented full representations from being made.
- 4.90 It is to be noted that it is accepted that two officers of West Lincolnshire PCT had financial interests in the successful applicant. Indeed D R Sceats client believes that the handwriting on the application of WestLee Ltd is that of the then chairman of the PCT's Professional Executive Committee. The PCT has expressed the view in correspondence to Messrs. Hempsons, that probably the officers had no access to relevant confidential information, but D R Sceats client remains deeply apprehensive and concerned about this question and almost every aspect of the making and the processing of the application of WestLee. It remains strongly arguable that on the ground alone of the financial interest of the PCT's officers, the decision at first instance was fundamentally flawed, being in breach of natural justice, and an appeal by way of a full rehearing should in any event occur.
- 4.91 D R Sceats submit such appeal should only occur after the matter of prejudice has been resolved, and if then required, should then involve the two applications being considered together and compared.

D R Sceats (on behalf of Cliff Villages Medical Practice - Appellant)

- 4.92 D R Sceats think it might still be helpful to the Pharmacy Appeals Committee if on behalf of their client the Cliff Village Medical Practice they attempt to summarise the case as to prejudice, especially in view of the very detailed submissions of Messrs Beachcroft on behalf of West Lincolnshire Primary Care Trust.
- 4.93 Their extensive comments are themselves indicative of the complexity of this matter. D R Sceats wonder in passing whether their client can technically be regarded as Respondent to this appeal when, having discharged its duties at first instance, the matter now comes before the Litigation Authority and it is WestLee Ltd which in practical terms challenges the appeal. But the Beachcroft submission, reiterating at length the basis for the decision now the subject of appeal, raises a number of points with which the Medical Practice must be concerned and if D R Sceats may, they will refer to these.
- 4.94 It is accepted that there is a distinction to be made between a prejudice to services as a result of financial prejudice and financial prejudice to the surgery. D R Sceats client's case is that the latter leads very naturally to the former. They say that their business facing a very large fall in income will institute an early curtailment of some contractual services, diminish others (e.g. by reducing hours of availability to patients), and its long term viability, (evidenced by recent recruitment attempts), will be in jeopardy .
- 4.95 It is also accepted that support of D R Sceats client's contentions by means of certified management accounts may be required. It is not however usual for a decision maker at first instance to require such information, and it is no doubt for such reasons that the Regulations provide for a full appeal mechanism by the Litigation Authority.
- 4.96 The contention that for prejudice to be established net profitability must be shown to be reduced to a figure identical to a national average is certainly not accepted. The evidential burden on the Practice is rather to show that deprived of the cross subsidy of dispensing income, it would be reasonable for them in all the circumstances to make such changes to the provision of medical services as would change their contractual provision (so changing in effect their terms of service). The dramatic fall in projected dispensing income is itself prima facie evidence of this.
- 4.97 Nothing currently turns on the current plans of the practice for enlarged premises at Navenby.
- 4.98 D R Sceats clients naturally consider all options. Similarly it is no secret that SPC Dartos Ltd is their vehicle and that company's application for inclusion in the pharmaceutical list is by way of a fall back should this appeal fail but in itself it is no indication that D R Sceats clients accept their practice will have a long term viability if this appeal fails.
- 4.99 Concerning procedural matters, these are mainly addressed in a letter D R Sceats are submitting on behalf of SPC Dartos, but so far as the Practice is concerned, it should be noted that the participation of officers of the PCT in the rival pharmaceutical application of WestLee, and the uncertain nature of the delegation of the decision to another PCT at the very least has given general cause for great concern. At the very least this suggests it would be inappropriate for this appeal to be dealt with only on the papers and an opportunity should be given to the Practice to put its case in person and with the detailed financial information normal in such matters.

WestLee Ltd (Applicant)

- 4.100 WestLee Ltd understood the time limit for written responses to the appeal arrangements was 11 August. The two letters from the appellants solicitors, D R Sceats, were both dated 18 August 2006 and received by yourselves on 22/8/06. Is

the substance of either letter to be considered and if so on what basis? If they are to be considered then WestLee Ltd would wish this response to be considered also.

- 4.101 WestLee Ltd are somewhat concerned that a decision has been made to “consider the applications together, and in relation to one another”. WestLee Ltd understand that the appeal is against the decision of West Lincolnshire PCT to grant the application of WestLee Ltd for the Navenby location. WestLee Ltd understood that the appeal process was for issues of procedure rather than a vehicle for completely rehearing applications. WestLee Ltd did not understand it to be a rehearing of the SPC Dartos application. WestLee Ltd also are concerned that if both applications are to be reheard that they are to be considered together. WestLee Ltd’s application, as stated previously, was submitted under the 1992 regulations several months prior to the submission of the SPC Dartos application under the 2005 regulations. There are completely different priorities, criteria for consideration and timescales for the different regulatory regimes and WestLee Ltd do not see how they can be considered under the same assessment criteria. Under which regulations will the appeal/s be considered?
- 4.102 If it is the Appeal Unit’s decision to rehear both applications then it is WestLee Ltd’s belief that the SPC Dartos application is invalid as it does not meet the necessary requirements of an application under either the requirements of West Lincolnshire PCT’s application process or the 2005 regulations i.e there is no superintendent pharmacist (or indeed any other pharmacist) named on the application form thus making it impossible to ascertain said pharmacist’s suitability or fitness to practice as superintendent.
- 4.103 To date WestLee Ltd have based their submissions during the application and appeals processes on the purely technical and regulatory requirements of the process. WestLee Ltd are concerned that repeated defamatory comments are being made by the appellants questioning the integrity and probity of the WestLee application.
- 4.104 There is no restriction under any regulation to an officer of a PCT applying to set up a pharmacy. Despite repeated comments by the appellants solicitors they have produced no evidence whatsoever that any officer of the PCT connected with the WestLee application has had access to any confidential information that may be somehow inappropriate related to the application, no evidence that any information held by the PCT would have any bearing on the success or otherwise of any application and no evidence of any capacity for or attempt at undue influence on the application process. WestLee Ltd would wish to strongly refute any suggestion of undue influence on process. At no stage has any person connected to the WestLee application had access to confidential information that might affect an application. WestLee Ltd understand that prescribing information related to practices is only accessible by authorised members of the PCT prescribing team who have personal passwords/access codes. Jo West has never been a member of the West Lincolnshire PCT prescribing team and has at no stage had either the authority or means to access this information.
- 4.105 Information on the demographics and age banding of patients in the Navenby area is available on the internet from a variety of free and commercial sources.
- 4.106 Assurances on these matters have been given to the appellants on several occasions by the Chief Executive of West Lincolnshire PCT and WestLee Ltd are surprised that the appellants and their legal advisers continue to level these accusations and innuendos. The application stands alone with no information within the application being in any way related to confidential information related to the Navenby practice. Interest in the application by officers of the PCT has been declared at the earliest stage. WestLee Ltd were very happy that assessment of the application was devolved to a PCT that was completely independent of West Lincolnshire and therefore no opportunity was available to influence any decision on the relative merits of any

applications. WestLee are also very happy that the appeal will be heard under due independent regulatory process.

The following comments were made to the PCT in response to notification of the applications :

Cliff Villages Medical Practice (Dr L J Broughton & Partners)

- 4.107 We are writing regarding the applications to provide pharmaceutical services in the village of Navenby and to express our opinion of their prejudiced effect via general medical services in the area.
- 4.108 The opening of a third party owned pharmacy within the village of Navenby would have a catastrophic financial effect on the Practice. In the last month, 40% of the dispensing income has been lost from our Practice due to the opening of a pharmacy in Waddington. We face a potential loss of a further 40% of our dispensing income over the next six months by the opening of a pharmacy in Navenby, especially as being a two centred practice, our service is subsidised by our dispensing income. Our premises at Navenby are woefully inadequate for the extent of services we need to provide. We wish to start building new premises, approved by the PCT board in May 2005, in the very near future. This will allow expansion of our current services but with increased cost to the Practice.
- 4.109 If we lose what will then amount to 80% of our dispensing income, the medical services which we provide already will be severely prejudiced. We shall be unable to offer our current surgery hours at both surgeries.
- 4.110 In the WestLee application, reference has been made to various services 'not currently provided' in the locality. We should wish to challenge this as smoking cessation, minor ailments, advisory service to Care Homes, emergency hormonal contraception and anti-coagulant monitoring are all freely available, free of charge, from the Practice.
- 4.111 There are five Care Homes in our Practice area in which we hold weekly doctors surgeries. (We have five times the National average of care home patients). In addition to regular surgery duties, medication reviews and public health advice are routinely given. These services would be impossible to support in the event of the third party owned pharmacy opening, due to pressure on medical staffing.
- 4.112 Based on the reduction in our overall income, and bearing in mind that remaining practice income would be required to provide medical services over two sites, we feel that the future viability of the Practice would be placed in severe jeopardy as, recently having tried to recruit a further partner (list size 7500 patients, currently 3 partners over 2 sites) the only applicant was unwilling to commit knowing of the pharmacy threat at Waddington. With one partner nearing retirement, we feel that should our income reduce even further, our ability to attract a replacement would be virtually impossible. This, coupled with the prospect of 2 partners serving two sites, would prove unmanageable.
- 4.113 At present the Practice is sustaining a service to both ends of the practice every day. The geographical nature of the practice dictates that premises are required at both ends in order to provide general medical services to all of our patients. As we already fall well below the PCT average in terms of staff costs reimbursement, the subsidy (enabling us to open both of these premises every day) which presently comes from our dispensing income will be virtually 'wiped out'.
- 4.114 The significant and obvious effect of this would be a severe reduction in opening hours outside the essential surgery times. This would restrict the work of our community staff and health visitors who presently reside in a rent-free office within Navenby Surgery.

- 4.115 As a Practice we are extremely keen to pursue new avenues and opportunities in the provision and development of further services for our patients but this would prove simply impossible if a third party owned pharmacy were to open.
- 4.116 We would like, therefore, to state that the opening of a third party owned pharmacy in the village of Navenby would severely affect our ability to provide medical services to our patients. If, however, the Dispensing Committee deems that it is entirely necessary for a pharmacy to be opened then the SPC Dartos Services Ltd., application would be favoured by the doctors, as it would enable the practice to retain income to ensure continuity of service to our patients.
- 4.117 We should like the Committee to take these comments into consideration when examining these applications.

The Committee also noted Cliff Villages Medical Practice' letter to the PCT dated 20 March 2006.

Lincolnshire Local Medical Committee

- 4.118 The LMC foresees great difficulty for the panel in considering these two applications, since the first, from WestLee Ltd is made under the 1992 regulations and the second from SPC Dartos Services is under the 2005 regulations.
- 4.119 We understand that they will be considered on the same day but separately and in date of application order. Since under normal circumstances, both applications would have fallen to be heard together we feel, regardless of the relative merits of each application, the second application is at a severe and unfair disadvantage over the first. We cannot see how the panel can deal with the second application until the first has been finally determined, which by the very nature of the old regulations may take many months. The outcome of the first application will of necessity have a bearing on the determination of the second especially in regard to the competition and choice criteria in Regulation 12(2)(b) of the 2005 Regulations
- 4.120 The LMC hopes that the panel will feel able to deal solely with the prejudice issue in both applications and contends that, more than in any other application dealt with in recent times, prejudice to the provision of medical services under regulation 12 of the 1992 regulations and regulation 18 of the 2005 regulations is self evident and thus neither application should be granted.

Comments on WestLee application

- 4.121 There is little doubt, given the history of recent pharmacy applications affecting the Waddington/Navenby Practice, that a further pharmacy opening in Navenby will create such a significant reduction in the resources available to the practice that the proper provision of general medical services in Navenby will be prejudiced, if this application were to be granted.
- 4.122 The practice has carefully considered all options and has reluctantly determined that then, the only realistic option would be to significantly downsize the provision of services at Navenby. If this occurs, while patients will still be able to access a full range of services at the Waddington site, patients living and attending the Navenby site will see an across the board reduction in services provided there. By definition this will be prejudicial to the services the patients now receive at Navenby.

Comments on the SPC Dartos Services application.

- 4.123 The comments on WestLee above hold true for Dartos, but will be heard using Regulation 18(2)(a) of the 2005 regulations - presuming the population to be served is above the 2750 limit for reserved location status. If the application is in a reserved

location then it is unlikely to proceed further since the pharmacy would be totally unviable.

- 4.124 But when this application is considered, a decision will already have been made or WestLee. If that decision was to not grant WestLee's application then despite the change of regulatory framework, it is the LMC's view that prejudice will be easily proven and the Dartos application should also be rejected. If however, the WestLee application was granted, then no further prejudice is likely to occur to the practice by granting the Dartos application.
- 4.125 The panel's decision would then rest on whether patients would be better served through- competition and choice or by a single provider of pharmaceutical services. It is the LMC's view that a strict reading of Regulation 12 (2005 Regs) gives little choice to the panel but to grant Dartos's application in addition to WestLee.

The Committee also noted the LMC's letter to the PCT dated 3 April 2006.

5 Consideration

- 5.1 The Pharmacy Appeals Committee appointed by the Family Health Services Appeal Unit of the NHS Litigation Authority, ("the Committee") had before it the papers considered by the PCT, together with a plan of the area showing existing pharmacies and doctors' surgeries and the site of the proposed pharmacies.
- 5.2 It also had before it the responses to the Authority's own statutory consultations.
- 5.3 On the basis of this information, the Committee considered it was not necessary to hold an Oral Hearing.

WestLee Ltd application

- 5.4 Navenby is in a controlled locality. As such, the application by WestLee Ltd was made under provision of Regulation 4(1)(a) of the National Health Service (Pharmaceutical Services) Regulations 1992 (as amended) ("the Regulations") and falls to be determined under the provisions of Regulation 12 in view of the provisions of Regulation 11(1). In particular, the Committee noted the provision of Regulation 12(13) which states Subject to regulation 6A (Deferral of consideration of certain applications), the Health Authority or Primary Care Trust shall refuse an application to the extent that it is of the opinion that to grant it would prejudice the proper provision of primary medical services under Part 1 of the Act, dispensing services, local pharmaceutical services or pharmaceutical services in any locality.
- 5.5 Dispensing Services are narrowly defined in the Regulations, although it is not necessary to go into more detail about this for the determination of this appeal.
- 5.6 The Committee was aware of the guidance issued by the Department of Health annexes to HSG(92)13.FPN560 and in particular paragraph 6 on page 37 which states, "*In determining applications in a controlled area, Authorities must apply the test that the proper provision of general medical or pharmaceutical services in any area means that people in that area should have available to them general medical and pharmaceutical services and that those services should be of the standard which GMPs and pharmacists are obliged to provide in order to comply with their respected terms of service. It is that which must be prejudiced if an application is to be rejected. The fact that the granting of an application could lead to a reduction in the level or standard of general medical or pharmaceutical service does not, of itself, constitute prejudice to proper provision*".

- 5.7 This is the test formerly used by the Secretary of State, and now by the Committee in relation to the appeal under the 1992 Regulations.

SPC Dartos Ltd application

- 5.8 The SPC Dartos Ltd application was made under provision of Regulation 5(1)(a) of the National Health Service (Pharmaceutical Services) Regulations 2005 (as amended) (“the Regulations”) taking into account the provisions of Regulations 18ZA and 12.
- 5.9 The Committee noted the PCT’s decision letter dated 26 May 2006. SPC Dartos Ltd had appealed against the PCT’s decision to refuse their own application, and grant that of WestLee Ltd. The Committee was aware SPC Dartos Ltd’s application was not received by the PCT until after 21 June 2005. In accordance with the Regulations, the company was not a party to whom the PCT was required to send a copy of the WestLee Ltd application in accordance with Regulation 12(1) of the 1992 Regulations.
- 5.10 SPC Dartos Ltd in the Committee’s view, had no right of appeal under Regulation 13(1) (1992 Regs) against the PCT’s decision to grant WestLee Ltd’s application. The Committee was not aware of any transitional provisions which would assist SPC Dartos Ltd in lodging their appeal. The Committee was however satisfied that SPC Dartos Ltd were able to appeal the refusal of their own application in accordance with Regulation 38 of the 2005 Pharmaceutical Services Regulations.
- 5.11 In so far as the appeal by Cliff Villages Medical Practice was concerned, the practice was properly invited, and did submit comments to the PCT on WestLee Ltd’s application. The Committee was satisfied therefore, Cliff Villages Medical Practice had the right of appeal in accordance with the 1992 Regulations, but only in respect of the ‘prejudice to proper provision’ test.
- 5.12 The Committee noted SPC Dartos Services Ltd’s appeal raised concerns regarding North Lincolnshire PCT’s involvement in consideration of the applications. In their decision letter on the applications, the PCT’s indicates some delegation during processing of the applications, to North Lincolnshire PCT. The Committee was mindful Regulation 6(2) of the 1992 Regulations and 24(1) of the 2005 Regulations allowed the PCT to consider the applications in such a manner as it thought fit. The Committee was satisfied that the PCT to whom the applications were made, namely West Lincolnshire, had finally determined them following a recommendation from North Lincolnshire PCT. The Committee saw no reason to conclude that West Lincolnshire PCT’s decisions were other than a valid however, if the Committee are wrong in this then there is no jurisdiction for the Committee to quash an individual decision.
- 5.13 The Committee next considered whether as claimed by Cliff Villages Medical Practice and inferred by SPC Dartos Services Ltd (and bearing in mind that the latter’s application could potentially be granted on appeal), there would be prejudice to the proper provision of pharmaceutical and medical services in any locality should one or more of the applications be granted.
- 5.14 The Committee considered the burden of proof in these cases falls on those alleging the prejudice. The Committee noted SPC Dartos Ltd’s appeal against the refusal of their own application, had included that there was a failure by the PCT to consider “extensive evidence” provided by Cliff Villages Medical Practice and the LMC. Cliff Villages Medical Practice had suggested to the PCT and then again on appeal, that the services they provide would be affected to the extent that there would be prejudice to the proper provision of medical services to their patients.

Information provided by both Cliff Villages Medical Practice and the LMC, was said to have demonstrated prejudice to the proper provision of medical services would occur should an application for inclusion in the pharmaceutical list be granted. Cliff Villages

Medical practice foresaw an 80% loss in dispensing income and a total lost income of £930,000 following loss of dispensing income at Waddington. The Committee noted suggestions of a reduction in medical services, staff, the number of surgeries offered at Navenby and renegotiation of a number of services that the practice are contractually required to provide. There was perceived threat to the future recruitment of a replacement partner and the to viability of the practice. However, the Committee was provided with no detailed financial information to substantiate these claims and lead it to conclude services would not be of the standard which a GP Contractor is obliged to provide in order to comply with their respective contract. The Committee was mindful of the judicial guidance that medical services should not be underpinned by pharmaceutical services. The Committee concluded that the burden of proof had not been discharged by Cliff Villages Medical Practice and that prejudice to primary medical services would not occur as a result of this application.

- 5.15 Turning to whether the proposed pharmacy were necessary or desirable to secure the adequate provision of pharmaceutical services, the Committee was mindful that it would be considering the applications afresh, and have regard to the requirements of both the 1992 and 2005 Pharmaceutical Services Regulations.
- 5.16 The Committee noted the PCT had defined the neighbourhood for the applications, as the “the settlements of Navenby, Wellingore and Boothby Graffoe”. The Committee was not aware of the PCT’s reasoning for defining a neighbourhood seemingly composed of three separate communities. Although neighbourhood was not an issue raised on appeal, the Committee considered the neighbourhood should be ‘Navenby village’ without recourse to specific boundaries. Even if the neighbourhood was to be more extensively defined, this would not affect the Committee’s decision on this occasion.
- 5.17 The Committee noted Cliff Villages Medical Practice had no right of appeal in respect of the PCT’s decision to grant WestLee Ltd’s application. The Committee noting that SPC Dartos could only appeal against the refusal of their own application was mindful of the requirements of the necessary or desirable test in both the 1992 and 2005 Regulations.
- 5.18 In the Committee’s view it is reasonable that an earlier application made under an earlier and now replaced regulations, should be considered before a later one. Given the Committees view that SPC Dartos Ltd had no right of appeal against the PCT’s decision to grant the WestLee Ltd application under the 1992 regulations, the only matter for consideration was whether a second pharmacy should be granted to secure adequate provision of services.
- 5.19 The Committee considered SPC Dartos appeal against a background that an application made under the 1992 Regulations (WestLee Ltd) had been granted by the PCT as being both necessary and desirable to secure the adequate provision of services. On appeal, the Committee has decided that there would be no prejudice to the proper provision of medical or pharmaceutical services in any locality. The question was therefore, whether the SPC Dartos Ltd application should, taking into account Regulations 12(1) to (4) of the 2005 Regulations, be granted to secure the adequate provision of pharmaceutical services in the neighbourhood. The Committee had no information to demonstrate that a second pharmacy was needed and therefore determined to refuse the application.
- 5.20 The Committee noted Regulation (13)(13) of the 1992 Regulations states :
- On an appeal under this regulation, the Secretary of State -
- (a) may allow the appeal;
 - (b) may, in a case where the Health Authority or Primary Care Trust, on determining the application, considered the question whether to impose conditions to postpone the making or termination of arrangements under regulation 20 for the provision by a doctor of pharmaceutical

- services to his patients, himself impose conditions to postpone for such period as he thinks fit, the making or termination of such arrangements;
- (c) shall, in a case where that question was not considered by the Health Authority or Primary Care Trust when it determined the application, remit the question to the Health Authority or Primary Care Trust for determination;
 - (d) shall, where he allows an appeal against a refusal of the Health Authority or Primary Care Trust as mentioned in paragraph (1)(b), remit the application to the Health Authority or Primary Care Trust and direct that regulation 12(17) shall not apply; or
 - (e) may dismiss the appeal.

6 **Decision**

The Committee has:

- 6.1 Dismissed Cliff Villages Medical Practice's appeal (prejudice test).
- 6.2 Refused SPC Dartos appeal in respect of their own application.

Given that the "question" was not considered by the PCT the Committee now considered the requirement of regulation 13(13)(c). The committee agreed to remit the question to the PCT for determination of that matter.

Ray Bushell Appeal Officer

A copy of this decision is being sent to:

Dr L J Broughton, Cliff Village Medical Practice – Appellant
 Mr J G McLoughlin, SPC Dartos Services Ltd – Applicant/Appellant
 copy to Mr D R Sceats
 Ms E S West, WestLee Ltd – Applicant
 Ms A McDermott – Lincs LPC
 Ms J Gardner, Beachcroft LLP (on behalf of the PCT)
 Mr A Farquhar – Lincolnshire Co-operative Ltd
 Dr P Twomey – Lincs LMC
 Mrs J O'Connor