From Dr Sarah Wollaston MP, Chair

The Rt Hon Jeremy Hunt MP
Secretary of State for Health and Social Care

22 February 2018

Dear Jeremy,

I am concerned about the issues raised in the following correspondence from Dr Margaret McCartney on the subject of private screening companies. I would be grateful in the first instance for your formal response to the points made by Dr McCartney.

Please find the correspondence below:

Yours sincerely,

Dr Sarah Wollaston MP
Chair of the Committee
Dear Dr Wollaston...

I have had a long standing concern that the impact of private screening companies in the UK are harmful to both individual patients and to the NHS.

I gave evidence on this several years ago to the Science Committee. They recommended in 2014

"that the Government clarifies, in its response to this report, where responsibility rests for ensuring that the information materials and advertisements produced by private providers of health screening are held to the same evidential standards as those produced by the NHS and that they enable people to make an informed choice about participating" [url: https://publications.parliament.uk/pa/cm201415/cmselect/cmsctech/244/24407.htm#a17]

This has not occurred. There are multiple companies, some of which advertise aggressively using direct mail shots and the appearance of a limited service which the person may believe they have been specially selected for. The screening costs anywhere from 100 upwards and comprises either things that the NHS already does (cardiovascular risk screening) or things it does not (peripheral arterial disease screening) - but because it is ineffective as judged by the UK National Screening Committee.

Over the years I have been successful in challenging the adverts from Lifeline, Bluecrest, Preventicum and several other companies. However I believe that that ASA are not able to insist on the balanced information which would reach Montgomery standard. The adverts these companies use do not make it clear, for example, that the tests they offer which are not done in the NHS are not done because they are ineffective. They do not explain false positives clearly. And they do not explain the lack of evidence of impact on mortality or morbidity.

Further, the patient is usually sent a large package of results which they are encouraged to take to their NHS GP. This is unfair: the NHS should not be expected to mop up the management of the inevitable false positives and the anxiety they bring.

I would suggest that these companies are made to pay insurance for follow up of all tests to be done in the private sector, and for this to be made clear to people at the point of purchase (e.g., by order of the NHS Executive, 'the NHS will not deal with any abnormalities found as a result of these tests and this will be done in the private sector paid for by us').

The NHS is under such strain that the cries for charging patients/blaming immigrants are louder and more frequent. However we rarely hear anything about dealing with some of the avoidable pressures produced by private companies who have long since profited and walked away. There is currently no legislation which ensures fairness of how these companies operate and I do not think the ASA's framework is fit for judging what advertising is informed consent.
In summary I would be grateful for your help in addressing:

1) the fact that the NHS has to deal with the consequences of tests, done in the private sector for profit, that it does not recommend, wasting NHS resources. Is statute required to deal with this and insist that follow up is done privately, or charged for by the NHS to these companies?

2) the fact that the advertising for these procedures is dealt with through the ASA, who though very hard working, do not hold these companies up to the standard of informed consent required by Montgomery, and who are unable to force compliance. Does advertising for medical tests require a higher standard which should be judged and corrected prior to publishing?

3) the regulation of owners of these clinics, who may not be medically qualified or registered but who are offering non evidence based services. The CQC does not judge services on the evidence for their interventions, and applies only in England. Does there need to be a clear customer clause that must be brought to the customers' attention which states whether the services on offer are judged effective by the NHS?

many thanks
Margaret McCartney (Dr)
Dr Sarah Wollaston MP  
Chair of the Health and Social Care Committee  
House of Commons  
London  
SW1A 0AA

21 AUG 2018

Dear Sarah,

Thank you for raising the concerns that you and Dr Margaret McCartney have about the impact private screening companies in the UK have on individuals and the NHS with my predecessor. I apologise for the lengthy delay in replying.

I welcome and respect your and Dr Margaret McCartney's efforts in suggesting improvements to provision in the private sector.

I can assure you the Government recognises it is essential that individuals get the right information and support whoever the provider may be. I must also recognise that the independent sector can play a useful role in adding capacity, promoting innovation and offering individuals choice.

You have expressed the following concerns in particular:

- "the fact that the NHS has to deal with the consequences of tests, done in the private sector for profit, that it does not recommend, wasting NHS resources. Is statute required to deal with this and insist that follow up is done privately, or charged for by the NHS to these companies?"

- "the fact that the advertising for these procedures is dealt with through the ASA, who though very hard working, do not hold these companies up to the standard of informed consent required by Montgomery, and who are unable to force compliance. Does advertising for medical tests require a higher standard which should be judged and corrected prior to publishing?"

- "the regulation of owners of these clinics, who may not be medically qualified or registered but who are offering non-evidence based services. The Care Quality Commission (CQC) does not judge services on the evidence for their interventions, and applies only in England. Does there need to be a clear customer
clause that must be brought to the customers' attention which states whether the services on offer are judged effective by the NHS?"

In response I can say that the Health and Social Care Act 2008 requires all providers of regulated activities, including NHS and independent providers, to register with Care Quality Commission (CQC) and follow a set of fundamental standards of safety and quality. The Act (Regulated Activities) Regulations 2014 define aspects of the quality of care to be regulated (for example Need for Consent; Dignity and Respect; Staffing).

The CQC carries out inspections of registered providers and, in the majority of cases, attributes an assessment rating ranging from Inadequate, Requires Improvement to Good, and Outstanding in respect of the quality of services provided.

In 2015, the Department introduced legislation requiring providers to display at their premises the rating that the CQC has given their services. Individuals who choose to access such services may wish to ask providers to provide details of any regulatory or professional standards that they are required to comply with.

I do understand your concerns about regulatory oversight; however, the existing regulatory regime operates by setting fundamental standards which registered providers must comply with when carrying on activities as set out above. Those requirements are broad, for example, that treatment which is provided must be appropriate and provided in a safe way. I am conscious that introducing additional regulations may not bring about the outcomes you would like to see.

In addition, in order to bring additional elements of private providers into CQC’s scope of regulation, the Department of Health and Social Care (DHSC) would need to undertake a regulatory change process through Parliament and would need to consult with providers and the public on any changes they are proposing. However, DHSC (along with all other government departments) is currently being asked to review proposing any secondary legislation because of EU exit legislation and pressures on the parliamentary timetable.

I thank you again for bringing this to my attention and I think we agree that it is essential that individuals get the right information and support whoever the provider may be.

Yours ever,

MATT HANCOCK
Dear Matt

Thank you for your reply to my letter of 23 February, enclosing correspondence from Dr Margaret McCartney concerning the effect of the activities of private screening companies on the NHS.

Essentially, your reply comes down to two points:

- introducing additional regulation “may not bring about the outcomes you wish to see”
- in any case, it is not possible to introduce additional regulation because all available Government and Parliamentary resource is currently taken up with Brexit.

While I understand (though regret) both points, neither address the substantive issue which Dr McCartney has raised. I would be grateful for your response to the following specific questions raised by Dr McCartney’s correspondence:

- What is your assessment of the extent of the additional costs to the NHS arising from unnecessary and ineffective tests done in the private sector, and do you consider that there is a case in principle for transferring the burden of those costs to the providers of such tests?
- Is there a case for subjecting advertising for such tests to a higher standard than is achieved under current advertising regulation?
- Is there a case for requiring the providers of such tests to bring to their customers’ attention information on whether the test being offered is judged effective by the UK National Screening Committee?
I am copying this letter to Dr McCartney. I will also be inviting the Health and Social Care Committee to publish the correspondence so far, including this letter.

Yours sincerely,

[Signature]

Dr Sarah Wollaston MP
Chair of the Committee
Dear Sarah,

Thank you for your letter of 31 August raising questions regarding the impact that private screening companies in the UK have on individuals and on the NHS.

In your letter, you have asked specific questions.

First, what is your assessment of the extent of the additional costs to the NHS arising from unnecessary and ineffective tests done in the private sector and do you consider that there is a case in principle for transferring the burden of those costs to the provider of such test?

In our previous correspondence, I noted that in order to bring additional elements of private providers into CQC’s scope of regulation, the Department of Health and Social Care would need to undertake a regulatory change process through Parliament.

There are currently no existing powers in legislation that would allow the creation of a charge against private screening companies in relation to the costs incurred by the NHS as a result of screening. DHSC is still being asked to review proposing legislation because of EU exit legislation and pressures on the parliamentary timetable. In addition, it would be difficult to legislate due to difficulties in defining which tests are ‘unnecessary’ and ‘ineffective’ as well as specifically identifying which NHS costs would arise as a result of these tests.

Is there a case for subjecting advertising for such tests to a higher standard than is achieved under current advertising regulation?
Current advertising regulations provide robust protections for consumers of private health screening tests, both through the Advertising Standards Authority (ASA) regulatory regime and through offences enforceable by Trading Standards and Ofcom. These advertising regulations have the ability to combat misleading advertising of private screening companies through their rules on medicines and health products, and on misleading or unsubstantiated advertising.

The two advertising codes that ASA apply (the UK Code of Broadcasting Advertising and the UK Code of Non-Broadcast Advertising and Direct and Promotional Marketing) contain sections that are relevant to the regulation of advertising private screening tests and to which Trading Standards or Ofcom would be able to carry out enforcement action should companies choose not to comply.

It would be possible to bring in specific advertising offences in relation to the advertising of private screening tests, which might expand the enforcement potential in this area; however, such provisions would also need to be brought in through primary legislation. It should also be noted that the Department for Digital, Culture, Media & Sport (DCMS) is the lead department in relation to advertising, so any policies implemented in relation to advertising would also need to be agreed with them.

_is there a case for requiring the providers of such tests to bring to their customers’ attention information on whether the test being offered is judged effective by the UK National screening committee?_

The UK National Screening Committee (UK NSC) emphasises that screening should only be introduced where there is evidence that it is effective, the benefits outweigh the harms and that it does not give misleading information to the person being screening. The UK NSC clearly highlights that some of the private provider tests are not recommended by the UK NSC because it is not clear the benefits outweigh the harms and advises individuals who are planning to pay for any of these screening tests to ask a range of questions first (as outlined on the website detailed below).

The UK NSC has also issued guidance for health professionals to help advise patients about private screening and has published relevant blogs. The guidance for healthcare professionals is available at [private screening for health conditions: NHS recommendations - GOV.UK](https://www.gov.uk/government/publications/private-screening-for-health-conditions) and UK NSC’s blog can be accessed at: [https://phescreening.blog.gov.uk/2018/03/02/a-reminder-about-private-screening-and-a-last-opportunity-to-order-leaflets-about-it/](https://phescreening.blog.gov.uk/2018/03/02/a-reminder-about-private-screening-and-a-last-opportunity-to-order-leaflets-about-it/).
As I said in my previous correspondence, the Health and Social Care Act 2008 requires all providers of regulated activities to register with CQC and to follow a set of fundamental standards of safety and quality. CQC inspection reports and ratings are intended to help individuals choose providers of health and care services. The CQC will therefore take action when it finds poor care, to ensure patients and the public receive high quality and safe care. CQC is not aware that there have been any incidents of patient harm or similar in connection with screening tests.

I entirely understand your concerns surrounding this issue and would like to reiterate that it is necessary that individuals get the right information and support to enable them to make decisions that are right for them, regardless of the provider.

I hope you find this response helpful.

Yours ever,

Matt

MATT HANCOCK
Dear Dr Wollaston,

Thank you for your letter of 12 November expressing concern over the practise of private screening in the UK and the possible burden this has on the NHS.

As we know, screening for a condition to be introduced as a population screening programme is only recommended by the Minister from advice of the UK National Screening Committee (UK NSC), where the high evidential barrier to meet the UK NSC’s strict criteria to ensure the balance of good outweighs the harms is met. We are aware that no screening programme is perfect and harms, often unintentionally can arise. It is because of the harms that screening is thoroughly examined before it is introduced.

The UK NSC has escalated concern over unregulated practice of private screening to the Government and CQC, emphasising that screening should only be introduced where there is evidence that it be effective, the benefits outweighs the harms and that it does not give misleading information to the person being screening.

The UK NSC would therefore welcome a more robust regulated and stringent process whereby providers of private screening are required to be candid about what it is they offer as well as be held accountable for any misrepresentation. It is a matter for the Government to ensure the safe practice of screening is being complied with for the benefit of the nation as well as ensuring fairness.

In the meantime the UK NSC continues to keep abreast of developing tests and conditions to ensure that screening is altered, updated and improved as quickly as evidence allows and implementation is possible but crucially only offered where appropriate.

The Committee recognises that some people may be tempted to undertake private screening especially in light of enticing claims, however as the UK NSC has no jurisdiction to stop such companies in promoting this service, the UK NSC has shifted focus to help support and provide information to people about the importance of participating in a recommended screening programme rather than just a test. The
UK NSC has issued guidance for GPs to help advise patients about private screening and blogged about this earlier this year.

The UK NSC is unable to comment on the extent to which additional costs may be burdening the NHS however can only emphasise that when screening is recommended in the NHS it is done so ensuring that there is a; test, treatment and support throughout the patients care pathway once they have made a personal choice to participate in screening and is cost effective for the NHS.

Yours sincerely,

[Signature]

Professor Bob Steele
Chair, UK National Screening Committee