Enforcement Notice:
Advertising Non-invasive Prenatal Testing

Who we are
We are the Committee of Advertising Practice (CAP). We write the advertising rules, which are enforced by the Advertising Standards Authority (ASA), the UK's independent advertising regulator. You can read about the UK advertising regulatory system on the ASA website.

Why are we contacting you?
Ads for Non-invasive Prenatal Testing (hereafter NIPT) commonly cite "Detection Rates" of 95%+ for their accuracy in screening potential genetic conditions. Although we understand that detection rates are clinically useful in some contexts, the ASA has recently ruled that quoting detection rates alone in marketing material is likely to mislead consumers.

Please read the following guidance and take immediate action to ensure your advertising complies, including online. If we see continued problems after **Monday 17th February 2020** we will take targeted enforcement action to ensure a level-playing-field. This can include – where advertisers are unwilling to comply – referral to our legal backstop or your professional regulatory body.

Scope
This guidance is limited to the promotion of NIPT to UK consumers in advertising, including websites and social media. The guidance does not comment on any claims for NIPT beyond those outlined below, and is distinct and without prejudice to any other rules or guidance on this issue.

Guidance – Case Studies

Case Study #1: Avoid quoting "Detection Rate" figures (but see #2)
The ASA investigated a website for NIPT which stated the test "is accurate and identifies Down's syndrome, Edwards' syndrome and Patau's syndrome in over 99% of cases". The ASA considered that consumers were likely to understand this to mean that there was a 99% chance that a foetus would have those conditions following a "positive" test.

The ASA understood, however, that the detection rate figure represented the proportion of foetuses that NIPT had identified to have the relevant condition out of all foetuses which ultimately had the condition. This figure did not give any insight into the proportion of positive results where the foetus would ultimately not have the condition, so its prominent use in the ad could potentially mislead consumers.

Case Study #2: If you quote a detection rate figure, it must be accompanied by a robust Positive Predictive Value figure and an explanation of both terms
The ASA investigated a website for NIPT which included claims that the test has "a sensitivity for the detection of Down's syndrome greater than 99%, 97.4% of Edwards syndrome and 93.8% of Patau's syndrome, with a false positive rate of less than 0.1%". The website also referred to a Positive Predictive Value, which the advertiser described as the proportion of patients given a "positive" result from NIPT who subsequently had the condition confirmed in the foetus.

The ASA understood that a systematic review of the performance of NIPT in general found that it had a Positive Predictive Value (PPV) of 82% for Down's syndrome, 37% for Edwards' syndrome and 49% for Patau's syndrome. It followed that out of all the foetuses with "positive" results, 82% would ultimately have Down's syndrome, as opposed to the 99% detection rate figure that consumers would understand from the ad.

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Advice:
Avoid using detection rate figures in your marketing communications. If you wish to include them, the detection rate figures should be accompanied by robust Positive Predictive Value figures, alongside explanations of both figures so consumers can understand what they mean. In line with the rulings, Positive Predictive Value figures of 82% for Down's syndrome, 37% for Edwards' syndrome and 49% for Patau's syndrome would be acceptable; although we would advise you make clear that these figures relate to NIPT generally, rather than your specific test. If you quote a PPV based on your own studies, you must ensure that the sample of women is representative of the general population.

Case Study #3: Do not refer to NIPT as "diagnostic"
The ASA investigated a website for NIPT which described the service, consisting of NIPT and an ultrasound scan, as a "30 minute diagnostic appointment". The ASA considered that consumers would understand this to mean that the appointment could identify with certainty whether the foetus had certain genetic conditions, including Down's syndrome. On the understanding that the PPV for Down's syndrome was 82%, and a "positive" result would require a further invasive test to confirm an accurate diagnosis, the ASA concluded that the claim "diagnostic" was misleading.

Advice:
Do not use the claim "diagnostic" to describe NIPT.

Guidance – Compliance check-list

1. **Do not** quote "Detection Rate" figures in ads, unless:
    - The figures are accompanied by (i.e. alongside):
        - A robust Positive Predictive Value figure; **AND**
        - Clear explanations about what both figures mean.

2. **Do not** use the term "diagnostic" to describe NIPT.

Appendix: Code rules, legislation and useful reading

Relevant CAP Code rules:

3.1 *Marketing communications must not materially mislead or be likely to do so.*
3.3 *Marketing communications must not mislead the consumer by omitting material information. They must not mislead by hiding material information or presenting it in an unclear, unintelligible, ambiguous or untimely manner…*
3.9 *Marketing communications must state significant limitations and qualifications. Qualifications may clarify but must not contradict the claims that they qualify.*
3.10 *Qualifications must be presented clearly.*

Want more? **Contact the CAP Copy Advice team, which offers a free and confidential bespoke pre-publication advice service**