Dermatologist, Dr B

A Skin Cancer Detection Company

A Report by the

Health and Disability Commissioner

(Case 11HDC00700)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

Background

1. On 2 August 2003, Mr A had a melanoma removed from his left arm. Between 2003 and 2010, Mr A had numerous skin checks conducted at a dermatology clinic in conjunction with regular consultations with his GP, Dr C.

2. Dr B was the dermatologist responsible for assessing Mr A's images and reporting whether there were any moles or lesions exhibiting suspicious malignant change. Between 2003 and 2009, Dr B reported that Mr A had no lesions or moles of concern.

3. On 23 June 2009, Mr A attended a skin check. The melanographer noted concerns in relation to a lesion on Mr A's right forearm and asked the diagnosing dermatologist for specific comments. Dr B assessed Mr A's images, including the lesion on his right forearm, and reported that there were no lesions or moles of concern.

4. In 2010, Mr A had another skin check. The melanographer again noted concerns about the lesion on Mr A's right forearm and also noted concerns in relation to a lesion on his right shoulder. Dr B assessed Mr A's images and reported that the lesion on Mr A's right forearm was a possible melanoma which should be excised. Dr B assessed the lesion on Mr A's right shoulder as benign but recommended that Mr A continue to monitor the lesion and to contact his GP if there was any change or continuing concern.

5. The lesion on Mr A's right forearm was excised and confirmed to be a malignant melanoma. The lesion on Mr A's right shoulder was excised the following year and was confirmed to be an early stage melanoma. Sadly, Mr A died from metastatic cancer.

Decision summary

6. Dr B failed to provide Mr A with services with reasonable care and skill by failing to identify the dermatoscopic changes to the lesion on Mr A's right forearm, which should have been apparent from as early as 2003. Accordingly, Dr B breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).

7. Dr B also breached Right 4(1) of the Code by failing to recommend excision of suspicious lesions on Mr A's chest and right shoulder.

8. The skin cancer detection company (the Company) took reasonable steps to assure itself that Dr B was meeting quality standards. Its audit programme indicated no concerns about Dr B's clinical competency, and a review of Dr B's false negative rate confirmed that Mr A's case was an aberration from Dr B's usually very accurate readings of images. While my expert advisor identified a number of areas where the Company could improve its programme and systems, I have received no evidence that the systems in place at the time were materially deficient. Accordingly, the Company did not directly or vicariously breach the Code.

Complaint and investigation

9. The Commissioner received a complaint from Mr A about the services provided to him by a dermatologist, Dr B, and a skin cancer detection company. The following issues were identified for investigation:

- *Whether Dr B provided Mr A with an appropriate standard of care from December 2003 to October 2010.*
- *Whether the skin cancer detection company provided Mr A with an appropriate standard of care from December 2003 to October 2010.*

10. An investigation was commenced on 17 January 2012.

11. Information was reviewed from the following parties who were directly involved in the investigation:

Mr A (now deceased)	Consumer/complainant
Dr B	Dermatologist/provider
The Company	Skin cancer detection company/provider

12. Information was also reviewed from:

Dr C	General practitioner/provider

Also mentioned in this report:
A medical centre
A dermatology clinic

13. Independent expert advice was obtained from a dermatologist, Dr John Sippe, and is attached as **Appendix A**.

Information gathered during investigation

The skin cancer detection company

14. The Company designed a skin cancer detection system (the System), which is diagnostic technology designed to help identify melanoma[1] and other skin cancers at an early stage. The Company licences the System to a number of health care providers, one of which is the dermatology clinic.

15. At a patient's first consultation at a clinic that utilises the System, a melanographer[2] takes a series of photographs of the patient's body to create a baseline of his or her

[1] Melanoma is the most serious form of skin cancer, being responsible for about three-quarters of all skin cancer-related deaths: see www.aafp.org/afp/20000715/357.html.
[2] A nurse trained in skin cancer and dermoscopic imaging.

skin and mole[3] locations. Each significant mole or lesion[4] is then digitally imaged. The individual images of the lesions are called "dermoscopic (micro) images", which are obtained using a digital camera fitted with a magnifying lens equipped with a cross-polarised light source. Any relevant data about the lesion, such as an apparent change, itchiness, tenderness or general patient concern is recorded by the melanographer alongside each imaged lesion.

16. The images and associated data are then sent electronically to a dermatologist who has been contracted by the Company to review the images and produce a report. The dermatologist's report identifies any moles or lesions of concern and makes recommendations as to the appropriate management. The dermatologist's report is then sent to the patient and his or her general practitioner (GP). If the dermatologist recommends further procedures, patients are advised to discuss and coordinate these with their GP or medical specialist. Patients who have had a melanoma excised are advised to have regular skin checks to detect any recurrences or new suspicious lesions at an early stage. Upon completion of this process, the patient's images and data are then permanently stored in a secure database for future mole or lesion comparisons. Each time the patient presents for a consultation, those images are made available to the contracted dermatologist. The Company advised HDC that a "key feature" of the System is that the "history of the dermoscopic images appears as a ribbon along the bottom [of the diagnosing screen]. This is used as a quick assessment of any changes that may have occurred."

17. The Company advised HDC that it requires all contracted dermatologists to provide it with evidence that they are maintaining their competency through continuing medical education. It advised:

> "[The Company] aims to provide excellent service to patients and achieve optimal health outcomes by constantly reviewing, assessing and monitoring its work. This is achieved through formal performance management processes, ongoing reviews, regular meetings with peers and managers, and liaison with world experts operating in our field."

Mr A — melanoma history

18. On 2 August 2003, Mr A had skin lesions removed from his left arm and shoulder by his GP, Dr C, at a medical centre. The lesion from Mr A's left arm was reported to be a melanoma. It had a Breslow depth of 1.3mm,[5] Clark's level three,[6] and a mitotic rate

[3] A non-malignant collection of pigmented cells in the skin.
[4] A lesion is a zone of tissue with impaired function as a result of damage by disease or wounding.
[5] Breslow depth is the depth to which the melanoma cells have grown into the skin. Generally speaking, the deeper the melanoma the worse the prognosis. The average five-year survival rate for melanomas with a Breslow depth of less then 1mm is 95–100%, 1–2mm is 80–96%, 2.1–4mm is 60–75%, greater than 4mm is 37–50%.
[6] Clark's level refers to how deep the tumour has penetrated into the layers of the skin. Level I: confined to the epidermis (top-most layer of skin); called "in situ" melanoma; Level II: invasion of the papillary (upper) dermis; Level III: filling of the papillary dermis but no extension into the reticular (lower) dermis; Level IV: invasion of the reticular dermis; Level V: invasion of the deep subcutaneous tissue.

of six mitoses in ten high power fields.[7] The lesion was reported to have no malignancy present.

19. On 18 August 2003, Mr A underwent surgery to excise a wider area of tissue around the site of the lesion on his left arm, and a sentinel lymph node biopsy (SLNB) was also performed.[8] The SLNB confirmed that the cancer had not spread to nearby lymph nodes or other organs.

20. On 18 November 2003, Mr A had images taken for the first time at the dermatology clinic. His history of melanoma was noted in his record. Mr A had subsequent images taken on 19 November 2004, 21 March 2006, 21 April 2007, 23 June 2009 and 23 September 2010. On each occasion, Dr B was the dermatologist responsible for assessing Mr A's images.

Dermatologist Dr B

21. During the relevant time, Dr B was contracted by the Company to review and report on images.

22. Dr B told HDC that he generally reviews images of 20 to 30 patients each day using the System but sometimes he may have to diagnose more than 100 patients a day. Dr B told HDC that the total number of lesions to be reviewed for each patient varies. In most cases, a patient will have 20 to 30 lesions but it can be as many as 150 lesions or more. Dr B stated that as well as reviewing each individual lesion, he also reviews the patient's "macro images and body shots". Dr B advised HDC:

> "I examine the images for each individual lesion one at a time. I am able to compare current and older images taken of the same lesion. I consider the history and comments and render an opinion and management recommendations on each lesion. If the lesion is thought to be benign no specific comments are required from me. I scroll through to the next lesion and repeat the process for the next lesion. After examining all the patient's lesions a final report is prepared and then sent to the patient's doctor and to the patient."

Mr A's skin checks — 2003 to 2010

GP consultations

23. Between 2003 and 2010, Mr A had skin checks at the dermatology clinic in conjunction with regular consultations with Dr C.[9] Between June 2004 and September

[7] The mitotic rate is a measure of how fast cancer cells are dividing and growing. To measure this, the pathologist counts the number of cells that are in the process of dividing (mitosis) in a certain amount of melanoma tissue. A high power field refers to the area that is visible under the maximum magnification power of the objective being used.

[8] A sentinel lymph node is the first lymph node(s) to which cancer cells are most likely to spread from a primary tumour. A sentinel lymph node biopsy can be used to help diagnose the extent, or stage, of cancer in the body.

[9] My in-house clinical advisor, Dr David Maplesden, advised that Dr C's clinical documentation demonstrates that he was conscientious in his monitoring of Mr A's skin. Dr Maplesden stated that it was reasonable for Dr C to be reassured by the reports, and Dr Maplesden would not have expected Dr C to review, or ask for a review of, the specialist dermoscopic reporting, unless there was a high degree of clinical suspicion for malignancy pre-dermoscopy. Dr Maplesden advised that it was reasonable for

2010, Dr C recorded 13 instances where he used liquid nitrogen to treat Mr A's actinic keratoses.[10] In addition to this, between August 2003 and April 2011, Dr C recorded 15 occasions where he performed a punch biopsy[11] or excision biopsy[12] of suspicious skin lesions on Mr A. All lesions that were excised were confirmed on histology[13] to be either basal cell carcinoma,[14] actinic keratosis,[15] or squamous cell carcinoma.[16]

Skin checks

24. Dr B reported that there were no lesions or moles of concern after Mr A's appointments of 19 November 2004, 21 March 2006, 21 April 2007, and 23 June 2009. Dr B did, however, note on 5 April 2006 and 1 May 2007 that Mr A's risk of developing melanoma was "Very High".

25. After each skin check, Mr A received a report that contained the following advice:

"
- Repeat [a skin check] at the recommended interval unless you become concerned about any new or changing moles in which case it is very important that you contact your doctor or [the Company] immediately.
- Annual clinical examination by your doctor or dermatologist.
- Monthly self-check to monitor for new or changing moles.
- Ongoing sun protection as covered in our brochure and on our website.
- [The System] is **not** a complete substitute for clinical examination. [It] provides an archive of the lesions selected for digital imaging and as such it is a useful diagnostic aid.
- Regular follow-ups are an important part of [the System] as the System aids in the identification of changes to your moles over time. A new or changing mole can be an early indicator of the development of melanoma.
- It is very important that the action plan and recommendations are followed or discussed with your doctor.
- If you, or your doctor, seek further clarification on anything in this report, please feel free to call [us]."

Dr C to assume that the lesion on Mr A's right forearm did not require active management until macroscopic changes were evidently noted by Mr A in September 2010. Dr Maplesden therefore concluded that Dr C's management of Mr A's right forearm was consistent with expected standards. I note that "macroscopic changes" refers to changes that are observable by the naked eye. This can be contrasted with "dermoscopic or dermatoscopic changes", which are observable through a microscope.

[10] Thick, scaly, or crusty patches of skin caused by sunlight; actinic keratoses may progress to a non-melanoma form of skin cancer if left untreated.

[11] A biopsy is the removal of living tissue from an organ or part of the body for microscopic examination. A punch biopsy is usually used for deep skin lesions or spots.

[12] An excision biopsy is the removal of the entire skin lesion.

[13] Histology is the study of the structure of tissues by examination under a microscope.

[14] A type of non-melanoma skin cancer.

[15] Lesions caused by damage from the sun's ultraviolet rays. Untreated actinic keratosis can advance to squamous cell carcinoma.

[16] A type of non-melanoma skin cancer.

Skin checks — 2009 to 2010

26. Mr A told HDC that, in 2009, Dr C expressed concern about a lesion on Mr A's right forearm. Dr C does not recall this and there is no record in the clinical documentation that such a concern was expressed.

27. On 23 June 2009, Mr A had an image taken of a lesion on his right forearm. Next to that image, the melanographer noted in a red box:

> "PHx size, shape change. MDx patient requires specific comment. Lesion appears bigger than 2007 [image]. Asymptomatic. Pt unaware of any changes."

Dr B assessed Mr A's images, including the lesion on his right forearm, and reported that there were no lesions or moles of concern.

28. On 22 September 2010, Mr A consulted Dr C for a skin check. Dr C noted in Mr A's clinical record: "[Irregular] lesions [right] shoulder and [right] forearm. Has [skin check] booked tomorrow. Await result of [skin check]."

29. Dr C advised HDC that he recalls looking at Mr A's forearm lesion and thinking it was "borderline" suspicious, so asked Mr A to mention this, and the irregular lesion on his right shoulder, to the melanographer at his next skin check appointment.

30. On 23 September 2010, Mr A had a skin check. The melanographer noted the following in a pop-up box headed "Melanographer concern" in relation to the lesion on Mr A's right forearm:

> "PHx colour change, PHx Size, shape change, MDx suspicious dermoscopy.[17] Lesion grown, GP concern ?blue/grey veil. Note: A diagnosis is required for this lesion."

31. In relation to a lesion on Mr A's right shoulder, the melanographer noted the following in a pop-up box headed "Melanographer concern":

> "A diagnosis is required due to:
>
> - Doctor concern
> - Patient concern
> - PHx unknown when appeared."

32. Dr B assessed Mr A's images and reported that the lesion on Mr A's right forearm was a possible melanoma and recommended excision of the lesion. Dr B assessed the lesion on Mr A's right shoulder as benign. Dr B recommended that Mr A continue to monitor the lesion but that if there was any change or continuing concern, Mr A should contact his GP.

[17] Dermoscopy or dermatoscopy refers to the examination of the skin using skin surface microscopy. It is used to evaluate pigmented skin lesions to assist in the diagnosis of melanoma.

Diagnosis of metastatic melanoma

33. On 13 October 2010, Dr C removed the lesion from Mr A's right forearm. The histology report confirmed that the lesion was a malignant melanoma with a Breslow depth of 0.65mm, a Clark's level of four, and a mitotic rate of zero. An absence of ulceration[18] was also noted. Dr C referred Mr A to a general surgeon for a wide re-excision of the lesion, and this was done on 29 October 2010.

34. In November 2010, Mr A suffered a stroke. A computed tomography (CT)[19] scan revealed that Mr A had two brain tumours. A further CT scan confirmed that he also had a lung tumour. The tumours were subsequently confirmed to be metastatic melanoma.[20] Mr A commenced radiotherapy.

35. On 24 March 2011, Dr C excised a lesion on Mr A's right shoulder. The histological diagnosis was that of melanoma in situ.[21] Neither Dr C nor Dr B could confirm to HDC if this was the same lesion that was flagged in 2010 as being of concern to Dr C, Mr A and the melanographer, but was assessed as benign by Dr B.

Mr A's complaint to HDC

36. Mr A complained to HDC about the management of his skin lesions and enclosed a report by an oncologist. Mr A was particularly concerned about Dr B's delay in recommending excision of the skin lesion on Mr A's right forearm. Mr A also raised concerns about the Company's quality assurance systems and marketing claims. Mr A queried how common misdiagnosis is and whether the misdiagnosis by Dr B was illustrative of a systemic problem at the Company.

37. During the course of HDC's investigation into Mr A's complaint, HDC's expert advisor identified a lesion on Mr A's chest to be of concern. This lesion was not identified by Dr B to be of concern, nor did he make any specific comments about the lesion between 2003 and 2010.

38. Sadly, Mr A later died.

Dr B's response to the complaint

39. Dr B offered his "sincere regret and apology" for missing the melanoma diagnosis on Mr A's right forearm. Dr B told HDC that after Mr A's diagnosis, he reviewed Mr A's films and accepted that he made an error in not picking up the changes to the lesion on Mr A's right forearm earlier. Dr B told HDC that:

> "[t]here were changes in the mole on [Mr A's] right arm that were suspicious and should have been picked up earlier, particularly from 2006. Somehow I failed to

[18] Ulceration is a breakdown of the skin over the melanoma.
[19] A medical imaging procedure that uses computer-processed X-rays to produce cross-sectional images of specific areas of the body.
[20] Metastatic melanoma, also known as Stage IV melanoma, is the general term for the spreading of melanoma into the lymph nodes and/or other parts of the body. Most often, the liver, lungs and brain become affected.
[21] Melanoma in situ is the very earliest stage of melanoma, affecting only the top layer of skin.

> see these changes or was not consciously aware of them. I do not deny that I made an error in [Mr A's] case."

40. While acknowledging his error, Dr B told HDC that he does not consider his standard of care to be "outside of accepted practice for the most competent and experienced of medical colleagues", noting that "false negatives are a recognised and accepted phenomena about which there is very little that can be done". Dr B added that "no diagnostic procedure will ever be 100% because it is well accepted in the profession that even in the best of hands and in the best of circumstances missed diagnoses unfortunately will occur". Dr B stated to HDC:

> "I do make every attempt to be focussed and maintain the highest level of care. It is, however, tiring work and it is difficult at times to maintain complete focus and I believe a degree of diagnostic fatigue can set in. Diagnostic fatigue is recognised in other fields of medical imaging, especially radiology and pathology.[22]"

41. Dr B told HDC that his personal rate of misdiagnosis is "exceptionally low". Information supplied by the Company shows that from the period of 1 January 2007 to 31 December 2011, Dr B was the reporting dermoscopist in 36,669 cases, reviewing a total of 675,153 lesions. Of these, he diagnosed 1,123 melanomas and missed 20 skin cancers (14 of which were melanoma skin cancers and 6 were non-melanoma skin cancers). Dr B told HDC that in each instance where he has missed a melanoma diagnosis, he has reviewed the images and, in all cases except for Mr A's, the lesions have not been obviously malignant by dermoscopy.

42. Dr B told HDC that since this complaint, he has carefully reviewed his practice. He now ensures that he does not spend longer than one hour at a time looking at images on the screen, and that he is uninterrupted during that time.

The Company's response to the complaint

43. The Company responded to Mr A's concern about whether misdiagnosis was a systemic problem. The Company told HDC that "[i]t does not accept that the use of [the System] as a diagnostic tool with regard to [Mr A's] malignant melanoma contributed in any way to the alleged misdiagnosis by [Dr B]".

44. The Company told HDC that its services and technology have been designed to assist in the early detection of skin cancer, but "diagnosis of malignant melanoma is by no means an exact science", and it is "at pains to emphasise to all patients that its process is not 100% accurate and rather this process is a tool to be used to help in the

[22] Fatigue has been documented as a source of medical errors. It has been recognised that the specialty of Radiology is particularly susceptible to "technology-induced fatigue", as the majority of a radiologist's time is spent viewing images on a computer, resulting in eye strain and visual fatigue. Radiologist eye strain and visual fatigue has been shown to adversely affect productivity and diagnostic accuracy by contributing to perceptual errors, performance errors, decreased reaction time, and burn-out. "Decision fatigue" has also been reported in instances of continuous and prolonged decision-making. In these circumstances, the brain responds by taking short-cuts to ease mental strain, which in turn leads to poor and/or inaccurate decisions being made. Reiner, B, Krupinkski, E, "The Insidious Problem of Fatigue in Medical Imaging Practice", *Journal of Digital Imaging*. February 2012, Vol. 25, Issue 1, pp 3–6 (accessed on 6 November 2012 from http://link.springer.com/article/10.1007).

monitoring of pigmented lesions and the diagnosis of melanoma". The Company told HDC that the following information is given to patients at the time of their consultation and in the report that is sent to the patient:

> "No melanoma surveillance programme can claim to be 100% accurate and as such [the skin check] is not a complete substitute for a clinical examination. It is therefore important to continue seeing your doctor or specialist for regular skin checks especially if you are at high risk of developing melanoma."

45. The Company advised HDC that it has adequate quality assurance systems, as demonstrated by the following:

> "
> - All clinical staff are formally reviewed by the Clinical Manager on an annual basis and areas for improvement are identified and an action plan is developed to address these;
> - Random audits of patient files are carried out by the Clinical Manager and the CEO to assess image quality and adherence to procedures and guidelines. Feedback is given when necessary;
> - The standard procedure for reported misdiagnoses is to open an adverse event case and assess the seriousness of the case. If appropriate, permission is sought from the patient to request further opinions from other determatologists consulting for [the Company] in New Zealand and Australia. These opinions are provided as feedback to the diagnosing dermatologist. The feedback from these opinions also provides management with the opportunity to assess any areas where improvements can be made;
> - Dermatologists regularly circulate interesting or difficult lesions for comments or for information to other members of the panel; and
> - The Board reviews adverse events at each Board meeting and directs management accordingly; and
> - It makes 50 outbound telephone calls each day to existing patients, which is an opportunity for patients to notify [the Company] of any misdiagnoses."

46. The Company told HDC that, prior to 2007, it did not formally review the performance of its dermatologists as it understood that it was not usual practice for dermatologists to have their practice audited. However, it has carried out audits into various aspects of its dermatologists' practice in 2007, 2008, 2009 and 2010. The Company told HDC that these audits allowed it to assess the performance of its contracted dermatologists relative to their peers, and no significant performance concerns were identified as a result.

47. The Company told HDC that it requires all its contracted dermatologists to provide it with evidence that they are maintaining their competency through continuing medical education. There is also ongoing informal review and discussion between dermatologists about complaints, adverse events and interesting or difficult diagnostic cases. The Company also told HDC that in 2010, the New Zealand Dermatological

Society carried out an audit of all New Zealand dermatologists, and the Company was informed that its contracted dermatologists generally performed above average.

Changes made since complaint

48. In light of Mr A's complaint, the Company sought advice from one of its own dermatologists. My independent expert dermatologist, Dr John Sippe, also reviewed the complaint. Both reviews resulted in the Company implementing changes to its service (see **Appendix B**). The Company advised HDC that in addition to these changes, it has also made the following changes to the System:

- A patient's melanoma history is clearly indicated on every screen.
- It is easier for its contracted dermatologists to go back and review any lesion after all the lesions have been reviewed.
- A facility has been added to measure a lesion for diameter and area to assist in determining the significance of change.
- The overview screen is the default screen. This will ensure that the patient's history is always displayed for follow-up.
- Patient reports are being made available on an electronic portal. This will:
  - provide faster turnaround for the receipt of results;
  - have the facility for patients to post comments on the overall satisfaction of the System and to log any complaints; and
  - provide patients with access to their full electronic file so that they can share this with their doctor.

Opinion: Breach — Dr B

Mr A's melanoma history

49. Mr A's first melanoma was discovered in 2003, and this was known to Dr B when he reviewed Mr A's images in 2003, 2004, 2006, 2007, 2009 and 2010. My expert dermatologist, Dr John Sippe, advised that a previous history of melanoma is a very strong predictor of future melanoma, with the risk being greatest in the first one to two years after the initial diagnosis. Therefore, it was Dr B's responsibility to take particular care when assessing Mr A's moles and lesions during that time.

Failure to diagnose the lesion on Mr A's right forearm

50. Dr B reviewed Mr A's images, which included the lesion on Mr A's right forearm, in 2003, 2004, 2006, 2007 and 2009. On each of these occasions, Dr B determined that there were no lesions or moles of concern, and recommended the standard follow-up action be taken; namely, return for a repeat skin check in 12 months, annual clinical examination; and monthly self-checks to monitor for new or changing moles and lesions.

51. Dr Sippe advised that the lesion on Mr A's right forearm underwent significant dermatoscopic changes[23] from 2003 to 2010 and that, in light of Mr A's history of melanoma, the lesion should have been excised for histological diagnosis as early as 2003.

52. Dr Sippe advised that by 2004, the lesion on Mr A's right forearm showed changes "suspicious of melanoma which were not present in the image of the previous year". Dr Sippe stated that accurate monitoring of the lesion was required, which could not be achieved by clinical or dermatoscopic review alone but required biopsy. Dr Sippe advised that by 2006, the lesion on Mr A's right forearm displayed further changes which should have raised concern. In particular, Dr Sippe noted that the lesion appeared to have changed in size,[24] there was more variation in colour, and blue/white structures were apparent.

53. Dr Sippe commented that in 2007, the images of the lesion showed "a pattern of steady evolution of a lesion suspicious of melanoma" and, by 2009, the lesion was "highly suspicious" of melanoma. Dr Sippe advised that as the changes to the lesion became more pronounced over time, the diagnosis became more obvious. Accordingly, Dr Sippe considered that Dr B's failure to identify the concerning features of the lesion, and recommend excision, became more serious with each subsequent review. Dr Sippe viewed Dr B's failure to recommend excision of the lesion in 2003 with moderate disapproval but at the "lower end of this spectrum", with the level of disapproval increasing in severity in each subsequent year, reaching the upper level of moderate disapproval by 2009.

54. Dr B advised HDC that Dr Sippe's advice was "rather harsh" but accepted that he missed the diagnosis.

55. In my view, Dr B had a responsibility to provide services of an appropriate standard to Mr A. I accept that no diagnostic procedure will ever be 100% accurate. However, the lesion on Mr A's right forearm was showing dermatoscopic changes suggestive of early melanoma in 2003, but this was not noted by Dr B. The changes to the lesion became more obvious over time, yet were not identified by Dr B at any of the reviews of 2004, 2006, 2007 and 2009. Dr B accepted that by 2006, the lesion on Mr A's right forearm "had some worrisome features and in retrospect [he] should have flagged it for excision at that time" but did not recommend excision until 2010 — one year after the melanographer flagged the lesion for Dr B's comment due to concerns that the lesion had changed size and shape.

56. Dr B advised HDC that he "make[s] every attempt to be focussed and maintain the highest level of care" but believes that "a degree of diagnostic fatigue can set in". Over the relevant period, Dr B was diagnosing up to 100 patients per day and reviewing on average 50 to 112 images per hour. According to the Company, 99% of the moles or lesions that Dr B reviewed were benign and therefore did not require

[23] As stated above, dermatoscopic changes are those observable under a microscope. This can be contrasted with macroscopic changes, which are observable by the naked eye.
[24] Dr Sippe acknowledged that this may be due to an image discrepancy.

detailed assessment. Dr Sippe advised that in this context, Dr B's workload of 50–112 images per hour was "not unreasonable".

57. I also consider that the data provided by the Company does not show a pattern of misdiagnosis in Dr B's assessments. For instance, between January 2007 and December 2011, Dr B was the reporting dermoscopist in 36,669 cases, reviewing a total of 675,153 lesions. Of these, he diagnosed 1,123 melanomas and missed 14, giving Dr B a false negative rate of 1.2%.[25] Dr Sippe advised me that if Dr B's ability to recognise melanoma was severely deficient, one would expect to see a significant diagnostic failure rate, but this was not the case. I agree with Dr Sippe that the false negative rate is very low, indicating that Dr B's failure to detect the suspicious changes in the lesion of Mr A's right forearm was "unusual" and not indicative of incompetence.

58. In my view, Dr B failed to identify the dermatoscopic changes to the lesion on Mr A's right forearm on five separate occasions despite those changes becoming more pronounced and more suggestive of melanoma at each successive review. While I note Dr B's comment that diagnostic fatigue may have been a contributing factor to the misdiagnosis, I do not consider that that is sufficient in the circumstances to mitigate against a finding that Dr B breached the Code. Accordingly, I find that Dr B failed to provide Mr A services with reasonable care and skill and, accordingly, breached Right 4(1) of the Code.

Failure to recommend excision of lesions on Mr A's chest and right shoulder

59. When reviewing Mr A's complaint, Dr Sippe expressed concern about the management of lesions on Mr A's chest and right shoulder. Dr B did not comment on Dr Sippe's advice in relation to these matters.

60. Dr Sippe commented that in 2003 there was "a great variation in colour" in a lesion on Mr A's chest. In light of Mr A's melanoma history, Dr Sippe advised that the lesion required biopsy diagnosis from as early as 2003. Dr Sippe advised that while the lesion on Mr A's chest had not changed significantly between 2003 and 2004, the changes were sufficient to warrant a biopsy diagnosis.[26] Dr Sippe viewed Dr B's failure to do so with moderate disapproval.

61. The lesion on Mr A's right shoulder had been imaged at each of the six skin checks. In September 2010, the melanographer noted the following in a pop-up box headed "Melanographer concern":

> "A diagnosis is required due to:
>
> - Doctor concern
> - Patient concern
> - PHx unknown when appeared."

[25] The false negative rate can be calculated as the number of false negatives (in this case 14) divided by all those Dr B reviewed who in fact had melanoma (in this case 1,137).
[26] There were no further images of this lesion after 2004, as it was excised by Mr A's GP, Dr C, in August 2005. The histological diagnosis was basal cell carcinoma.

62. Dr B assessed the lesion on Mr A's right shoulder as benign but recommended that Mr A continue to monitor the lesion. Dr Sippe advised that the changes in this lesion between 2003 and 2010 were subtle but, with Mr A's history of melanoma, required a biopsy.

63. I agree with Dr Sippe's advice. In my view, Dr B's failure to recommend a biopsy of the lesions on Mr A's chest and right shoulder amounted to a breach of Right 4(1) of the Code.

Opinion: No breach — The Company

64. Dr B's failures to recognise the changes in the lesions on Mr A's right forearm, shoulder and chest were matters of individual clinical error. However, I also need to consider whether the Company is vicariously liable for Dr B's breaches of the Code. Dr Sippe advised the following:

> "Clinical audits and individual monitoring of dermatologists was arranged and [Dr B's] misdiagnosis as compared to other dermatologists was comparable considering his workload. This system appeared adequate at the time."

65. I agree with Dr Sippe's advice. In my view, the Company took reasonable steps to assure itself that Dr B was meeting quality standards. Its audit programme indicated no concerns about Dr B's clinical competence, and a review of Dr B's false negative rate confirmed that Mr A's case was an aberration from Dr B's usually very accurate readings of images. I am also satisfied that Dr B's workload at the relevant time was reasonable. Accordingly, I do not consider that the Company is vicariously liable for Dr B's breaches of the Code.

66. I am also satisfied that the Company has not directly breached the Code. While Dr Sippe identified a number of areas where the Company could improve its systems, I have received no evidence that the systems in place at the time were materially deficient. I accept Dr Sippe's advice that the system was adequate for its purpose and did not contribute to the poor standard of care that Mr A received.

67. Finally, I consider that this case is a clear demonstration that every adverse event is an opportunity for learning, and Dr Sippe has identified a number of areas for improvement of the Company's services. These are set out in **Appendix B**. Since Mr A's complaint, the Company has made significant improvements, which are ongoing.

Recommendations

68. As per my recommendation in my provisional opinion, Dr B provided HDC with a written apology for forwarding to Mr A's widow for his breaches of the Code.

69. I recommend that the Company:

- conduct a follow-up review of Dr B's practice since the complaint and report back to my Office by **8 August 2013**; and
- report on the progress in relation to the changes and improvements outlined in **Appendix B** by **10 January 2014**.

Follow-up actions

70.
- A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Medical Council of New Zealand, the Royal Australasian College of Physicians, and the DHB, and they will be advised of Dr B's name.

- A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the New Zealand Dermatological Society and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A — Independent dermatology advice to the Commissioner

The following expert advice was obtained from dermatologist Dr John Sippe:

"Thank you for your request to provide an opinion to the Commissioner concerning [Mr A], Case Number 11/00700.

I have read and agreed to follow the Commissioner's Guidelines for Independent Advisors.

My CV has previously been submitted and you have a copy of this.

My training qualifications and work in dermatology are relevant in the area of identification of pigmented lesions and melanoma by dermatoscopy to be used in compiling this report. In one of my roles, I am the Senior Dermatologist at the Melanoma Unit, Calvary Mater Hospital, Newcastle. I am aware of [the System] and have used similar programmes for the surveillance of evaluation of naevi.

Instructions from the Commissioner are noted in the attached questions and will be addressed in this report.

The sources of information for the report are:-

1. Letter of complaint and accompanying documentation
2. Letters notifying [Dr B] and [the Company] of investigation
3. Information from [the Company]
4. Information from [Mr A's] doctor, including clinical records
5. Information from [Dr B]
6. Copies of various medical and pathology reports
7. Further information has been obtained from the Commissioner in regard to the dermatoscopic images as used in the monitoring of [Mr A's] skin lesions
8. [The images] supplied for [Mr A] have been viewed and discussed by another specialist Dermatologist.

Acknowledgement.
1. [Dr B] is not known to me and I have no obligations to him.
2. The dermatoscopic images have been viewed and discussed with me by a specialist dermatologist trained in dermoscopy.

[At this point in his report Dr Sippe outlines the background to the complaint. This has been removed for the purpose of brevity.]

1. Did [Dr B] provide [Mr A] with an appropriate standard of care in December 2003?

[Dr B] reviewed [the images] taken by the melanographer. These images were assessed to be of no concern.

Review of the dermatoscopic images shows a variety of pictures consistent with benign or lesions suspicious of malignant change. The images were well taken and accurately documented.

Several of the lesions possibly show early malignant change or certainly dysplastic features.

[Image number] [lesion on right forearm] of a clinically unremarkable nevus showed dermatoscopic changes that are suggestive of early melanoma. The dermatoscopic evidence visible in this image is irregular colour and pigmentation, the presence of blue/white structures, and probable pseudo pods (bulbous extensions of pigment at the lesion edge) are noted at the 11.00am and 4.00pm margins. These changes raise concern that melanoma was present in this lesion.

[Image number] [lesion on chest] is of a probable dysplastic nevus showing a great variation in colour.

In a patient with a background of melanoma both these lesions required biopsy diagnosis and as this did not occur the appropriate care was not provided. A moderate level of disapproval is noted.

Other images were assessed at an appropriate standard.

2. Did [Dr B] provide [Mr A] with an appropriate standard of care in 2004?

The images were reported as benign by [Dr B].

[Image number] [lesion on right forearm] showed there were changes suspicious of melanoma which were not present in the image of the previous year. This was assessed as being of no concern by [Dr B]. Concern should have been noted, particularly in [Mr A's] case as he had a past history of melanoma. There was a need for accurate monitoring of this nevus which could not be achieved by clinical or dermatoscopic review alone. This lesion required a biopsy diagnosis and this did not occur.

[Image number] [lesion on chest] had not changed significantly from the image taken in 2003 but still showed changes that warranted a biopsy diagnosis.

The appropriate standard of care was not followed for these lesions and moderate level of disapproval is noted.

Other images were assessed appropriately.

3. Did [Dr B] provide [Mr A] with an appropriate standard of care in 2006?

[Dr B] was aware of the past history of melanoma in [Mr A], and again the images were noted to be of no concern. There does appear to be a change in the size of the lesion, in [Image number] [lesion on right forearm] (although this may be an image discrepancy only). There was also an irregular pigment increase showing variation in colour and the appearance of blue white structures, all of which would raise concern. This was not noted by [Dr B].

This lesion required a biopsy diagnosis which did not occur. The standard of care was not appropriate.

[Image number] [lesion on chest] of dysplastic naevi was not seen again and should have been re-evaluated (if it was not excised) as it was a lesion of concern.

A moderate level of disapproval is noted.

The other lesions were all assessed and an appropriate standard of care was performed.

4. Did [Dr B] provide [Mr A] with an appropriate standard of care in 2007?

Regarding [Image number] [lesion on right forearm] changes had occurred in the lesion which were not noted by [Dr B]. The images show a pattern of steady evolution of a lesion suspicious of melanoma. A biopsy diagnosis was required at this time. The appropriate care was not provided. A moderate level of disapproval is noted.

Other images were assessed to be of no concern and the care was appropriate for these.

5. Did [Dr B] provide [Mr A] with an appropriate standard of care in 2009?

The [Image number] [lesion on right forearm] showed changing features highly suspicious of melanoma but were said to be of no concern by [Dr B]. Again a steady evolution of pattern changes consistent with melanoma occurred in the lesion showing changes from 2003. The lesion required a biopsy diagnosis. This lesion was not assessed at an appropriate standard. A moderate level of disapproval is noted.

Other images were assessed appropriately by [Dr B].

6. Did [Dr B] provide [Mr A] with an appropriate standard of care in 2010?

A change in the mole on [Mr A's] right arm was noted by the melanographer and [Mr A's] General Practitioner was also concerned about this lesion. [Dr B's] analysis of the [Image number] [lesion on right forearm] registered concern and he recommended excision of this lesion.

The standard of care provided by [Dr B] was appropriate for this.

It is noted that [the System] is intended for early diagnosis of Melanoma and aims to diagnose melanoma early before features are clinically obvious.

The report of September 2010 on [Image number] [lesion on right shoulder] did not state if action was required. There had been concern re this image both by the patient and attending doctor. The changes in the images over time were subtle but with [Mr A's] history of melanoma a biopsy was required. In the report of 28 September 2010 this image was reported as benign but recommended it continue to be monitored.

This image had shown some changes over the time it had been followed and in view of [Mr A] developing a further melanoma on his arm then this lesion required a biopsy diagnosis.

That this did not occur registers a mild disapprovement. In the report of 28 September 2010 this image was reported as benign but should be monitored.

It is not clear from the notes whether this was the subsequent melanoma in situ excised on 24th March 2011. Attempts to obtain this information have not been successful.

7. If not already addressed above, please advise on the following:

(a) At what point should the lesion on [Mr A's] right forearm (described as [number]) have been identified as suspicious of malignancy by [Dr B]?

Review of the [image number] [lesion on right forearm] of [Mr A's] naevi taken in December 2003 shows a variety of features that could be interpreted as early changes of melanoma. A biopsy at this time was required. Subsequently, with change in the appearance of the [images] in 2004 a biopsy was definitely required to determine if a melanoma was present.

(b) When should [Dr B] have recommended to [Mr A] that the lesions on [Mr A's] right forearm be excised?

In 2003 the lesion on [Mr A's] right forearm presented an atypical dermatoscopic image and where a person has a past history of melanoma, a histological diagnosis is necessary. A biopsy excision would have been best arranged at this time. By 2004 the image had changed and excision was warranted then.

(c) At what point should the lesion on [Mr A's] abdomen (described as [image number] [lesion on abdomen]) have been identified as suspicious of malignant?

From the clinical records the lesion removed from the abdomen on April 4, 2011 was reported as a compound nevus. The images of this lesion were of a benign nevus. The lesion had not undergone any substantial clinical or dermatoscopic variation and no change into malignancy had occurred. It was managed appropriately by [Dr B].

The notes by [Dr B] discuss the removal of a dysplastic nevus on March 23, 2009 from the abdomen but it appears no lesion was removed at this time. (Confirmed by Investigator […] — email May 30, 2012).

(d) At what point should [Dr B] have recommended to [Mr A] that the lesion [on] [Mr A's] abdomen be excised?

The lesion on [Mr A's] abdomen was excised at the appropriate time in 2011 with no lesion being excised in 2009.

8. Was [Dr B's] methodology for diagnosis using [the software] from 2003 to 2010 adequate?

The methodology for diagnosis using [the Images] by [Dr B] was adequate. The images were good and the opportunity of comparing in sequence, current and past images was adequate. The lower field allowed a sequence of images to be evaluated and was adequate.

9. Do you consider [Dr B's] quality control/auditing processes from 2003 to 2010 to be adequate?

[Dr B] did not note the changes of [image number] [lesion on right forearm] over time from 2003. There has been a failure of recognition in this image which underwent significant dermatoscopic changes during this time from 2003 to 2010.

There was a process of internal review of cases and referral to international experts was available and provided for expert discussion. This audit programme, however, did not allow for individual misdiagnosis to occur. It is not possible, because of the numbers of images involved, to have every dermatoscopic image reviewed by a panel of experts which would be the only way to avoid individual misdiagnoses. In the review of his work [Dr B] performed well and the audit programme was adequate.

10. Please comment on [Dr B's] personal rate of dermatoscopic misdiagnoses from 2007.

From the information supplied, [Dr B] had a very low rate of misdiagnoses (1.2%) and show there was a high degree of accuracy in the assessment of dermatoscopic images by [Dr B]. The accuracy of diagnosis of such images depends on the quality of the images and the skill of the assessor.

Trials have shown an increase in diagnostic accuracy for melanoma increase from 60% to 90% when comparing clinical diagnosis to clinical/dermatoscopic evaluation. A skilled operator, using a programme such as [this], would be expected to be well above this level. [Dr B's] false negative rate of 1.2% is quite acceptable. Any clinical information also allows this figure to be kept low.

11. According to the information supplied by [the Company], [Dr B] diagnosed 36,669 patients over a four year period (2007–2011.) [Dr B]

has advised that in most cases the number of lesions per individual is 20–30, but it may be as many as 150 or more. Given concerns about the diagnostic fatigue, is this a reasonable case load?

The case load that [Dr B] commented on depends on the number of images he had to assess per hour. [Dr B] stated that he worked in one hour intervals. This was still a significant number of images that he would have to review. If only suspicious lesions are imaged then the load is heavy as each image presents particular features which have to be evaluated closely.

The number of images [Dr B] evaluated was some 50 to 112 images per hour and it is stated by [the Company] that '99% of the images were benign and not suspicious … and do not require detailed assessment.' The number of images evaluated per hour will always depend on how difficult the lesions that have been selected are. With a skilled operator and with the ability to diagnose images to keep a high sensitivity at the expense of specificity then 50 to 112 images is not an unreasonable work load. This is particularly so if there are a large number of benign images to be screened as appears the case. Other programmes assess far larger numbers per hour with good results.

Overall, the number of images that had to be viewed placed a not unreasonable work load on [Dr B]. However, [the Company] has subsequently reduced the work load for [Dr B]. This has been an evolutionary change in [the System] and shows [the Company] adapts to changes as required.

12. Are the changes made by [Dr B] since this incident adequate?

The changes in [Dr B's] assessment of any images, their presentation, reducing of his work load are progressive changes. In addition, ensuring that the review of images by the same dermatologist does not occur and the updating of his clinical knowledge will add an improvement to the assessment of the images that [Dr B] does. These changes appear adequate but need to be supplemented with an active tissue biopsy programme. That is to say, that clinical diagnosis is in itself not accurate enough in many pigmented lesions to make the correct diagnosis and needs the histology of the lesion to provide this level of preciseness. As such the dermatologist should recommend biopsy diagnosis if any suspicious changes are noted in pigmented lesions and particularly so in a patient with a past history of melanoma.

13. Do you have any other comment to make?

The images reviewed by [Dr B] provide a wide variety and spectrum of presentations of pigmented lesions. The dermatoscopic images seen in naevi are not always diagnostic of melanoma as often dermatoscopic changes may mimic melanoma only to reveal a benign lesion on histology (or vice versa).

The changes noted in [image number] [lesion on right forearm] did raise concern and these should have been noted earlier than 2010 and [Dr B] acknowledges this. It was unusual that this was not detected in view of the small diagnostic error

rate that [Dr B] has. If [Dr B's] ability to recognise melanoma was severely deficient then his diagnostic failure rate would be significant and this does not appear to have been the case. It is difficult in such a setting to understand how the lesion was not recorded as suspicious of melanoma earlier by [Dr B].

If [image number] [lesion on right shoulder] is of the later excised Melanoma in situ then this raises concern also. The changes noted were of lesser intensity than in the images of lesion [number] [lesion on right forearm] but with concern raised by the patient and doctor and [Mr A's] background of melanoma then this lesion should also have had a biopsy diagnosis. It is always easier to review information in retrospect and it could be understood how the [image number] [lesion on right shoulder] did not raise concern early on as the changes were mild and probably did not show any suspicious changes that were diagnostic.

It was noted that [image number] [lesion on chest] was not seen after the images of 2003 and 2004. The reason for this is not known and this also is an image of concern and the long term monitoring was required for this lesion.

It is not clear from the records if the melanoma in situ excised from the right shoulder in March 2011 ever had [an image] performed or if this was a new lesion.

[The Company]

1. Is [the System] adequate for its purpose?

[The System] is to provide a record of images [of] suspicious naevi and to monitor any changes over time. It is not a substitute for clinical examination as [the information] to the patient states. [The System] is good and achieves what it aims to provide, namely a monitoring and record keeping of the progressive clinical and dermatoscopic changes of 'suspicious' naevi. The images were well presented showing good characterisation of the features and colour. Comparison to other images taken of the same lesion in previous years was readily available and was adequate for its purpose.

2. In your view, did [the System] contribute in any way to [Dr B's] misdiagnosis of [Mr A's] melanoma?

[The images] provided by [the System] were adequate to make a diagnosis and did not contribute, in my view, to misdiagnosis of [Mr A's] melanoma on the right arm.

3. Did [the Company] have adequate systems in place to reduce the risk of misdiagnosis through perceptual error or diagnostic fatigue?

The systems in place at the time were adequate as previously discussed. Through the audit programme it appeared that [Dr B] performed well despite his high work load suggesting the system was adequate. The new programme however, which

has been instituted helps to overcome any errors or failures in the system through perceptual error or diagnostic fatigue.

4. In your view, are there any areas where improvements could be made to the orientation/training provided to dermatologists using [the System].

Once an image has been mapped it should continue to be imaged unless it has proven to be definitely benign or has been excised.

Diagnostic labels would best be attached to each image to ensure continuity and allow for review of this opinion by the dermatologist and other reviewers over time. This will in itself be an added audit.

The attached history of any previous melanoma or risk factors should be made available on all fields.

[The System] needs to ensure trainees understand the need to have diagnostic biopsy of atypical lesions and not rely on the appearance of the image alone to make the diagnosis.

5. In your view, are there any areas where improvements could be made to [the System] itself (or how it is used) to reduce the risk of misdiagnosis?

[The System] should allow for patients' comments to be included and the melanographer should make a comment on each series of images whether there were any lesions of concern. This does occur to some extent already.

Currently [the System] does not have a system in place where the individual images have a diagnostic label placed upon them. Thus, when reviewed 12 months later the original diagnosis is not available to the dermatologist. Labelling of all lesions examined with a diagnostic tag would allow the dermatologist or his peers to review his diagnosis more accurately. This labelling should initially be hidden and then made available on the next link to ensure the dermatologist is assessing the image with a new perspective.

A blind audit programme where a series of dermatoscopic images is provided to a dermatologist for assessment could be instituted and this would allow more accurate monitoring of the performance of the doctor in the undertaking of the dermatoscopic images. This currently does occur to some extent but an ongoing programme is necessary and be reviewed by another skilled image reader (sic).

Once an image has been mapped it should continue to be imaged unless it has proven to be definitely benign or has been excised. The histology of any such lesion should be made available to the dermatologist as [the Company] recommends.

[The Company's] system expected [Dr B] 'To practice competently and to engage in ongoing professional development.' None of his work was reviewed formerly. However, assessments were provided in evaluating the accuracy of his

diagnostic rate and [Dr B] performed highly in this area. The level of false positive he expressed were assessed as 'very good'. While the monitoring system appeared adequate, there has been a failure in this case and supports the view that monitoring is required for the benefit of the doctor and the patient.

6. Please comment on the adequacy of [the Company's] systems for monitoring [Dr B's] competence and performance from 2007 onwards.

Clinical audits and individual monitoring of dermatologists was arranged and [Dr B's] misdiagnosis as compared to other dermatologists was comparable considering his work load. This system appeared adequate at the time.

7. Please comment on the adequacy of [the Company's] systems and processes for reporting, following up and learning from incidents of misdiagnosis.

The changes instituted by [the System] have been pro-active and they have made significant improvements in the system to overcome any error rate. [The Company] has presented images to international experts for review to ensure their programme is of high international standard. Appropriate changes and recommendations including the updating of computer image technology, the details of the patient's presentation, reduction of the dermatologist's work load and for the images to be made available to the individual patient's doctor for review at the time of consultation have been included in the system and are adequate.

8. Based on the information available, was there any reason for [the Company] to be concerned about any aspects of [Dr B's] competence or performance between 2003 and 2004?

No. The failure was of [Dr B] to recognise the changes of the dermatoscopic images suspicious of a melanoma. It does not appear that there was a way in which this could be detected under [the System] then or even now. All programmes will have a failure rate and with [Dr B's] low false negative diagnostic rate of 1.2%, being within the accepted level, [the Company] would be aware of this. As such this would not raise significant concern in regard to [Dr B's] competence or performance.

9. Please comment on the adequacy of [the Company's] photographic quality between 2003 and 2010.

The sequential presentation of clinical photographs and the dermatoscopic images in this time period were of good quality and allowed the evaluation of the various pigmented lesions to be assessed adequately.

10. Please comment on the adequacy of the information provided by [the Company] to consumers (both from its website and information provided in its reports to consumers).

Information provided by [the Company] in regard to this programme confirms that it is a system of monitoring naevi. These naevi are evaluated against past images and any changes of the naevi are then evaluated clinically and by a dermatoscopic image. [The Company] makes the specific point that its process is not 100% accurate and rather this process is a tool to be used to help in the monitoring [of] pigmented lesions and the diagnosis of melanoma.

Some of the reports could explain more adequately rather than stating 'There are no areas of concern' when there are obvious areas of dysplasia on the images which can not be clinically identified accurately and need biopsy diagnosis. [The System] stresses the importance of having changing naevi reviewed.

A statement is made that [the System] is '[n]ot a complete substitute for clinical examination.' Patients under going such a screening programme should be provided with information brochures which **HIGHLIGHT** this.

The statement provided by [the Company] following evaluation of lesions noting ('You currently have no lesions of concern') results in over reassurance of the patient, particularly when the dermatoscopic images are not 100% accurate. The patient could thus become less vigilant and less aggrieved if consequently this diagnosis was proven not to be correct.

An assessment of the lesions with the diagnostic label of each lesion and re-emphasising the importance of clinical examination and at times that histological diagnostic evaluation is required could be included in the information provided to the patient.

It is recognised that dermatoscopic evaluation of melanoma can never be 100% accurate. At times, even the histology of melanoma can not be totally definitive and may require a variety of special stains, such as HMB 45, to diagnose the lesion. Some lesions, after a review by a panel of histologists, can not be stated to categorically be melanoma so it can not be expected that a visual system such as [the System] to be totally precise.

Overall, the information appears adequate but needs some small changes.

11. Are the changes made by [the Company] since this incident adequate?

[The Company] has made a number of changes following outside assessment of their process. The assessment of the images by a variety of dermatologists would address the problem of a dermatologist working in isolation and to overcome any of his diagnostic deficiency.

Clinical audit meetings were arranged and would be of help to the dermatologist but working in isolation does not allow the dermatologist to be evaluated by this procedure. Blind individual audit programmes with positive feedback to the doctor would go some way to addressing this concern.

The other changes as noted in the documents are otherwise adequate.

12. Do you have any other comment to make?

The monitoring of patients for melanoma is not a simple task. The variation in benign naevi is considerable and benign naevi may, at times show features of melanoma both on clinical and dermatoscopic examination. The Clark nevus, one of the most common naevi on the body, often shows features both on clinical and histological examination suggestive of malignancy but is a benign nevus.

The absolute number of naevi in the population and the inappropriateness of excising every lesion for histology means that naevi need to be reviewed clinically. Exposure through the media ensures that considerable publicity is given to moles and the danger of melanoma. In view of this, monitoring and assessment programmes of naevi have been instituted. This is the role of [the System]. This has provided a very useful tool in the evaluation of naevi and as such provides a very positive service.

The misdiagnosis of the melanoma on [Mr A's] right arm by [Dr B] appears to be an unusual failure in his assessment of [images]. He, himself, is at a loss to understand this misdiagnosis. It is not possible to explain how this occurred given the changes in [image number] [lesion on right forearm] showed a steady evolution suspicious of the melanoma. While this is a most unwelcome outcome, it appears to have been very isolated in that [Dr B] has had a very high diagnostic rate in a heavy work load.

In regard to the missed early diagnosis of melanoma [image number] [lesion on right forearm] this lesion showed a very slow growth, the features were variable and changeable due to areas of regression and growth. The Breslow depth of invasion on biopsy was 0.68mms some seven years after its variable image changes first appeared. These early changes suggestive of melanoma, however, may have been dysplastic changes only at this time. However, the lesion required biopsy diagnosis. Regression, at times, may underscore the depth of invasion of the lesion but no regression was reported in the histology of this melanoma and the measurement consequently appears a realistic Breslow depth of invasion.

It is more probable that the melanoma excised from [Mr A's] left arm in 2003, measuring Breslow depth of 1.3mm was the source of the metastatic spread of his melanoma. It was a deeper melanoma, which may have been deeper than the reported 1.3mm, as some features of regression (the lesion disappearing) were noted in the report of [a pathologist in] August 2003. The lesion was a nodular melanoma and because of its not uncommon lack of pigment and size (4mm) may have been overlooked for some time by [Mr A].

The melanoma on [Mr A's] opposite arm (the right arm) did not show aggressive features suggestive of rapid growth with a low mitosis rate (rate of cell replicating and thus slower growth) and arose in a pre-existing nevus (Report of 13 October 2010).

While the sentinel node biopsy of [Mr A's] left arm melanoma was reported as negative it is well recognised that some secondary metastatic cases show negative

sentinel node biopsy. This is because metastatic melanoma occurs not only by lymphatic spread but through the blood vessels. At times the melanoma cells may block the lymphatics and not spread to the node. As such the melanoma cells are not isolated in the sentinel lymph node. It is estimated that up to 11% of secondary melanomas have negative sentinel node biopsy. (Ref. 1)

A delay of many years may occur between the initial melanoma and a secondary metastatic lesion appearing depending on the immune status of the patient. (Ref 1: 2: 3). It is for this reason that patients with thick melanomas showing deeper Breslow levels are followed up yearly beyond the customary 10 year period.

A previous history of melanoma is a very strong predictor of future melanoma with the risk being the greatest in the first one to two years after the initial diagnosis. Particular care should be taken in evaluation of any pigmented lesions in this time frame. This is the time at which [Mr A's] arm lesion was first monitored and suspicious changes are noted on the images and required a histological diagnosis.

Opinion Re: [Dr B] Standard of Care and [the Company].

[Dr B] is a well qualified dermatologist with additional specialist degrees not usually held by other specialist dermatologists. By the nature of his other qualifications he would be expected to have a deep understanding of the nature of skin lesions and melanoma. From the information [Dr B] has a large experience in the diagnosis by dermoscopy of pigmented lesions.

It is noted that [Dr B] recognises his acceptance of the missed diagnosis of the melanoma on the right arm of [Mr A] and this could have been made earlier. There does not appear to be a pattern of misdiagnosis in [Dr B's] image assessments from the audits conducted by [the Company] in which he performed well. The missed diagnosis is within the limits of human error and does not appear to be widespread in [Dr B's] work.

I do not consider that [Dr B] has breached his ethical duties or his responsibility to the patient. He has not shown a lack of skill otherwise or demonstrated a need not to address the issues raised by the case of [Mr A]. However, the missed diagnosis of [Mr A's] melanoma on the right arm is significant.

The changes in the images of the melanoma over the right arm became more pronounced with time and the diagnosis more obvious. The level of disapproval becomes more severe over time with the diagnosis not being made. Thus, while the possibility of making an important diagnosis was missed in 2003 it became more important as the lesion presented with more changing features. The level of disapproval, I consider is moderate but within this area was initially at the lower end of this spectrum rising to the upper level in 2009.

Given all the facts, I do not consider the level of disapproval of [Dr B's] work was at the severe level of disapproval and I would register a level of moderate disapproval for his assessment of the images of [Mr A].

With the changes that [Dr B] has made, the continuing education and the improving [of] his diagnostic skills, then it would be expected that his diagnostic accuracy rate would be enhanced. In [Dr B's] situation, mis-diagnosis such as this [is] less likely to occur again but owing to the very nature of melanoma and its variable presentations, the diagnosis of melanoma by dermatoscopic images will never be 100%.

It is emphasised that programmes such as [this] allow the evaluation of patients' naevi by a process of dermatoscopic imaging, evaluation and monitoring over time. This is one of the more accurate systems for monitoring changes and generally is an effective system with well trained operators. It is not a system to replace clinical examination and biopsy diagnosis of pigmented lesions.

Monitoring programmes such as [this] can never be expected to be absolutely accurate in the diagnosis of pigmented lesions. Consequently it needs to be supported by an active programme of lesional biopsies (a simple process) for indeterminate lesions and changing pigmented lesions.

If there are any areas of this report which you need to discuss then please contact me.

Yours sincerely

JOHN R SIPPE

MB,BS,DDM,FACD

Reference:

1. J.E. Gershenenwald et al. J. Clin.Oncology 1998.16.6.2253.

2. N.J. Crowley et al. Ann Surg 1990.212(2).173-177.

3. L. Ossowski et al. Pigment Cell Mel Res. 2010 Feb.23 (1) 41."

Appendix B — Recommendations and the Company's response

Recommendation	Response
Once an image of a mole or a lesion has been mapped, it should continue to be imaged unless it is definitively proven to be benign or has been excised.	The Company is currently assessing methods to determine when a lesion can be proven to be benign. In the meantime, all lesions continue to be monitored unless they have either been excised or have disappeared.
Diagnostic labels be attached to each image.	This recommendation may have been based on the assumption that the majority of the imaged lesions are inherently suspicious. In fact, the majority of images are benign and are not suspicious. These lesions are generally easily recognised and do not require detailed assessment. Any lesion that has been diagnosed for action and monitoring is labelled as such and is apparent to the dermatologist who reviews the images in subsequent years.
The attached history of any previous melanoma or risk factors should be made available on all fields.	This feature is now incorporated into the current software release and is in use.
The System needs to ensure that trainees understand the need to have diagnostic biopsy of atypical lesions and not to rely on the appearance of the image alone to make the diagnosis.	The Company confirms that the importance of biopsy as a diagnostic tool is emphasised to all trainees.
The diagnosis is initially hidden for subsequent diagnoses.	This has merit and will be discussed by the panel of dermatologists for future implementation.
A blind audit programme, where a series of dermatoscopic images is provided to a dermatologist for assessment, could be implemented on an ongoing basis, to allow for more accurate monitoring of the performance of the doctor.	This suggestion is under development and will become regular practice in the future.
The statement that the System is "not a complete substitute for clinical examination" should be highlighted in more obvious print.	This will be implemented together with a new consent process whereby this is explained to the patient by the melanographer.
The statement: "You currently have no lesions of concern" may result in over-	The Company acknowledges the merit in this suggestion and is currently exploring

reassurance to the patient, resulting in the patient becoming less vigilant.	alternative wording to ensure that the risk of over-reassurance to patients is avoided.
Strong consideration should be given to presenting the most recent lesion against the initial image of a lesion in both macroscopic and dermatoscopic views to enable a greater period in which change may have occurred to be visually apparent.	This feature has been included in the latest software release.
Melanographers should remain at the patient interface.	Further training on presenting relevant information to the dermatologists has been provided at the annual melanographer conference.
There may be benefit in benchmarking key performance indicators between dermatologists on a routine basis and on a specific number of cases per month, which would be viewed by all dermatologists. Individual dermatologists would be offered information regarding any significant deviation of their activity from the standard.	Software to track key performance indicators is under development and partially deployed.
The current process means that it is likely a patient will have their images read by the same dermatologist year after year. This should be reconsidered to assist dermatologists to use "fresh eyes" for each patient.	The clinics have been reallocated to different dermatologists as suggested. This allocation will be reviewed and changed on an annual basis.
Consideration should be given to providing melanographers with an opportunity to request a second diagnostic reading for lesions which are of concern to them, but which have not been specifically commented on by the diagnosing dermatologist.	Melanographers are now keeping a manual record of concerning lesions and have the dermatologist's diagnosis available within their point of care software to follow up on when the diagnosis is incomplete. They are encouraged to request a second opinion through the clinical manager if they have continuing concern.
To avoid diagnostic fatigue and minimise perceptual error, consideration should be given to limiting the number of lesions that a dermatologist may assess in any one diagnostic session and for limiting the speed at which lesions can be assessed.	The caseloads for dermatologists have been reallocated, and [Dr B] now has approximately 50% of his previous case load.

Delete all information from the initial screen in a patient case which does not suggest an increased risk for melanoma, so as to place more emphasis and to highlight the information which does suggest increased risk.	The most important factor for increased risk of melanoma, patient history of melanoma, is highlighted in the initial screen and on every lesion diagnosis screen.