Volume **5** (2) 2023 https://doi.org/10.5204/lthj.3083

The Independent Medicines and Medical Devices Safety Review: Regulatory Reform and Remedies

Sonia Macleod
Centre for Socio-Legal Studies, University of Oxford, United Kingdom

Abstract

For years, groups of patients and their families in the United Kingdom raised their concerns about three medical interventions. The first was a possible link between hormone pregnancy tests and fetal malformations and deaths; the second was the physical and neurodevelopmental impacts of in utero valproate exposure; and the third was life-changing adverse events caused by pelvic mesh implants for pelvic organ prolapse repair and stress urinary incontinence management. In response to their tireless campaigning, the Independent Medicines and Medical Devices Safety (IMMDS) Review was commissioned by the Secretary of State for Health and Social Care in 2018. The review, chaired by Baroness Cumberlege, found a catalogue of institutional, systems and structural failures within both the medical establishment and healthcare system more broadly.

Drawing on the IMMDS Review findings on pelvic mesh, in this article, I consider the dire consequences when medical devices go wrong. Drawing on firsthand experience as lead researcher for the IMMDS Review, I examine some of the background, outline some key findings and reflect on the strategic changes recommended to medical device regulation and the redress prompted by the pelvic mesh scandal. In so doing, I contextualise and consider the relevant regulatory frameworks, the fundamental systems failures and the other issues identified. Three years on, this article also provides an opportunity to assess the extent to which the IMMDS Review recommendations have been successfully operationalised, as well as to take stock of the improvements that still need to be made.

***Keywords**:* Medical device; adverse event; regulation; redress; compensation.

1. Introduction

In the United Kingdom (UK) the Independent Medicines and Medical Devices Safety (IMMDS) Review (also known as the Cumberlege Review) concluded in July 2020, publishing its findings in a lengthy and hard-hitting report.[1] The IMMDS Review took place to investigate the way concerns relating to the effects of three medical interventions had been handled. These were: (1) a possible link between hormone pregnancy tests (HPTs including Primodos) and fetal malformations/deaths, (2) the physical and neurodevelopmental impacts of in utero valproate exposure and (3) life-changing adverse events caused by pelvic mesh implants. The report—*First Do No Harm*—outlined a litany of institutional, systems and structural failures within both the medical establishment and healthcare system more broadly. In the report press launch, IMMDS Review Chair Baroness Cumberlege pointedly noted:

> In our research we have been astonished how the healthcare system – which includes the NHS, private providers, the regulators and professional bodies, manufacturers, and policymakers – is disjointed, siloed, unresponsive and defensive. It does not adequately recognise that patients are its sole purpose. It has failed to listen to their concerns.[2]

As the lead researcher on the review, I heard firsthand the concerns of those affected by these interventions. In this article, I reflect on these and on the findings of the review; in particular, I focus on the only medical device included in the review, pelvic mesh. The effect of mesh injuries cannot be underestimated. In the press conference speech, Baroness Cumberlege described the impacts on women the review team had met:

[1] IMMDSR, First Do No Harm.
[2] IMMDSR, "Baroness Cumberlege's Press Conference Speech," paragraph "à."

> An operation they thought would cure them has ruined their lives. They have lost their independence, their careers, life partners, sex life, even their ability to go for a walk. Their relentless physical pain is like razors inside their body. They feel helpless, alone, and ignored. Some have suicidal thoughts.[3]

At the very beginning of the review, in 2018, recognising the appalling suffering of those affected, the review called for a pause on all operations using pelvic mesh for the treatment of stress urinary incontinence (SUI).[4] The pause was to be lifted if a (very specific) set of conditions were met. By the end of the review, these conditions had not been met. As of the time of writing, these conditions still have not been met in full.

In this article, we will see the dire consequences when medical interventions go wrong and consider the need for redress and regulatory reform. To these ends, the article is structured as follows. Section 2 provides some background on the events that led up to the IMMDS Review, including the introduction of pelvic mesh products onto the market and the medical device regulatory framework against which this sat. Section 3 moves on to discuss the IMMDS Review and its findings. There, we will see that the review found that some women who received pelvic mesh implants suffered numerous serious adverse events. In this section, I also explore the causes for the increase in mesh implantation surgery, the commercial interests of manufacturers and the lack of disclosure of risks to patients (some of whom were not even aware they were receiving mesh implants).

Having provided a clear understanding of the harms caused by pelvic mesh implants and explored why their use increased, Section 4 provides an overview of the redress mechanisms that were available to women harmed by pelvic mesh implants. Principally, these were support via the welfare system offered by the Department for Work and Pensions and compensation from litigation. What will become apparent is that these mechanisms were inadequate for the task at hand, both individually and collectively. These failures set the stage for Section 5, in which I outline the IMMDS Review's nine recommendations for improvement. As part of this, I critically assess the UK government's response and the extent to which the recommendations have been implemented, noting what lessons have been learned and improvements made, as well as examining further avenues for redress and regulatory reform.

2. Background: The Use and Regulation of Pelvic Mesh

2.1 Pelvic Mesh Use: Evolution and Concerns

Pelvic mesh is inserted either through an incision in the abdomen (transabdominal) or through an incision in the vagina (transvaginal) to treat SUI and/or pelvic organ prolapse (POP). SUI is involuntary urination when the bladder is under pressure. SUI ranges from a mild leakage to a debilitating condition when even low-pressure activities such as standing up cause significant leakage. Most pelvic mesh surgery carried out in the UK was to treat SUI. POP occurs when one or more organs (the bladder, rectum, uterus or, post-hysterectomy, the vaginal vault) drop out of their normal position, prolapsing into the vagina. A small proportion of UK pelvic mesh use was in ventral mesh rectopexy to treat rectal prolapse in men and women. The vast majority of UK POP mesh use was to treat women. SUI and POP mesh will be examined in turn.

During the 1960s, surgeons began to treat severe SUI using 'slings' to support the bladder neck. Early slings were bespoke, created in the operating theatre from various materials, including the patient's own tissue (autologous slings), cadaverous tissue or flat sheets of mesh. These bespoke slings prompted device manufacturers to develop preshaped sling kits made from synthetic mesh. Kits saved time, were easier to use and removed the risk of disease transmission from cadavers. The first commercial SUI kit, Boston Scientific's ProteGen Sling, was cleared by the Food and Drug Administration (FDA) and launched in the United States (US) in November 1996; it contained a preshaped polyester mesh sling and inserters. SUI kits by other manufacturers, marketed on the basis they were equivalent to the ProteGen Sling, quickly followed. In 1998, Ethicon's polypropylene tension-free vaginal tape (TVT) was launched in the UK. In 2001, the TVT-Obturator (TVT-O) variant was introduced. TVT-O sling 'arms' exit through the groin via the obturator foramen rather than exiting via the abdomen as the TVT does. The TVT-O is harder to remove than a TVT and is associated with higher levels of serious adverse events.[5]

In 1999, the ProteGen Sling was voluntarily recalled due to higher-than-expected rates of mesh erosion into pelvic organs and wound reopening. This recall did not trigger any regulatory response for the daughter devices. This is not unusual, with Everhart et al. estimating that 4.3% of US medical device clearance applications cite a recalled predicate device.[6] However, from 1999 onwards, 'all' of the mesh kits for SUI were marketed on the basis of equivalence originally derived from a device that was

[3] IMMDSR, "Baroness Cumberlege's Press Conference Speech," paragraph 15.
[4] IMMDSR, "Baroness Cumberlege's Press Conference Speech," paragraph 10.
[5] IMMDSR, First Do No Harm, paragraph 5.55.
[6] Everhart, "Association Between Regulatory Submission Characteristics."

recalled because it was harmful. There was thus an early opportunity for regulatory action, but none was taken. Had regulators acted to establish the complication rates in the daughter devices for the treatment of SUI, it is likely far fewer women would have been exposed to the risk of life-changing mesh injuries.

Ordinarily, POP repairs use larger areas of mesh than SUI mesh operations. During the 2010s, concerns over adverse events led to increasing restrictions on transvaginal mesh POP surgery. Risk factors included: (i) contamination during transvaginal insertion as the vagina cannot be disinfected and (ii) the larger surface area of a POP mesh having greater potential for foreign-body reaction and inflammatory immune reactions when implanted. In 2011, an FDA public health notice concluded that serious adverse events relating to mesh were 'NOT' rare.[7] Using their powers under Section 522,[8] the FDA ordered studies. In 2016, transvaginal POP kits were reclassified as Class III—the highest risk.[9] In April 2019, the FDA stopped the sale and distribution of these kits.[10]

In the European Union (EU) and the UK, a similar story developed, whereby recognition of serious adverse events was followed by increasingly cautionary advice and guidance over transvaginal POP mesh. In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) commissioned the 2012 York Report[11] and, in 2014, published its own summary.[12] These reports recommended caution when using transvaginal POP mesh but said that SUI mesh was safe. The 2015 EU Scientific Committee on Emerging and Newly Identified Health Risks opinion reached broadly similar conclusions: that transvaginal POP repair should only be considered when non-mesh repair had failed but that SUI mesh was safe.[13] Some EU member states continue to follow this advice. Others, such as France, have further restricted transvaginal POP mesh use. The 2017 Scottish Transvaginal Mesh Implants Independent Review,[14] using the results from the PROSPECT (**PRO**lapse **S**urgery: **P**ragmatic **E**valuation and randomised **C**ontrolled **T**rial) study,[15] recommended stopping transvaginal POP mesh surgery. The National Institute for Health and Care Excellence (NICE) guidance[16] was promptly changed, restricting transvaginal POP mesh surgery to research trials only, effectively preventing UK usage.

2.2 Regulating Medical Devices

To contextualise how the use of a device that has caused such harm became so widespread, we need to understand medical device regulation, which lags behind pharmaceutical regulation. Statutory regimes for pharmaceuticals predate medical device regulations by 42 and 30 years, respectively, in the US and EU.

US medical device regulation started in May 1976.[17] Products already on the US market in 1976 were grandfathered in and continued to be marketed without any additional checks. Under the legislation, low-risk devices can be placed on the market without premarket review; all other devices need to be either approved or cleared for sale. The premarket approval process requires significant technical device-related data.[18] Clearing under the 510(k) process is lighter touch and allows a device to be marketed on the basis that it is equivalent to a product that is already on sale. The risk category into which a device falls determines the route to market. Class I devices, such as plasters, present minimal risk and do not require any premarketing review. Class II devices present a moderate risk to the user. Class II devices require either premarket approval or clearing. Class III devices present the highest risk and include devices that sustain or support life, are implanted or carry a high potential to cause illness or injury.[19] Class III devices must use the premarket approval route unless they have a humanitarian device exemption.

Pelvic mesh kits were launched as Class II devices and mostly used the 510(k) approval route.[20] Many mesh kits claimed equivalence to flat surgical meshes, most of which had limited testing as they were grandfathered in. In 2012, amid growing concerns, particularly over transvaginal POP mesh, the FDA announced that it was considering reclassifying pelvic mesh as a

[7] FDA, Public Health Notification: Urogynecologic Surgical.
[8] *Food Drug and Cosmetics Act*, 21 USC §3601, Section 522.
[9] FDA, "Classify Your Device."
[10] FDA, "FDA's Activities: Urogynecologic Surgical Mesh."
[11] Mahon, Medicines and Healthcare Products Regulatory.pma
[12] MHRA, A Summary of the Evidence.
[13] SCENIHR, Opinion on the Safety.
[14] Scottish Independent Review, Final Report.
[15] Glazener, "Mesh, Graft, or Standard Repair."
[16] NICE, Transvaginal Mesh Repair.
[17] *Medical Devices Amendments 1976*, subpart D.
[18] Title 21 of the Code of Federal Regulations, paragraph 814.20.
[19] *Medical Devices Amendments 1976*, 90 stat 5394.
[20] Voreacos *'J&J sold vaginal mesh implant without regulatory approval'*

Class III device. To inform this decision, on 3 January 2012, the FDA ordered mesh manufacturers to carry out Section 522 postmarketing safety and efficacy studies.[21] On 5 January 2016, transvaginal POP mesh was reclassified as Class III. Transabdominal POP mesh and mesh used to treat SUI remained Class II. As noted earlier, on 16 April 2019, on the advice of the Obstetrics and Gynaecology Devices Panel, the FDA determined that the risks of transvaginal POP mesh kits outweighed the benefits and issued an order to stop their sale and distribution.

Regulation in the EU trailed the US. The first pan-European statute, the *Medical Devices Directive* (MDD),[22] was not mandatory until June 1998. Although the MDD was recently replaced by the EU *Medical Devices Regulation* (MDR),[23] which has updated and tightened the requirements across a number of areas, the general structure of the EU regulatory system remains unchanged. Under EU law, medical devices are certified to show they meet legal requirements on safety and performance. Once the statutory requirements are met, the manufacturer can CE mark the device and sell it throughout the EU without further checks. The EU framework also uses device classes.[24] Class I devices are low-risk devices that do not interact with the body. Class IIa—medium risk—is limited to interacting with natural orifices and may involve power, for example, hearing aids. Class IIb—medium risk—includes most surgically active devices, and most partially or totally implantable devices. Class III—high-risk—includes devices that support/sustain life, significantly prevent health impairment or have a high potential to cause illness/injury. Certification for implantable medical devices can be awarded either by putting the device through premarket testing to establish safety and performance in a clinical investigation or by demonstrating equivalence to a device that is already on the market in a clinical evaluation. Clinical investigations are scientific and clinical testing of device performance once implanted and are carried out according to legislative requirements. Clinical evaluation reports review the published literature on clinical experience with the applicant device or a similar equivalent device (a predicate device) that is already in use. Clinical evaluation reports based on equivalence must detail how the device seeking certification is equivalent to the predicate. All devices except Class I devices require a notified body for the certification processes. The notified body checks device compliance with relevant legislative requirements. The notified body must assess the quality system, including premarket testing, clinical investigations/evaluations, manufacturing processes and postmarketing vigilance systems. Under the MDD, pelvic mesh kits were classified as Class IIb. They were most likely certified based on equivalence, but there are no centralised resources to confirm this. Under the new EU MDR, pelvic mesh was reclassified as a Class III device.

The UK was governed by the EU framework, transposed into British law,[25] until 31 January 2020. As a transitional measure, the provisions that were in force when the UK left the EU remain in place, with the exception of Northern Ireland (NI).[26] As such, Great Britain (GB; England, Wales and Scotland) is governed by the MDD-derived provisions contained in the *Medical Devices Regulations 2002*. Meanwhile, due to the agreement in place between the EU and UK via the Northern Ireland Protocol, NI is governed by the EU MDR (again via the provisions of the 2002 regulations, as amended).[27] CE-marked products can still be supplied to the GB market. When the UK left the EU, pelvic mesh was a Class IIb device. The current GB classification of pelvic mesh as medium risk (Class IIb) is out of step with the high-risk classification applied in the EU and the US. Dame June Raine, chief executive of the MHRA, has confirmed that pelvic mesh will become Class III[28] when the new UK regulatory system is created. Until then, this disparity is ameliorated by the pause on SUI mesh surgeries (more on this in Section 3).

International medical device regulation systems vary, but there are important commonalities relating to pelvic mesh. First, pelvic mesh was marketed based on equivalence. The interpretation of equivalence for pelvic mesh has been the subject of criticism. In the EU, for instance, the ProteGen Sling was used as a predicate device for the Ethicon TVT.[29] This is despite the ProteGen Sling never having been marketed in Europe. This has been changed by the MDR, which requires a predicate device to have been marketed within the EU. Another well-known equivalence issue is 'product creep',[30] whereby iterative changes in each generation of daughter devices mean that, over time, daughter devices can become far removed in design, materials and indeed functionality from the original predicate. Product creep has also been addressed in the EU MDR, which now contains

[21] *Food Drug and Cosmetics Act*, section 522.
[22] Medical Devices Directive 93/42/EEC.
[23] *Medical Devices Regulation (EU) 2017/745*, as of 26 May 2021 (a year after its original intended implementation date due to the COVID-19 pandemic see *Amending Regulation (EU) 2020/561*).
[24] *Medical Devices Regulation 2017/745*, art 51; *Medical Devices Directive 93/42/EEC*, Annex I; MDCG, Guidance on Classification of Medical Devices.
[25] Medical Devices Regulations 2002, SI 2002 no 618.
[26] *The Medical Devices (Amendment) (EU Exit) Regulations 2021*, SI 2021 no 873. See Quigley "The Shape of Medical Device Regulation in the United Kingdom?"
[27] MHRA, Guidance: Regulating Medical Devices; Quigley "The Shape of Medical Device Regulation in the United Kingdom?"
[28] Health and Social Care Select Committee, Follow-up Report, 7.
[29] IMMDS Review, Written Evidence, attachment 1.
[30] Lefkovich, "Identification of Predicate Creep."

much tighter equivalence requirements overall.[31] Second, across different regulatory systems, and as we saw earlier, risk classification changed over time. In the US and EU (including the UK), all pelvic mesh products were initially considered to be medium risk. Thus, there was no differentiation between the risks posed by transabdominal and transvaginal mesh kits or between POP kits POP and SUI kits. Mesh products were marketed for years before regulators reclassified them as high risk. Now that we have a background understanding of medical device regulation in the US, EU and UK, in the next section, I explore the developments that led to the IMMDS Review.

3. Pelvic Mesh Use and the IMMDS Review

The IMMDS Review was commissioned because campaigners felt that the frequency and severity of adverse events associated with pelvic mesh use had been neither understood nor acted upon by the healthcare system. This section explores why this may have been the case.

3.1 Adverse Events Following Pelvic Mesh Surgery

Mesh complications raised with the IMMDS Review included pain, recurrent infections, mobility issues, recurring or new incontinence/urinary frequency, recurring or new prolapse, haemorrhage, bowel issues, erosion of the mesh into the vagina and/or other organs, sexual difficulties, autoimmune issues and psychological impacts. In some cases, coroners mentioned mesh complications at inquests into deaths. Regulatory awareness of the existence of mesh complications was longstanding; for example, the FDA's October 2008 public health notification into transvaginal mesh stated:

> The most frequent complications included erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence. …In some cases, vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia.[32]

In addition to direct mesh complications, a number of wider impacts were reported to the IMMDS Review, including relationship and family breakdown, unemployment, loss of a home and financial hardship.

Pelvic mesh adverse events could develop immediately post-operatively or many years after the surgery. In his foreword to National Health Service (NHS) England's 2017 *Mesh Oversight Group's Final Report*, Professor Keith Willett identified widespread dismissal of women's concerns following pelvic mesh surgery: 'These women felt their concerns had been ignored'.[33] This mirrors the IMMDS Review's findings on the failure to gather appropriate outcomes data:

> Time and time again women told us that those conducting follow-up research only asked about selected outcomes, often only surgical outcomes. For example, in following up SUI surgery, they asked about continence. Objective surgical outcomes are vital, but so are patient-reported outcomes. The women tell us that questions were not asked about other important outcomes, such as pain or sexual functioning. Information on risks and complications is incomplete and not representative.[34]

First Do No Harm sets out plainly that the absence of information on the true rates of mesh complications is due to a lack of vigilant, long-term monitoring:

> The system does not know, so neither do we, just how many women have been treated for stress urinary incontinence and the repair of pelvic organ prolapse using polypropylene mesh. The system does not know, so neither do we, how many women have been cured of their incontinence, or been successfully treated for their prolapse – only then to experience a long list of life-changing conditions that include loss of sex life, chronic pain, infection, difficulty voiding, recurrent urinary incontinence, permanent nerve damage or damage to surrounding organs, haemorrhage, autoimmune disease and psychiatric injury ....
> … In short, the system does not know the true long-term complication rate for pelvic mesh procedures.[35]

To address this lacuna, the IMMDS Review suggested a retrospective audit on patients implanted with pelvic mesh during 2010. This has been completed and is due to be published in 2023.[36] This is three years after the publication of the IMMDS

[31] MDCG, Clinical Evaluation – Equivalence.
[32] FDA, Serious Complications.
[33] Mesh Oversight Group, Mesh Oversight Group Report, forward.
[34] IMMDSR, First Do No Harm, paragraph 5.39.
[35] IMMDSR, First Do No Harm, paragraph 1.16.
[36] Health and Social Care Select Committee, Government Response, 4.

Review report and many years after such studies could, and should, have been undertaken. While this audit will provide valuable data, it does not explain why the lack of data was not addressed before and the consequences that flowed from this.

3.2 Commercial Interests, a Lack of Information and Failures of Informed Consent

Once mesh kits were launched, there was a sharp uptick in SUI surgery. Women who would not have been offered non-mesh SUI surgery were offered mesh. SUI mesh was seen as a quick, easy fix. There were also commercial interests at play. The influence of device manufacturers on clinicians was a concern to patient groups. Mesh manufacturer Ethicon held mesh up as the 'gold standard'.[37] The IMMDS Review described this term as 'a phrase that appears to have been used by so many surgeons in so many parts of the country that it could be no coincidence'.[38] A number of concerns over various conflicts of interest were raised with the IMMDS Review, including:

i. pressure from manufacturers on the Safety and Efficacy Register for New Interventional Procedures committee to reclassify the tension-free vaginal tape (TVT) as safe to use based on non–peer reviewed observational data from conference abstracts
ii. concerns over the financial interests of the inventor of the TVT
iii. funding by industry of research groups assessing the efficacy of the TVT compared to the traditional colposuspension surgery
iv. concerns about the roles of medical device representatives.[39]

The increase in harm caused by the uptick in the use of the mesh kits, in part driven by these commercial interests, was compounded by the lack of informed consent experienced by many women. The report describes the paucity of information provided to some patients. Women describe how mesh surgery risks were not raised and that alternatives were not even discussed. Some women were unaware that they were having mesh inserted, describing discussions of a POP 'repair' with no mention this involved mesh or SUI operations where surgeons referred to mesh as a 'tape', 'sling' or 'ribbon' instead. This flies in the face of good and proper medical practice, in which clinicians should inform patients about the nature of and risks associated with any procedures they are about to undergo. The 2015 case of *Montgomery v Lanarkshire Health Board* outlines that a doctor must:

> take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.[40]

A clinician has a duty to provide information on the risks and suitability of a medical device tailored to each specific patient. There is a parallel requirement for manufacturers to provide accurate, clear risk information to clinicians (learned intermediaries) to enable them to deliver individualised risk/benefit assessments. The Australian mesh litigation found that the TVT instructions for use supplied to clinicians by Ethicon did not contain a warning about dyspareunia ('Pain with intercourse which in some patients may not resolve') until 2015.[41] Ethicon had known of this risk for almost 20 years. There was a clear discrepancy between the risks known by manufacturers, who have a commercial interest in their products, and the information provided to clinicians and, in turn, to patients. Patients had a right to know about the risks of adverse events following surgery, such as permanent pain with intercourse, so they could choose whether to take that risk or not.

3.3 A Pause on SUI Mesh Surgery

Against this background, in July 2018, shortly after starting the IMMDS Review, the IMMDS Review team recommended a pause in mesh procedures for SUI. The team felt that women were being exposed to the risk of life-changing injuries without adequate information to make a fully informed decision, and measures were urgently needed to mitigate these risks. The pause was immediately enacted by NHS England and the Department of Health and Social Care (DHSC).[42] Under the pause, the use of mesh to treat SUI rapidly declined as it was only permitted in exceptional circumstances and under high vigilance. The IMMDS Review was clear:

[37] IMMDS Review, Written Evidence, attachment 1.
[38] IMMDSR, First Do No Harm, paragraph 5.51.
[39] Richards, "Regulation of Medical Device Representatives."
[40] Montgomery v Lanarkshire Health Board [2015] UKSC 11, 87.
[41] *Gill v Ethicon Sàrl (No 5)* [2019] FCA 1905, paragraph 2879.
[42] IMMDSR, First Do No Harm, paragraph 5.79.

> When the pause was put in place it was not based on new data. The pause was based on listening to existing evidence from affected women; evidence which had been available to the healthcare system for years. The IMMDS Review was formed to address the concerns raised by women, but surely others could and should have listened and taken action before.[43]

The IMMDS Review never intended to make interim recommendations. However, the pause could not wait; an immediate measure was needed to prevent further harm.

3.4 Lifting the Pause

The IMMDS Review set out the conditions required to lift the pause:

I. Surgeons should only undertake operations for SUI if they are appropriately trained and only if they undertake operations regularly;
II. They report every operation to a national database;
III. A register of operations is maintained to ensure every procedure is notified and the woman identified who has undergone the surgery;
IV. Reporting of complications via MHRA is linked to the register;
V. Identification and accreditation of specialist centres for SUI mesh procedures, for removal procedures and other aspects of care for those adversely affected by surgical mesh; and
VI. NICE guidelines on the use of mesh for SUI are published.[44]

The conditions required to lift the pause had all been suggested before but had not been consistently implemented. The IMMDS Review team's opinion was that consistent implementation of these conditions would have likely spared many hundreds, perhaps thousands, of women from mesh complications. Progress has been made on several of these conditions, such as updated NICE guidelines. Nevertheless, as I will set out below, the pause remains in place. Before looking at the substantive recommendations of the IMMDS, however, it is worth considering what was done prior to the IMMDS Review to support and compensate affected women for the substantial harm and distress caused by pelvic mesh. The answer to this, as we are about to see, is 'not enough'.

4. Redress for Harms? Preexisting Support and Compensation

To fully understand the IMMDS Review's recommendations, it is important to understand the context in which they were written. In this section, I explore the support available to affected people at the time the IMMDS Review was initiated. As we will see, there was some, albeit limited, redress available. This included health and social care provision, as well as access to compensation from litigation or other financial redress. I explore each of these in turn below.

4.1 Health and Social Care Support

Given the distress and damage caused by pelvic mesh, one might conclude that a reasonable response would be to remove it. However, pelvic mesh integrates into the recipient's tissues and is difficult to explant. There was no guidance from manufacturers in the instructions for use on how to treat mesh complications, and in the early stages, there was no body of surgical expertise. It is hardly surprising, therefore, that women told the IMMDS Review that they felt like 'guinea pigs'.[45] The IMMDS Review noted that removal surgery, particularly the removal of meshes passing through the obturator foramen, is complex, and few UK surgeons were able to perform it. Additionally, there was a lack of consensus over whether it is better to remove the entire mesh (full removal) or the vaginal portion of the mesh (partial removal); NICE guidance does not prefer one or the other.[46] This led to regional variation where some areas of the UK had provision for mesh removal and other areas did not. Therefore, the IMMDS Review team were engaged in dialogue with NHS England over the commissioning and establishment of a national specialist mesh complications service, as per Recommendation 5 below.

Injuries that impact an individual's ability to work have clear financial implications. The IMMDS Review heard of difficulties accessing a number of social security benefits and payments. Personal independence payments (PIP), tax-free payments made by the Department of Work and Pensions to assist working-age individuals with a condition or disability that impacts daily living or mobility activities, were a particular concern. Patient groups described a lack of understanding of mesh complications amongst those carrying out PIP eligibility assessments. Another concern was periodic reassessments when the PIP recipient's condition had not and/or would not improve. The IMMDS Review team discussed this with the Department for Work and

[43] IMMDSR, First Do No Harm, paragraph 5.79.
[44] IMMDSR, First Do No Harm, paragraph 5.8.
[45] IMMDSR, First Do No Harm, paragraph 5.94.
[46] NICE, Urinary Incontinence and Pelvic Organ.

Pensions, who, with input from affected groups, developed condition insight guides for PIP assessors to use.[47] In Scotland, PIP is being replaced with the adult disability payment between summer 2022 and summer 2024.[48]

In Scotland, some state-funded financial support has been made available. From 2020 to 2022, the Scottish Government provided £1,000 one-off payments for emotional or practical support for mesh victims.[49] There is also a scheme[50] to reimburse the reasonable costs of people who had paid to have their vaginally inserted mesh removed prior to the establishment of the Scottish specialist centre. England and Wales have not followed suit. Devolution and differing levels of political will may explain this variation. Usage patterns may also have contributed. The TVT-O, which is associated with higher instances of leg and groin pain than the TVT, was more commonly used in Scotland.[51]

In summary, although there was some health and social care support available to women before the IMMDS Review, the support was both patchy and largely insufficient. This leads us to the second potential avenue of redress: litigation.

4.2 Compensation from Litigation

The litigation options available to mesh-injured patients depend upon their individual circumstances. A claim can be made for clinical negligence against the healthcare provider, which can include failing to appropriately obtain informed consent. For operations performed in the private sector, there is the potential for a breach of contract claim. Alternatively, a product liability claim could be initiated against the device manufacturer. In the UK, where healthcare is provided by the state, the litigation route chosen has financial implications for the government. A successful clinical negligence claim is paid from state funds. In contrast, a successful product liability claim will be met by the manufacturer.

The UK comprises separate jurisdictions with different profiles in relation to pelvic mesh cases: (1) Scotland, (2) England and Wales and (3) NI. In Scotland, several hundred cases were brought against mesh manufacturers Johnson & Johnson.[52] In January 2020, these cases were settled on a without-liability basis for a confidential sum.[53] Meanwhile, in England and Wales, and separately in NI, various law firms have gathered potential claimants for product liability claims, but to date, there has not been a group litigation order or settlement.

The UK litigation position contrasts with other jurisdictions. In the US, it is estimated that manufacturers have paid around US$8 billion;[54] in Australia, a A$300 million settlement has been reached against Johnson & Johnson,[55] with cases against other manufacturers pending. This disparity could be due to claimants in England and Wales preferring a clinical negligence route, particularly post-*Montgomery*. The IMMDS Review noted that NHS Resolution (an arm's-length body of the DHSC that defends such claims) had handled few cases (tens per year). Since the review, NHS Resolution has received a few hundred mesh claims per year, but the number of claims remains low relative to the number of UK women implanted with pelvic mesh. NHS Resolution recently implemented two gateways to facilitate claiming by unrepresented individuals affected by pelvic mesh and valproate. As of 24 April 2023, just 16 claims (valproate and mesh) had been made to these gateways.[56] NHS Resolution aims to settle legitimate claims promptly, including settling out of court when possible. While efforts to facilitate mesh-injury claims are laudable, asking defendants to advise claimants on the viability of their claim is questionable as it creates clear conflicts of interest.

The IMMDS Review noted that litigation had not served the patient groups well. While the reasons for the relative paucity of litigation in England and Wales are unclear, what is clear is that the vast majority of mesh-affected individuals there have not received any compensation. Given this backdrop of inadequate support and redress, let us turn to the final substantive section to examine the recommendations made by the IMMDS Review. Here, I assess, three years on, what progress has been made on these and what still needs to be done.

[47] IMMDSR, "Problems with Personal Independence Payments."
[48] Public Services Scotland, "Moving from Personal Independence Payment."
[49] NHS Scotland, "About the Original Scottish Government."
[50] *Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Act 2022*, asp 1; Scottish Government, Transvaginal Mesh Removal Reimbursement Scheme.
[51] Lim, "Surgical Management of Stress Urinary."
[52] *AB vs NHS Ayrshire & Arran* and *Johnson & Johnson* 2016 CSOH 120 (Outer House, Court of Session 12 August 2016).
[53] IMMDSR, First Do No Harm, Errata.
[54] Macleod, Pharmaceutical and Medical Device Safety.
[55] Shine Lawyers, "Johnson & Johnson/Ethicon Class Action."
[56] Health and Social Care Select Committee, Government Response.

5. Preventing Future Harms and Implementing Change: The IMMDS Review's Recommendations Three Years On

The IMMDS Review report set out nine recommendations and almost 50 'Actions for Improvement'. The Recommendations and Actions for Improvement were designed to better the patient experience, improve patient safety and help restore trust in the healthcare system. As a Health and Social Care Select Committee report[57] on the implementation of *First Do No Harm* noted, while some good progress has been made, more action is needed.

In this section, I outline the recommendations, as they detail strategic changes. For ease, Table 1 summarises the recommendations and the government's response thus far. Following this, I then deal with each recommendation in turn. We will see that of the nine recommendations, only two have been fully implemented, and two were rejected, with the others falling somewhere in between.

Table 1: Government responses to the IMMDS recommendations

Recommendation		***Government Response***
1.	An apology	Accepted and implemented
2.	A patient safety commissioner	Accepted and implemented
3.	A Redress Agency	Rejected
4.	Redress schemes for those affected	Under consideration for mesh (and valproate)
5.	Specialist centres	Accepted and implemented for mesh (Not accepted for adverse effects from medicines taken in pregnancy)
6.	MHRA revision	Accepted; implementation is underway
7.	Implantable devices database	Partially accepted, with limited implementation
8.	Transparency of payments	Partially accepted but not implemented
9.	Taskforces to oversee the implementation of the recommendations	Rejected

5.1 An Apology

The IMMDS Review report was clear that the healthcare system had not responded in a robust, speedy and appropriate manner to the concerns over these three interventions. The first recommendation was that the government apologise on behalf of the healthcare system for the lack of action and the avoidable harm this had caused. On 9 July 2020, the minister for patient safety, suicide prevention and mental health apologised for the time the health and care system took to listen and respond.[58]

5.2 A Patient Safety Commissioner

The creation of a patient safety commissioner (PSC) was the second recommendation. The PSC was envisaged as a champion of the value of listening to patients who promotes users' perspectives in seeking improvements to patient safety around the use of medicines and medical devices. Baroness Cumberlege's amendment to the *Medicines and Medical Devices Bill* was accepted by the government and subsequently passed into law, creating the PSC role.[59] Dr Henrietta Hughes OBE, the first PSC, was appointed on 12 September 2022.[60]

5.3 A Redress Agency

The IMMDS Review highlighted that affected individuals' needs for compensation were seldom met by litigation. The review proposed a Redress Agency, which was intended to be forward-looking for those harmed by medicines and devices in the future. Unfortunately, this recommendation has been rejected outright. Instead, the government response has been to focus on litigation, developing new claims pathways. This is a missed opportunity: focusing on litigation claim pathways fails to address the fact that this system has not delivered for most harmed individuals.

[57] Health and Social Care Select Committee, Follow-up Report, paragraph 3.
[58] HC Deb 9 July 2020.
[59] Medicines and Medical Devices Act 2021, c.3.
[60] DHSC, "First Ever Patient Safety Commissioner."

The Redress Agency was intended to be an alternative to litigation, not to replace it, and was designed for the resolution of disputes between patients and the healthcare system. The support or redress offered could be broader than the monetary damages offered by the courts and could include both financial and nonmonetary remedies. Redress Agency decisions would be based on avoidable harm, look at systemic failings and be administered using a non-adversarial process. In order to respond to different situations, each injury type would have its own eligibility criteria and funding. Levies for pharmaceuticals and levies for devices could be paid into separate schemes. Levies would be a condition of placing a product on the UK market. Compensation would, therefore, be funded by industry, though it is likely that levies would be priced into purchasing agreements. The cost of running the Redress Agency would be jointly met by the government and industry, though the agency must be independent of both.

Litigation is risky for manufacturers; a more predictable prepaid alternative, which can provide feedback, may make the UK a more attractive market, facilitating device supply.

5.4 Tailored Redress Schemes

The IMMDS Review found that the three interventions had led to avoidable harm, and mesh had caused significant psychological and physical harm. They felt the state and manufacturers had an ethical responsibility to provide *ex gratia* payments. Each intervention was to have its own scheme with tailored eligibility criteria. These schemes were not intended to cover the costs of services already provided, such as healthcare, but were to cover additional needs, such as respite breaks, emergency payments, etc. Each scheme was to be structured in such a way that it could be incorporated into the Redress Agency at a later date.

The response to this recommendation has changed a few times. Initially, the interim government response stated that the government was considering introducing the schemes.[61] However, in the full government response to the IMMDS Review published on 26 July 2021, this was rejected.[62] Subsequently, the government's position has shifted. In December 2022, the minister for mental health and women's health strategy stated that the PSC had been asked to review redress schemes for those affected.[63] Her report is expected in Autumn 2023.

5.5 Specialist Centres

The IMMDS Review recommended creating a network of specialist centres to provide comprehensive treatment, care and advice for those affected by implanted mesh and a separate one for those affected by medications taken during pregnancy. During the review, the team held a number of discussions with NHS England about the specification for commissioning the mesh centres under NHS England's specialised commissioning framework. These centres are now up and running in England.[64] Similarly, a specialist centre has been established for Scotland.[65] There have been concerns over some of the centres, and the government response to the Select Committee inquiry states that the DHSC will continue to work with NHS England to review mesh centre outcomes and patient experience. Establishing these centres was a condition of lifting the pause, both directly and because they provide the specialist expert training for surgeons. These elements are now in place.

5.6 MHRA Revision

The IMMDS Review recommended that the MHRA needed substantial revision to both adverse event reporting and medical device regulation. Knowledge of how to report an adverse event needs to be more widespread. The IMMDS Review recommended that both medicine and device adverse events should be included in a publicly searchable database. The Yellow Card website can be searched for reports on a specific pharmaceutical, but not for medical devices. Additionally, the IMMDS Review recommended that the MHRA engage more with patients and their outcomes. In particular, to raise awareness of its public-protection roles and to ensure that patients have an integral role in its work. The pandemic and the authorisation of COVID-19 vaccines have pushed the MHRA into the public consciousness. Change is also being driven from within; MHRA's *Delivery Plan 2021-2023* [66] sets out that the agency's core purpose is delivering for patients and the intention to engage more with patients and their outcomes.

[61] HC Deb 11 January 2021
[62] DHSC Government Response to the Report of the IMMDS Review (26 July 2021)
[63] HC Deb 7 December 2022
[64] NHS England, "Specialised Services for Women."
[65] NHS Scotland, "Complex Mesh Surgical Service."
[66] MHRA, Medicines and Healthcare Products.

In the broader regulatory context, in which the MHRA takes on a central role, there are also positive developments. The IMMDS Review was published pre-Brexit when the UK was still under EU-wide regulation of medicines and devices. Transitional provisions based on the EU rules at the point the UK left the EU are currently in force. The *Medicines and Medical Devices Act 2021* contains enabling powers to reform the future UK regulatory framework but no detailed provisions. The MHRA consulted on proposals for a new medical device regulatory framework from September to November 2021.[67] The UK has opted to continue with an EU style of device regulation for GB, using approved bodies (akin to notified bodies) and competent authorities. Devices that are compliant with GB legislation will be granted a UK Conformity Assessed mark. CE-marked products are accepted on the whole UK market until 30 June 2028 if compliant with the EU MDD or 30 June 2030 if compliant with the MDR.[68]

A notable improvement from the previous EU regime is that since 2021, all devices placed on the UK market have been registered with the MHRA. A publicly searchable database[69] of medical devices on the UK market has been created. When the EUDAMED database goes live (expected to be in 2024), this will provide a similar function for the EU.

As we saw earlier, equivalence was a particular concern to the IMMDS Review. The review team wanted to see a UK regulatory system that was *at least as* stringent as the EU MDR. The MHRA consultation followed this, proposing *entirely equivalent*, which is stricter than the EU MDR. Further details are needed on *entirely equivalent* to properly assess its impact on patient safety and device availability.

As per the IMMDS Review's recommendations, the MHRA consultation suggested a more proactive role for MHRA in the premarket phase. The consultation proposed making premarket adverse event recording and reporting, including introducing extra provisions in relation to serious adverse events, more stringent.[70] The government agreed with this. This should facilitate the detection of rare events, as the MHRA would be able to use this data to look across different devices of the same type. There are also plans to strengthen postmarket vigilance requirements.[71] The responses to the consultation on mandatory adverse event reporting indicated strong support (83%) for requiring manufacturers to summarise their postmarket surveillance into a postmarket surveillance report or periodic safety update. The government is yet to offer further clarity on the requirements for postmarket surveillance plans. It is unclear whether adverse event reports received by MHRA will be publicly accessible, as the IMMDS Review suggested.[72]

However, a clear divergence from the IMMDS Review's recommendation is seen in the introduction of medical devices to the market. Prompted by the rapid upsurge in pelvic mesh use in a relatively short time, the IMMDS Review's recommended marketing approval for devices should be a staged process progressing towards wider use as more information becomes available. This precautionary approach is not in the MHRA's consultation but would merit being considered. Although some might view this slower approach as a barrier to innovation, this must be balanced against decreasing the chances of harm, such as that outlined in the IMMDS Review report.

5.7 Implantable Devices Database

The IMMDS Review recommended creating a mandatory central patient-identifiable database so patients with an implanted device could be easily traced if safety concerns were raised. Patients from the database could be asked to participate in specialist registries that focus on detailed outcomes studies for particular device types. Until this recommendation is implemented, the conditions for lifting the pause are not fulfilled.

This recommendation has been accepted, but there are concerns about how it is being implemented. A ministerial direction issued by the secretary of state mandating the capture of this information for all implantable devices has not been implemented. Instead, following a scoping exercise, it was decided to expand the coverage and breadth of existing registries, which would potentially fulfil the conditions for lifting the pause as they relate specifically to pelvic mesh devices.

However, this is not the universal implantable devices database that the IMMDS Review recommended. The government's position is that their information system 'will cover the priority medical specialities and therapeutic areas, prioritised according

[67] MHRA, Consultation on the Future Regulation.
[68] MHRA, Implementation of the Future Regulations.
[69] MHRA, Public Access Registration Database.
[70] MHRA, Government Response, paragraphs 45.1–45.2.
[71] MHRA, Government Response, paragraphs 48.1–48.2.
[72] MHRA, Government Response, paragraphs 48.1–48.2.

to patient and clinic risk'.[73] The problem with this approach is that pelvic mesh was considered a medium-risk device for many years and so would almost certainly not have been included in such a programme. Without a comprehensive database of all implantable devices, the system is arguably still 'flying blind' and risking a repeat of the pelvic mesh scandal.

5.8 Transparency of Payments

The UK does not have either a central register of clinicians' financial interests or anything akin to the American *Physician Sunshine Payment Act*.[74] The IMMDS Review made a two-part recommendation. First, the General Medical Council register should be expanded to include financial and non-pecuniary interests for doctors. Second, there should be mandatory reporting for the pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions and clinicians. Transparency of payments is key to restoring trust in the medical profession.

The government accepted this recommendation in principle, but progress has been insufficient. The government felt clinician's financial interests should be held locally by employers rather than centrally. Provision for the secretary of state to enact a sunshine payment Act was included in the *Health and Care Act 2022*;[75] it took until September 2023 for consultation to be launched. Disappointingly this consultation does not propose a compulsory centralised register of payments made by industry, instead proposing a patchwork approach of disclosure either to a voluntary centralised disclosure or on the company's own website.[76]

5.9 Taskforce

The IMMDS Review's final recommendation was to establish a task force to implement the review's recommendations. The government rejected this proposal, instead establishing a patient reference group to discuss and report on the IMMDS Review's recommendations.[77] The Patient Reference Group was advisory only, and for Recommendation 3, a Redress Agency, the group was informed in advance that the government would not be implementing this recommendation. There are, therefore, open questions about the group's ability to influence and effect change.

6. Conclusions

At the press launch, Baroness Cumberlege stated that '[t]aken together [the] Recommendations are wide ranging and radical'.[78] If, collectively, they were acted upon, they would indeed be wide-ranging and radical. There have been some positive actions, but to date, only two of the IMMDS Review's recommendations have been fully implemented. Those are Recommendation 1, the issuing of an apology, and Recommendation 2, the appointment of a PSC. Whether there is sufficient political will to implement the outstanding recommendations remains to be seen.

Pelvic mesh kits were marketed from the mid-1990s; this was not a 'historic' scandal. The fact that in 2020, the healthcare system had limited knowledge of how many women had had mesh implanted, let alone who they were, is shocking. The government's preferred choice for creating an implantable medical devices database (Recommendation 7) by expanding existing registry provision risks a similar scandal arising from some other, yet unidentified, seemingly medium-risk implantable device. The short-term gains of cost savings and lifting the pause quickly should not outweigh the long-term risks of incomplete data collection. There is an alternative course of action: utilising the existing ministerial direction would implement Recommendation 7 as intended, providing information on *all* implantable devices.

No regulatory system is perfect, and harm from medical devices will occur in the future. The IMMDS Review's recommendations aimed to care for those who are harmed and to minimise the risk of such harm. Specialist mesh centres are delivering healthcare, but other forms of redress are still needed, and the PSC's redress report (Recommendation 4) is keenly awaited. The Redress Agency (Recommendation 3) could administer any redress the PSC recommends and schemes covering future pharmaceutical and device harms. It could also rationalise government redress provision by incorporating other *ex gratia* payments such as infected blood and vaccine injury payments. Rejecting the Redress Agency maintains the current position whereby individuals harmed by medicines or devices are often unable to access the support they deserve.

[73] Health and Social Care Select Committee, Government Response page 3.
[74] Physician Sunshine Payment Act of 2009.
[75] Health and Care Act 2022, section 92.
[76] DHSC, The Disclosure of Industry Payments.
[77] Patient Reference Group. Independent Report of the Patient Reference Group.
[78] IMMDSR, "Baroness Cumberlege's Press Conference Speech," paragraph 30.

UK medical device regulation is still under development, and with that comes the chance to adapt and redefine priorities. The priority should be on ensuring that the events that led to the IMMDS Review are never repeated. Significant improvements have been made, but some risks remain, and there is scope for further positive change.

Bibliography

DHSC. *Consultation on the Future Regulation of Medical Devices in the United Kingdom* (MHRA and Sajid Javid, September 16, 2021). https://www.gov.uk/Government/consultations/consultation-on-the-future-regulation-of-medical-devices-in-the-united-kingdom.

DHSC. "First Ever Patient Safety Commissioner Appointed." July 12, 2022. https://www.gov.uk/Government/news/first-ever-patient-safety-commissioner-appointed.

DHSC. *The Disclosure of Industry Payments to the Healthcare Sector* (DHSC, September 4, 2023). https://www.gov.uk/government/consultations/the-disclosure-of-industry-payments-to-the-healthcare-sector.

DHSC Government response to the Report of the Independent Medicines and Medical Devices Safety Review (DHSC, 26 July 2021) https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1005847/IMMDS_Review_-_Government_response_-_220721.pdf

Everhart, Alexander O, Soumya Sen, Ariel D Stern, Yi Zhu and Pinar Karaca-Mandic. "Association Between Regulatory Submission Characteristics and Recalls of Medical Devices Receiving 510(k) Clearance." *JAMA* 329, no 2 (2023): 144–156. https://dx.doi.org/10.1001/jama.2022.22974.

FDA. *FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence* (FDA, October 20, 2008). https://wayback.archive-it.org/7993/20170https://wayback.archive-it.org/7993/20170111190506/http:/www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm061976.htm111190506/http:/www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm061976.htm.

FDA. *Public Health Notification: Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse* (FDA, July 13, 2011).

FDA, "Classify Your Device." Updated July 7, 2020. https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device.

FDA. "FDA's Activities: Urogynecologic Surgical Mesh." Updated October 17, 2022. https://www.fda.gov/medical-devices/urogynecologic-surgical-mesh-implants/fdas-activities-urogynecologic-surgical-mesh.

Glazener, Cathryn Ma, Suzanne Breeman, Andrew Elders, Christine Hemming, Kevin G Cooper, Robert M Freeman, Anthony Rb Smith, Fiona Reid, Suzanne Hagen, Isobel Montgomery, Mary Kilonzo, Dwayne Boyers, Alison McDonald, Gladys McPherson, Graeme MacLennan and John Norrie (PROSPECT study group). "Mesh, Graft, or Standard Repair for Women having Primary Transvaginal Anterior or Posterior Compartment Prolapse Surgery: Two Parallel-Group, Multicentre, Randomised, Controlled Trials (PROSPECT)." *Lancet* 28, no 389 (2017): 381–392. https://dx.doi.org/10.1016/S0140-6736(16)31596-3.

Health and Social Care Select Committee. *Follow-up Report on the IMMDS Report and the Government's Response: Sixth Report of Session 2022-23* (House of Commons, January 20, 2023). https://committees.parliament.uk/publications/33601/documents/183831/default/.

Health and Social Care Select Committee. *Government Response to the Committee's Report on Follow-up on the IMMDS Report and the Government's Response. Fifth Special Report of Session 2022-23* (House of Commons, April 24, 2023). https://committees.parliament.uk/publications/39130/documents/192387/default/.

Independent Medicines and Medical Devices Safety Review. *Written Evidence* (December 2018). https://immdsreview.org.uk/Evidence.html.

Independent Medicines and Medical Devices Safety Review. "Problems with Personal Independence Payments and an Opportunity to Improve the System." September 12, 2019. https://immdsreview.org.uk/news.html.

Independent Medicines and Medical Devices Safety Review. "Baroness Cumberlege's Press Conference Speech." July 8, 2020. https://immdsreview.org.uk/downloads/IMMDSReview_Baroness_Cumberlege_speech.pdf.

Independent Medicines and Medical Devices Safety Review. *First Do No Harm* (Crown, July 8, 2020). https://immdsreview.org.uk/Report.html.

Lefkovich, Charlotte, and Sandra Rothenberg. "Identification of Predicate Creep under the 510(k) Process: A Case Study of a Robotic Surgical Device." *PLoS One* 18, no 3 (2023): e0283442. https://dx.doi.org/10.1371/journal.pone.0283442.

Lim, Min Yu, Mahesh Perera, Ian Ramsey, John Tierney and Chris Hardwick. "Surgical Management of Stress Urinary Incontinence in Scotland and Wales: A Questionnaire Study." *International Journal of Surgery* 5, no 3 (2007): 162–166. https://doi.org/10.1016/j.ijsu.2006.06.018.

Macleod, Sonia and Sweta Chakraborty. *Pharmaceutical and Medical Device Safety: A Study in Public and Private Regulation.* Hart Publishing, Oxford 2019.

Mahon, James, Maria Cikalo, Danielle Varley and Julie Glanville (York Health Economics Consortium). *Summaries of the Safety/Adverse Effects of Vaginal Tapes/Slings/Meshes for Stress Urinary Incontinence and Prolapse – Final Report* (2012).

Medical Devices Coordination Group (MDCG). *Clinical Evaluation – Equivalence, A Guide for Manufacturers and Notified Bodies 2020-5* (MDCG, April 2020).
MDCG. *Guidance on Classification of Medical Devices 2021-2024* (MDCG, October 2021).
MHRA. *Public Access Registration Database*. https://pard.mhra.gov.uk/.
MHRA. *A Summary of the Evidence on the Benefits and Risks of Vaginal Mesh Implants* (MHRA, October 28, 2014). https://assets.publishing.service.gov.uk/Government/uploads/system/uploads/attachment_data/file/402162/Summary_of_the_evidence_on_the_benefits_and_risks_of_vaginal_mesh_implants.pdf.
MHRA. *Consultation on the Future Regulation of Medical Devices in the United Kingdom* (MHRA and Sajid Javid, September 16, 2021). https://www.gov.uk/Government/consultations/consultation-on-the-future-regulation-of-medical-devices-in-the-united-kingdom.
MHRA. *Government Response to the Consultation on the Future Regulation of Medical Devices in the United Kingdom* (Crown, June 26, 2022). https://assets.publishing.service.gov.uk/Government/uploads/system/uploads/attachment_data/file/1085333/Government_response_to_consultation_on_the_future_regulation_of_medical_devices_in_the_United_Kingdom.pdf.
MHRA. *Medicines and Healthcare Products Regulatory Agency Delivery Plan 2021-23* (MHRA, updated October 27, 2022). https://www.gov.uk/Government/publications/the-medicines-and-healthcare-products-regulatory-agency-delivery-plan-2021-2023/medicines-and-healthcare-products-regulatory-agency-delivery-plan-2021-2023.
MHRA. *Guidance: Regulating Medical Devices in the UK* (MHRA, updated April 28, 2023). https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#legislation-that-applies-in-great-britain.
MHRA. *Implementation of the Future Regulations* (MHRA, updated July 27, 2023). https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period/implementation-of-the-future-regulations.
Mesh Oversight Group. *Mesh Oversight Group Report* (July 25, 2017) https://www.england.nhs.uk/publication/mesh-oversight-group-report/.
NHS England. "Specialised Services for Women with Complications of Mesh Inserted for Urinary Incontinence and Vaginal Prolapse." https://www.england.nhs.uk/commissioning/spec-services/npc-crg/group-e/e09/complications-of-mesh-inserted-for-urinary-incontinence-and-vaginal-prolapse/.
NHS Scotland. "About the Original Scottish Government Mesh Fund that Closed on 30 June 2022." June 29, 2022. https://www.nss.nhs.scot/patient-support-schemes/mesh-scheme/about-the-original-scottish-Government-mesh-fund-that-closed-on-30th-june-2022/.
NHS Scotland. "Complex Mesh Surgical Service." December 13, 2022. https://www.nss.nhs.scot/specialist-healthcare/specialist-services/complex-mesh-surgical-service/.
NICE. *Transvaginal Mesh Repair of Anterior or Posterior Vaginal Wall Prolapse: Interventional Procedures Guidance [IPG599]* (NICE, December 15, 2017). https://www.nice.org.uk/guidance/ipg599.
NICE. *Urinary Incontinence and Pelvic Organ Prolapse in Women: Management*: *Guidance [NG123]* (NICE, April 2, 2019). https://www.nice.org.uk/guidance/ng123.
Patient Reference Group. *Independent Report of the Patient Reference Group*. (Traverse, July 21, 2021). https://assets.publishing.service.gov.uk/Government/uploads/system/uploads/attachment_data/file/1004531/independent-report-of-the-patient-reference-group-response-to-the-IMMDS-review-report.pdf.
Public Services Scotland. "Moving from Personal Independence Payment to Adult Disability Payment." November 8, 2022. https://www.mygov.scot/personal-independence-payment-is-moving.
Quigley, M, Downey, L., Mahmoud, Z., & McHale, J., "The Shape of Medical Devices Regulation in the United Kingdom? Brexit and Beyond". *Law, Technology and Humans* 5, no 2 (2023): 21-42. https://doi.org/10.5204/lthj.3102.
Richards, Bernadette, Susannah Sage Jacobson, Mianna Lotz and Wendy Rogers. "The Regulation of Medical Device Representatives: A Question of Trust?" *Law, Technology and Humans* 4, no 1 (2022): 117–128. https://doi.org/10.5204/lthj.2281.
SCENIHR. *Opinion on the Safety of Surgical Meshes Used in Urogynecological Surgery* (EU, December 3, 2015). http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_049.pdf.
Scottish Government. *Transvaginal Mesh Removal Reimbursement Scheme 2022* (Scottish Government, June 17, 2022). https://www.gov.scot/publications/transvaginal-mesh-removal-reimbursement-scheme-2022/.
Scottish Independent Review. *Final Report on the Use, Safety and Efficacy of Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse* (Scottish Government, March 27, 2017). http://www.gov.scot/Resource/0051/00515856.pdf.
Shine Lawyers. "Johnson & Johnson/Ethicon Class Action." https://www.shine.com.au/service/class-actions/johnson-johnson-ethicon-class-action.

Voreacos, David and Alex Nussbaum. "J&J Sold Vaginal Mesh Implant without Regulatory Approval." Bloomberg, March 21, 2012. https://www.bloomberg.com/news/articles/2012-03-21/j-j-sold-vaginal-mesh-implant-without-u-s-regulatory-approval.

Primary Legal Material

Legislation

European Union
Amending Regulation (EU) 2020/561.
Medical Devices Directive 93/42/EEC.
Medical Devices Regulation (EU) 2017/745.

United Kingdom
Health and Care Act 2022. https://www.legislation.gov.uk/ukpga/2022/31/contents/enacted.
Medical Devices Regulations 2002. https://www.legislation.gov.uk/uksi/2002/618/contents.
Medicines and Medical Devices Act 2021. https://www.legislation.gov.uk/ukpga/2021/3/contents/enacted.
The Medical Devices (Amendment) (EU Exit) Regulations 2021. https://www.legislation.gov.uk/uksi/2021/873/made.
Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Act 2022. https://www.legislation.gov.uk/asp/2022/1/section/1/enacted.

United States of America
Food Drug and Cosmetics Act, 21 USC §3601.
Medical Devices Amendments 1976.
Physician Sunshine Payment Act of 2009.
Title 21 of the Code of Federal Regulations.

Cases

AB vs NHS Ayrshire & Arran, and Johnson & Johnson; AS vs Greater Glasgow and Clyde (NHS Trust), and Johnson & Johnson; CK vs Greater Glasgow Health Board, and Johnson & Johnson; and SH vs RH, BMI Healthcare, and Johnson & Johnson [2016] CSOH 120. https://www.scotcourts.gov.uk/search-judgments/judgment?id=e0a11ba7-8980-69d2-b500-ff0000d74aa7.
Gill v Ethicon Sàrl (No 5) [2019] FCA 1905. https://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2019/2019fca1905.
Montgomery v Lanarkshire Health Board [2015] UKSC 11.

Parliamentary Statements and Debates

HC Deb 9 July 2020, vol 687, col 1147. https://hansard.parliament.uk/commons/2020-07-09/debates/5190E4DD-1319-4187-B1A2-13E9ACC3098D/IndependentMedicinesAndMedicalDevicesSafetyReview.
HC Deb 11 January 2021, vol 687, col WS1. https://www.gov.uk/Government/speeches/update-on-the-Governments-response-to-the-independent-medicines-and-medical-devices-safety-review.
HC Deb 7 December 2022, vol 724, col 478. https://hansard.parliament.uk/Commons/2022-12-07/debates/B2D90D97-EB69-4003-A813-A478491CA0A8/FoetalValproateSpectrumDisorderFatalities.