

**Impact case study (REF3b)**

<p><b>Institution:</b> Queen’s University Belfast</p>
<p><b>Unit of Assessment:</b> 32 - Philosophy</p>
<p><b>Title of case study:</b> Leadership of Fertility Treatment and Embryo Research in the UK</p>
<p><b>1. Summary of the impact</b> (indicative maximum 100 words)</p> <p>The Human Fertilisation and Embryology Authority (HFEA) regulates a central domain of current biotechnological practice: fertility treatment and embryo research. Appointed as the only philosopher on an Authority of 12 members and as Deputy Chair of the HFEA’s Ethics and Law Advisory Committee Archard has provided ethical advice on all new biotechnological developments affecting those tens of thousands of prospective parents seeking fertility treatment. As Chair of its Statutory Approvals Committee he has developed guidelines for the licensing of Pre-Implantation Genetic Diagnosis (PGD) that allows thousands of couples to avoid transmitting serious genetic conditions to their children.</p>
<p><b>2. Underpinning research</b> (indicative maximum 500 words)</p> <p>In January 2013 the Government retained the HFEA as an independent regulator with sole authority for the statutory review of fertility treatment and human embryo research throughout the United Kingdom. The independent review of the Human Tissue Authority and HFEA by Justin McCracken in July 2013 recommended the continued independent existence of the HFEA. Its role is to protect patients and the public interest, to drive improvement in the treatment and research sectors, and to provide information to the public and policymakers about treatment and research.</p> <p>Archard’s original appointment to the HFEA in November 2005, and his re-appointment in December 2012 as the sole moral philosopher on the Authority was made in recognition of his internationally distinguished research in moral, legal and political philosophy.</p> <p>Archard’s published research since his appointment at QUB on June 1<sup>st</sup> 2012 confirms his reputation and distinctive role within the Authority. This research also supplies key and original insights of direct relevance to his work on the Authority. These concern the significance of a best interest principle as determinative of law and policy in respect of children, and the nature of the role of philosophers in collective decision-making in non-ideal circumstances.</p> <p>The principle of best interest is controversial, and is charged, famously, with being ill-defined and indeterminate. Archard’s work has sought to explicate the principle and to evaluate its proper limits, especially in relation to other regulative principles, such as the presumptive rights of parents over their own children, the public good, and the right of a child to have its views in respect of its own interests given appropriate weight. The welfare of the child provision is a key constraint in the regulation of fertility treatment. It is also critically relevant to the interpretation of PGD licensing, where the relevant statutes demand that only where children are at ‘significant risk’ of ‘serious conditions’ can a genetic abnormality be licensed.</p> <p>Archard has also conducted underpinning research into the proper role of the normative theorist in developing and implementing public policy. This has resulted in important and entirely original work on the nature of ‘moral compromise’ and on the complicity of the public in the morally sub-optimal decisions of law makers.</p> <p>Applied normative theorists trying to change the law and policy in the light of their own theory must acknowledge that any such changes can only be managed in non-ideal contexts. Crucially philosophers must make decisions conjointly with non-philosophers and in circumstances where the views of any individual philosopher need not have any especial or determinative weight. Archard acts as one Member but the sole philosopher on the Human Fertilisation and Embryology Authority. The specific and distinctive nature of that contribution is acknowledged. His research on ‘moral compromise’, the ‘moral authority’ of the philosopher, and complicity in non-ideal collective decision-making, all directly contribute to the manner in which he has discharged the critical role of Chair of the</p>

Licence, and then Statutory Approvals Committee, guiding its collective deliberations to the fair and proportionate licensing of genetic conditions.

**3. References to the research** (indicative maximum of six references)

- (1) D. Archard, 'Moral Compromise,' *Philosophy*, 87, No. 341 (July 2012): 403-420  
Contribution to a peer-reviewed journal  
Publication is in a leading A-ranked philosophy periodical.
- (2) D. Archard, 'Dirty Hands and the Complicity of the Democratic Public,' *Ethical Theory and Moral Practice*, 2012  
Contribution to a peer-reviewed journal  
Publication is in a leading A-ranked philosophy periodical.
- (3) D. Archard, 'Children, Adults, Best Interests and Rights,' *Medical Law International*, Special Issue 'Best Interests and Rights,' 13:1 (March 2013): 55-74  
Contribution to a peer-reviewed journal.

**4. Details of the impact** (indicative maximum 750 words)

In 2013 Archard was re-appointed after 7 years' service as one of twelve members of the Authority and as its sole philosopher. In 2013 the Government reversed its decision to abolish the Authority in acknowledgement of its importance in shaping policy and practice at a national level. The HFEA's example of regulation and licensing has been hugely influential on other regulators of fertility treatment and embryo research throughout the world.

Archard's role on the Authority is three-fold, and in all three aspects his expertise as a moral philosopher is critical.

First, he provides ethical oversight of all of its policy and regulatory decisions. He thereby influences professional standards and behaviour within the fertility sector, and provides expert guidance to Government. Ensuring that the Authority acts in an ethically appropriate manner retains public confidence in its key regulatory role and Government contentment with delegation of that role to an independent body. The Chief Executive of the HFEA comments that 'his voice is listened to with great respect and he is one of the Authority's most influential members'.

Archard has been prominent in discussion of every major HFEA issue over the last seven years, thereby influencing critical debates in public policy.

This has included the appropriateness of making payments to gamete donors, where his 'lone' dissenting voice was reported in the national press

(<http://www.telegraph.co.uk/health/healthnews/8836470/Egg-donors-to-receive-750-flat-fee.html>),

and the debate on the licensing of the treatment of mitochondrial conditions, a new and morally controversial procedure. Archard made critical changes to the final consultation document submitted to the Government. As a result of the decision taken in March 2013 by the Authority the door is now open to the United Kingdom being the first and perhaps only government to allow research into such treatment. ([http://www.huffingtonpost.co.uk/2013/03/20/three-parents\\_n\\_2917206.html](http://www.huffingtonpost.co.uk/2013/03/20/three-parents_n_2917206.html))

Second, Archard has brought the insights of moral philosophy into direct relation with all those stake-holders affected by the general decision-making of the Authority, thereby contributing to widening public access to and participation in the political process. Thus he has convened and chaired workshops on the ethical aspects of key Authority policy, such as that on the morality of gamete donation (<http://www.bica.net/external-event/ethical-issues-gamete-and-embryo-donation>) and contributed to workshops with clinics on PGD.

Third, Archard has performed a particular licensing role. In 2013 the HEFA delegated the authorisation of pre-implantation genetic diagnosis, of the export and import licences for gametes, and of the use of any novel or controversial processes in fertility treatment to a small

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Statutory Approvals Committee, chaired and guided by Archard, meeting monthly.

The Committee is legally authorised to license the testing of embryos to detect genetic conditions by means of Pre-Implantation Genetic Diagnosis (PGD). The statutory test that must be met before a licence can be approved is that the embryos being tested are at 'significant risk' of inheriting 'serious genetic conditions'. The Human Fertilisation and Embryology Act (1990) does not specify what is 'significant' or 'serious'. Understanding, interpreting and applying this test is down to the Committee Archard directs, which is in effect an expert panel determining official policy in this area on behalf of the Government.

Archard ensures that decisions are fair, proportionate, protect the best interests of all children, are morally and legally permitted, and are the best possible within the context of non-ideal decision-making. This work has been directly informed by his own research on the ethics of procreation, the best interests of children, and the appropriate role of ethical theory in collective decision-making. Well over a hundred such genetic conditions – including Alzheimer's, Beta Thalassaemia, Huntington Chorea, Muscular Dystrophy, and Sickle Cell Anaemia - have now been licensed and around five new conditions are submitted for license approval monthly.

The impact of this work has been on thousands of prospective carrier or affected parents who have been able to avoid the transmission of serious genetic conditions to their children, and on all those children born without the conditions in question. It has also determined the scope of the lawful work that may be done by fertility clinics licensed in the United Kingdom to perform PGD. It has impacted upon the work of the Government thereby able to delegate decision-making to the Authority, and upon a general public that can retain its confidence in the proper regulation of the uses of biomedical developments. The Chief Executive of the HFEA reports, 'that we have not been challenged [in the courts] to date is testimony to the quality of decision-making and the skills of Professor Archard as Chair.'

**5. Sources to corroborate the impact** (indicative maximum of 10 references)

[www.hfea.gov.uk](http://www.hfea.gov.uk) provides comprehensive evidence of the regulative activities of the Human Fertilisation and Embryology Authority. In particular:

Archard's membership of the Authority is set out at

<http://www.hfea.gov.uk/Authority-members.html>

His role as Chair of the Licence Committee is to be found at

<http://www.hfea.gov.uk/Licence-Committees.html>

Baroness Deech's letter to the Guardian summaries the importance of the HFEA's continued regulatory role:

<http://www.guardian.co.uk/commentisfree/belief/2011/feb/09/hfea-regulation-public-confidence>

The list of PGD conditions licensed by the Licence Committee that Archard chairs is to be found at: <http://www.hfea.gov.uk/cps/hfea/gen/pgd-screening.htm>

Letter on file from Chief Executive, HFEA