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OPINION

Malaysian IVF Patients Must Be Warned About US Lawsuits Involving PGT-A (PGS) — Dr Alexis Heng Boon Chin, Dr Rosazra Roslan & Dr Sayyed Mohammed Muhsin

Patients must be made aware of ongoing class-action lawsuits against PGT-A in the US, where it has been identified as the most glaring and widespread example of fraud within the IVF landscape.

By **Ova** Published 5 hours ago











A mother with her newborn child. Photo by blankita_ua from Pixabav.

Currently in Malaysia, IVF patients are strongly encouraged to add-on costly preimplantation genetic testing for aneuploidy (PGT-A) to their already expensive IVF treatment cycles.

PGT-A is intended to screen for chromosomal abnormalities to potentially improve pregnancy success rates and reduce miscarriage risks among IVF patients.

However, evidence of its effectiveness in improving live birth rates is doubtful, especially for **certain age groups**.



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To sweeten the deal, IVF patients are often discreetly told that they can covertly select the sex of their baby with PGT-A testing, even though non-medical sex selection for social reasons is strongly discouraged by the Malaysian Medical Association.

This practice raises ethical concerns, especially when cultural and religious views on gender selection vary significantly in a multiracial country like Malaysia.

In our present era of rapidly declining birthrates, whereby parents willingly invest more money, time and effort per child, PGT-A testing thus represents a lucrative market.

A rather convincing sales pitch is that it would be wiser for patients to spend a bit more on PGT-A, rather than risking the trauma of aborting a genetically abnormal foetus, or spending more money on the special education and health care needs of a Down Syndrome child.

Nevertheless, many local IVF patients are often ignorant that the PGT-A technique has been given a **red light rating**

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(indicating caution) in the United Kingdom, with regards to its ability to improve IVF success rates.

Additionally, patients must also be made aware of ongoing class-action lawsuits against PGT-A in the United States, where it has been identified as the most glaring and widespread example of fraud within the IVF landscape.

These lawsuits are underpinned by substantial evidence suggesting that PGT-A tests are often inaccurate and based on flawed assumptions, and that their effectiveness is often overstated, raising ethical and financial concerns for IVF patients.

Additionally, the practices surrounding PGT-A testing do not sufficiently disclose the **inherent risks** to patients, such as the potential for misdiagnosis and the risk of embryo damage due to the extraction of cells for genetic testing (biopsy).

Although some published clinical studies have demonstrated that embryos are not harmed by the biopsy procedure, these results were often based on good-quality embryos from younger women.

Older women tend to produce fewer lower-quality embryos that are more vulnerable to damage by biopsy.

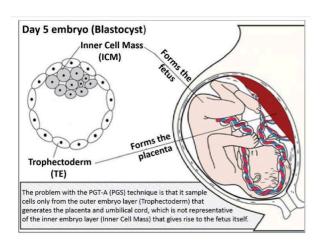
Moreover, the busier the IVF lab, the greater the risks of human error damaging the embryo during the delicate biopsy procedure.



Because the biopsy process involves taking cells only from the outer embryo layer that forms the placenta and umbilical cord, but not the baby itself, this can sometimes yield inconclusive or misleading results, making treatment decisions complicated.

Moreover, PGT-A may inadvertently reduce the chances of a successful pregnancy, as it often results in **fewer embryos** being available for transfer.

Potentially viable embryos erroneously deemed to be 'abnormal' may be discarded, thus lowering overall IVF success rates.



The lawsuits, initiated by national class action law firm Berger

Montague LLC, along with cocounsel Constable Law LLC and Justice Law Collaborative LLC, target multiple genetic testing companies, including CooperGenomics Inc, CooperSurgical Inc, The Cooper Companies Inc, Reproductive Genetic Innovations LLC, Progenesis Inc, and Natera Inc.

These companies regularly advertise PGT-A as a genetic test for evaluating the normality of human IVF embryos by screening for chromosomal abnormalities.

In the US, IVF patients are often encouraged to add on PGT-A as an additional screening test, which can cost several thousand dollars and is typically not covered by insurance.

The complaints assert that the defendants have provided misleading information regarding the accuracy of PGT-A testing, thus making them complicit in consumer fraud and breach of warranty.

To date, several large clinical trials have already demonstrated that PGT-A does not significantly improve IVF outcomes, and that it is unproven, unreliable, experimental, and inaccurate.

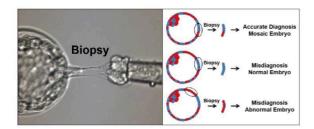
Such essential information was not disclosed to vulnerable patients charged with making critical decisions about which embryos to transfer based on the test results.

This has potentially prevented patients from making fully informed decisions, raising ethical concerns regarding transparency and patient autonomy.

The case also highlights that PGT-A testing often lead to false negatives, whereby **mosaic embryos** containing a mixture of

genetically normal and abnormal cells, which can potentially give rise to a healthy baby, are mistakenly identified as unsuitable for transfer and are therefore discarded.

This created emotional distress for patients who were previously unaware that viable embryos have been lost due to inaccurate testing, while also diminishing their opportunity for a successful pregnancy.



The plaintiffs thus seek to recover their out-of-pocket costs spent on PGT-A. Additionally, there are also statutory claims and other damages resulting from the defendants' allegedly false and misleading promotion of PGT-A.

Many former IVF patients claim that they would not have purchased the test if they had been provided with more accurate information regarding its effectiveness and potential risks, including misdiagnosis and embryo damage during biopsy.

Even so, the use of PGT-A has increased significantly. From 2014 to 2021, the utilisation of PGT-A increased from being used in 13 per cent of IVF cycles to approximately 40 per cent of IVF cycles, thus generating hundreds of millions in revenue for the companies that sell these tests.

Paula Bliss, partner and cofounder of Justice Law
Collaborative LLC and counsel for the plaintiffs, emphasized the serious consequences of the misleading information, stating, "Our clients have been forced to make consequential decisions based on PGT-A testing that was falsely marketed as having unproven benefits... we seek justice on their behalf."

Allison Freeman, managing partner of Constable Law LLC, highlighted the motivation behind these lawsuits, asserting that they aim to hold the industry accountable: "We have filed these class-action lawsuits to seek accountability in an industry that seems to be increasingly guided by financial gain.

"As someone who personally utilised fertility treatments, I know what it is like to experience IVF and seek medical assistance to build a family.

"Members of this widening community should not be taken advantage of with misleading and deceptive assurances when they are at their most vulnerable state and are entitled to damages under consumer fraud statutes."

Shanon J. Carson, a shareholder at Berger Montague LLC, remarked, "We are committed to litigating these vital cases for our clients and others throughout the nation who have paid for PGT-A as part of their IVF cycles, and we seek to hold the defendants accountable for the damages they have caused."

In summary, the plaintiffs argue that these companies misled patients for monetary profit, exploiting their desperation during a vulnerable moment in their lives when they were struggling with infertility.

There have been gross violations of the core principles of the healthcare industry, including

"non-maleficence" and "first, do no harm".

Hence, they are seeking not only financial reimbursement for their financial expenses but also punitive damages for the emotional and psychological distress caused by misleading marketing practices.

As legal actions unfold, Berger

Montague LLC and its cocounsels also plan to file similar
lawsuits against additional
companies such as Ovation
Fertility and Igenomix.

With the ongoing debate over how to regulate IVF add-ons like PGT-A, which includes discussions around their safety, efficacy, and marketing practices, this issue continues to gain international attention, highlighting the need for transparency and accountability within the reproductive health sector.

In a **similar lawsuit** in Australia, the fertility giant Monash IVF has agreed to a payout of A\$56 million to compensate 700 former IVF patients who had their viable embryos destroyed due to inaccurate genetic testing, which

had robbed many of them of their chances of motherhood forever.

This lawsuit highlighted the heartbreaking consequences that can result from reliance on flawed genetic testing procedures, leaving many patients with unresolved grief.

It is hoped that the Ministry of Health will pay close attention to such legal developments on PGT-A at the international stage and impose stringent regulations at home to avoid the occurrence of such mishaps in Malaysia.

This may involve implementing stricter standards for genetic testing, requiring transparency in advertising practices, and ensuring that patients receive comprehensive information related to the risks and limitations associated with PGT-A.

Dr Alexis Heng Boon Chin is an associate professor of biomedical sciences at Peking University. Dr Rosazra Roslan is a medical lecturer and assistant professor at International Islamic University

Malaysia. Dr Sayyed Mohamed Muhsin is an expert in Islamic jurisprudence and an assistant professor at International Islamic University Malaysia.

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