

The Independent Medicines and Medical Devices Safety Review

Patient Timelines

In addition to contributing to our timelines of key events in the history of HPTs, Sodium valproate and pelvic mesh, we invited the patient groups who had worked with us throughout the Review to provide a summary of their own campaigning activity. These are the responses we received.

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Disclaimer

The statements made and the opinions expressed in response to the Independent Medicines and Medical Devices Safety Review's ('IMMDSR) Call for Evidence and in the video recording of the IMMDSR's oral hearings are those of the authors. They do not purport to reflect the opinions, views or conclusions of the IMMDSR or its members. The statements and opinions made do not imply the expression of any opinion whatsoever on the part of the IMMDSR concerning the truthfulness, veracity, accuracy or legal status of any statements or opinions made and published on the IMMDSR website. Nor does the IMMDSR accept any legal liability arising from any statements or opinions so expressed and published published

WARNING: Please be aware some evidence contains descriptions, pictures and audio of the harm suffered by individuals. Some may find this distressing.

#FACSAware chronology of events to add to IMMDS review timelines

Colour	Evidence Source/Action taken by	
	Patient groups and Charities	
	Regulatory / Public bodies	
	Manufacturers	
	Key Studies	
	Mainstream Media	
	Medical Media	
	Online Media	
	International / Devolved Administrations	
	Significant events	
	Parliamentary Activity	
	Legal	
	Social Media	
	Source	Evidence/Action taken
	Elsevier Science Direct	158 results VPA.
	RJGP	41 results VPA 3 results VPA birth defects 16 results VPA pregnancy Top result VPA and Pregnancy Prevention Programme
	SAGE publishing	No results
	Wiley.com	392 results VPA 134 results VPA Pregnancy 36 results VPA pregnancy 1980-2000 105 results VPA birth defects.
	BMJ	598 results VPA 1840-2019 8 results VPA editorial
	Pulse	34 results VPA
	Hansard	56 results Sodium Valproate 142 results for Epilim
1892	NSEE	National society for employment of epileptics (NSEE) colony set up at Chalfont.
1942	NSEE	Chalfont - 575 colonists, 100 children
1957	NSEE	Chalfont school closed and children went to Lingfield National centre for Young persons with Epilepsy.
1964	BEA	British Epilepsy Association established.
1965	NSEE	Chalfont employed resident Doctors.
1967	Manufacturers	License Valproate in France
	Manufacturers	License Valproate in more European Countries.
1970	NSEE	Increase in research by resident Doctors at Chalfont.
	MISSED OPPORTUNITY	Was any research conducted at Chalfont on use of Valproate in different cohorts? Were any patients pregnant when admitted or became pregnant while residents at research facility?
1971	Legal/Hansard	Medicines Act 1968
	Manufacturers	Submit application for Valproate license
1972	NSEE	Reid report – Hospital and residential patients stayed for 3-6 months.

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1972	National Society Epilepsy	NSEE became NSE
1972	Regulator	Conditional license for Valproate granted
	Research	It was known that Valproate caused birth defects in animals. Knowledge was referenced in 1983 by Geoffrey Finsberg MP. http://bit.ly/32qXGXR (Hansard)
1973	Manufacturers	Valproate marketed in the UK.
	MISSED OPPORTUNITY	Monitoring of Valproate does not appear to have been conducted by the Department of Health and Medicine Regulation Department.
1977	Sanofi	Representative ██████████ met with Abbott Laboratories to discuss marketing of Valproate in the USA and warned of teratogenicity.
1978	Research	Hanson et al define Fetal Valproate Syndrome.
	Hansard	March 1978. Pearson Commission on Civil Liability and Compensation for Personal Injury. 20 recommendations. " Chapter 22 - Products (Volume 1 pp 255-274) p.272 para 1273 : ' The demand for fuller and surer compensation for injuries caused by drugs is now an international phenomenon. The context is one in which the industry finds itself under pressure, whatever its legal liabilities in any one country. These difficulties and the more fundamental problem of trying to produce safe drugs, would not be solved by avoiding a change to strict liability in the United Kingdom" https://discovery.nationalarchives.gov.uk/details/r/C11496026
	MISSED OPPORTUNITY	Sanofi and Medicine regulator do not appear to have informed the medical profession about teratogenicity.
1980	National society Epilepsy	Medical staff at Chalfont internationally recognised.
	MISSED OPPORTUNITY	No discussion about teratogenicity appears to have taken place at Chalfont by the internationally recognised medical staff.
	Researchers	23 papers in 1980s, no substantial articles in journals. (See OACS Ireland references submitted to IMMDS review via dropbox).
	EUROCAT	EUROCAT report 7. Surveillance of congenital anomalies across Europe for 15 years. 1980-1994.
	BMJ	22/05/80. Article related to Valproate.
	Lancet	Article. Teratogenic potential of Valproate.
	MISSED OPPORTUNITY	Medical journals and associated Royal Colleges do not appear to have run a series of articles about Valproate or encouraged long term discussion among the profession unless they developed the GP training.
1980	GP Training	Trainee GPs were informed that Valproate was not suitable for use in females of childbearing potential due to teratogenicity. (Personal testimony from a GP who trained in the 1980s. GP was horrified that Valproate had been reassessed as being suitable for women of childbearing potential).
	Wiley	Outcome of Lennox Gastaut syndrome. 60 effects of chronic phenytoin & Valproate exposure on fetal mouse cortical cultures.

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		74 possible delayed brain maturation and hepatic dysfunction in infant mice receiving chronic valproate therapy.
1981	Wiley	ADR Phenobarbital on morphological and biochemical development of fetal mouse spinal cord neurons in culture.
	CSM	July. Valproate data sheet updated to include ADRs. Listed in Current problems No 6.
	Hansard	27/07/81. John Morris MP asks about Valproate license and adverse effects. Dr Vaughan responds with license details and informs CSM has updated Data sheet to include more ADRs. http://bit.ly/2BmauTo
	Hansard	31/07/81. Mr Roy Hughes asks about Valproate ADRs. Dr Vaughan refers to response to John Morris on 27/07/81. http://bit.ly/35KrLna
1982	Research	Robert and Guibaud.
	BMJ	23/01/82. Article. Crying wolf on drug safety. 'associations may prove false alarms which cast an unwarranted blight on a useful drug'
	Drug and Therapeutics Bulletin	Volume 19, Number 24 includes information about Valproate adverse drug reactions.
1982	Lancet	Report on Congenital Abnormalities. Robert & Guibaud.
	Hansard	27/04/82. Mr Wigley asks if there are revised guidelines following the Drug and Therapeutics Bulletin, Volume 19, No 24. Geoffrey Finsberg responds that CSM updated Data sheets in July 1981 and this was in Current problems No 6. http://bit.ly/31md5r5
1983	CSM	January. Current Problems. No 9. 1 in 10 risk of Congenital Malformation
	FDA	Issued Dear Doctor letter warning of teratogenicity of Valproate
	Hansard	Miss Richardson MP requests Public Inquiry. Geoffrey Finsberg, DHSS responds that there is no clear evidence of risk to fetus and 19 deaths from Valproate do not indicate causal relationship. http://bit.ly/2qhVhk0
	Hansard	03/02/83. Mr Alan Williams MP asks about what assessment has been done regarding congenital abnormalities and report in the Lancet 11/12/82. Geoffrey Finsberg MP responds that committee concluded no clear evidence and advice available in Current Problems no:9 http://bit.ly/2nSFreP
1983	Hansard	09/03/83 Valproate Official report c412.
	Hansard	15/03/83 Mr Williams asks how many reports on Valproate ADRs have been received before CSM consideration and since. Geoffrey Finsberg confirms he will reply at a later date. http://bit.ly/2ORlqiV
	Hansard	23/03/83. Mr Alan Williams MP asks about records of adverse reactions to Valproate. http://bit.ly/2OWdWML
	British Journal Pharmacology	Article.

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1984	Hansard	<p>25/07/84 Debendox debate. Greville Janner MP raises concerns about Product Liability Law and Access to Justice for those affected by in utero exposure to Debendox.</p> <p>Ken Clarke MP Secretary of State for Health responds 'It is also right that British Law should produce compensation for people who have suffered damage and are entitled to compensation' 700 Claimants in USA, Merrell Dow pay £92million as a nuisance payment for Debendox birth defects.</p> <p>'This Government like the previous Government have not rejected Pearson outright. We are waiting for progress on a draft European Community directive.' 'it would not be right to make amendments to UK law whilst a draft EC Directive on Product Liability is being discussed'. https://api.parliament.uk/historic-hansard/commons/1984/jul/25/debendox</p>
	MISSED OPPORTUNITY	<p>Debendox was reviewed eight times by CSM and expert panel, no causal link was established, Merrel Dow removed Debendox from the market due to numerous Claims made in the USA and product was no longer commercially viable.</p> <p>Why wasn't Valproate given the same level of scrutiny?</p>
	MISSED OPPORTUNITY	<p>No follow up by Government on recommendations in Pearson Commission or efficacy of EC Product Liability Directive.</p>
1985	CSM	<p>Doctors advised to monitor women carefully during pregnancy.</p>
1986	Research	<p>Robert et al.</p>
1986	MISSED OPPORTUNITY	<p>DHSS were asked by several MPs about Adverse reactions of Valproate. No further action taken by Politicians, Regulators or Medical profession.</p>
1987	Drug and Chemist	<p>Article about teratogenicity</p>
	Consumer Protection Act	<p>1987. Consumer Protection Act passed into Law.</p>
1988	Research	<p>Fetal Valproate Syndrome Phenotype. Ardinger AJMG.</p>
	MISSED OPPORTUNITY	<p>Nothing appears to have happened 1988-1990. The number of research papers on record falls between 1989 and 1996. Was research being done? Did studies conducted remain unpublished?</p>
1991	RJGP	<p>VPA and Carbamazepine & Spina bifida GPs have important role to play in counselling teenage girls and women of childbearing potential taking Anti convulsant drugs. – references Pippa Oakeshott 1983 1-2% risk of Spina bifida.</p>
	MISSED OPPORTUNITY	<p>Doctors not provided with resources to highlight the importance of and facilitate counselling for teenage girls and women of childbearing potential.</p>
1992	BMJ	<p>VPA in pregnancy – Professor Geoffrey Chamberlain suggest VPA may be preferred in treatment of epilepsy during pregnancy as it has an apparent lower risk of neural tube defect than other AED. Letter from Richard Orrell in response to GC – A significant increased risk of neural tube defect has been associated with the use of VPA during pregnancy. GC response references 1986 Bailey Adverse effects of drugs in first trimester of pregnancy, Phenytoin, troxidone, primidone, ethosuximide, carbamazepine, valproate.</p>
	MISSED OPPORTUNITY	<p>BMJ did not highlight importance of caution. Reassurance given to Doctors.</p>

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1993	CSM	Current Problems in Pharmacovigilance. Volume 19. Reminder of 1983 Current problems. Issued Dear Doctor letter advising of teratogenicity,
1994	CSM	Doctors advised problems associated with monotherapy only.
	Hansard	09/03/94, Gareth Wardell MP asks what evidence of correlation between valproate and defects in newborn. Mr Sackville responds that several other anti epileptics are also known to be teratogenic and risk and benefit is considered. Warning was issued by CSM in 1983 and a reminder in 1993 CSM Current problems Volume 19. http://bit.ly/2qmW3MN
1995	NFACSA	National Foetal Anti Convulsant Syndrome Association launched (approximate date).
	Research	Fetal Valproate Syndrome. Clayton-Smith & Donnai JMG.
	Hansard	12/07/95. Paul Flynn MP. Valproate is unlicensed for pain but is being used. http://bit.ly/2O8ew9B
	Hansard	24/10/95 Mr Battle, asks for Centres of Excellence for epilepsy, Valproate syndrome, information for practitioners. Mr Bowis responds local services responsibility, occasional abnormalities, Royal Colleges responsibility to educate health professionals. Substantial funding provided to British Epilepsy Association for supporting people with epilepsy, RCGP and National Society for Epilepsy Fellowship for providing information to professionals and what should be offered to patients. Sponsored conference to share information. Conference report will be disseminated. http://bit.ly/2nUgUGp
1995	Hansard	24/10/95 Mr Battle asks what assessment of Sodium Valproate syndrome. Mr Bowis advises that royal colleges are responsible for educating clinicians. Report of 17 January 1995, 576-577 seeks to raise awareness among GPs and Primary Care teams. http://bit.ly/2pvG9z2
	MISSED OPPORTUNITY	Efficacy of Royal colleges in educating their members does not appear to have been assessed.
	MISSED OPPORTUNITY	No apparent assessment of whether money provided to BEA was used effectively. No outline for recording measurable outcomes.
	MISSED OPPORTUNITY	Medical Journals have not encouraged discussion among the medical community.
1996	Epilepsy Pregnancy register	Voluntary Register established
	Research	Epinasse et al
	Research	Spina Bifida and Cleft lip. King. AJPH
	CSM	Doctors advised that risk is for all epileptic women taking AEDs not just Valproate.
	MISSED OPPORTUNITY	No apparent scrutiny of whether the Epilepsy Pregnancy Register was collecting the right data to establish risks and benefits.
	Legal	Claims made against various Health Authorities
	Sunday Telegraph	December, Women to Sue over birth defects. 70 women to pursue legal action against health authorities. Interviews with mothers Sharon Walker, Miss Rowland, Christine Stafford.

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		Dr Ley Sanders, Consultant from National Hospital for Neurology and Nervous diseases says risks are well known and recognised. British Epilepsy Association to lead campaign to inform professionals.
	Daily Post	11/12/96, Ready to Sue Merseyside Health Authority. Interview with Diane Walker.
	MISSED OPPORTUNITY	No apparent collection of data on what clinicians knew about risk and whether they had received any educational materials from the BEA.
1997	CSM	September, volume 23. Current problems in pharmacovigilance lists teratogens.
	Research	AEDs and Major Congenital Malformations. Samrem. Epilepsia.
	CSM	Doctors advised Epilim for severe cases only.
	CSM	Patients advised to consult a Doctor if you become pregnant.
	MISSED OPPORTUNITY	No description of what constitutes a 'severe case' provided to Doctors. Patients not advised of risk.
1998	RCOG	Obstetricians were aware of teratogenicity as parent reports Obstetrician was in communication with Neurologist during pregnancy
	Hansard	15/12/98. Sir Nicholas Lyell asks what representations have been received regarding Valproate for epileptics during pregnancy. Ms Jowell responds not aware of representations, information is available, patients should be informed, Specialist will weigh risk and benefit, antenatal screening offered. http://bit.ly/2Mmx5Wg
1999	OACS	Organisation for Anti Convulsant Syndrome charity founded by Janet Williams.
	Hansard	26/04/99. Mr Lock asks about Lamotrogine inquiries including those where Valproate and other AEDs were taken in polytherapy. Mr Denham confirms the Medicines Control Agency and Yellow Card have received reports and data is being collected. http://bit.ly/33GIPsB
1999	Hansard	25/05/99. Baroness Gould asks what the interactions are between oral contraceptive and AEDs and the risk of abnormality. Baroness Hayman responds Medicine Control Agency has approved information from manufacturers about abnormality. It is for the Doctor to decide risk versus benefit as it is not known whether it is epilepsy or AEDs that are causing malformations. http://bit.ly/2Mm1971
1999	Access to Justice Act	Access to Justice Act passed into Law. http://www.legislation.gov.uk/ukpga/1999/22/contents
	MISSED OPPORTUNITY	Was research commissioned by Government to establish whether it is epilepsy or AEDs causing the birth defects?
	MISSED OPPORTUNITY	Chalfont had the facilities and expertise to answer the questions regarding Epilepsy or AEDs causing birth defects, was any research conducted?
	MISSED OPPORTUNITY	Absence of professional curiosity into adverse reactions of AEDs generally and during pregnancy. Not discussed in the Medical Journals.
2000	Research	Fetal Valproate Syndrome. Moore et al. JMG
	Research	Diagnostic Criteria. Dean. Seizure.
	MISSED OPPORTUNITY	Doctors not advised of diagnostic criteria, therefore cases of FVS were not being accurately recorded as a syndrome.

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	Hansard	24/05/00, Countess of Mar, asks when Valproate was licensed for children, details of ADRs in children, surveillance and what is being done to collect reports. Lord Hunt of Kings Heath responds licensed for children in 1976. provides statistics and Medicines Control Agency advisors to CSM and Yellow Card review evidence. Reports do not show Causation. http://bit.ly/2Bh3HKV
	Epilepsy Action	December. Valproate may impair brain development
2001	Regulator	Patient Information Leaflet update
	Epilepsy Action	May, Lamotrogine, Valproate and Poly cystic ovary syndrome
	Wikipedia	12/12/01. Sodium Valproate page added by Malcolm Farmer. 'possible teratogen', 'congenital anomalies 4-6% risk overall' https://en.wikipedia.org/w/index.php?title=Valproate&oldid=293935
2003	BMJ	18/01/03, Medicine Control Agency must be more open. MCA needs to communicate better with the public about the safety of medicines and become more transparent.
	National Audit Office	13/02/03, Publish report. Safety, quality, efficacy: Regulating Medicines in the UK.
	MISSED OPPORTUNITY	Absence of MP questions in HoC regarding the NAO report.
	Epilepsy Action	Valproate and women not ovulating during menstruation
	Regulator	Specialist Neurologist advice, folate, developmental delay
	Regulator	Current Problems in pharmacovigilance
	Legal	Product Liability Claim regarding Epilim started.
	Hansard	26/06/03, Committee of Public Accounts publish report. Safety, quality, efficacy: Regulating medicines in the UK.
	MISSED OPPORTUNITY	Medical Journals do not encourage discussion about medicine regulation.
	Pulse	29/6/03 NICE guideline under fire for cost ruling on epilepsy drugs
	Pulse	28/9/03 VPA alert puts GPs in quandary
2003	Epilepsy Action	1/10/03 Committee on Safety of Medicines warning based on Epilepsy Pregnancy register, Women should not be prescribed unless specialist advice.
	Pulse	27/10/03 GPs face conflict on epilepsy
	Pulse	27/10/03 Birth defect doubled (VPA)
	Epilepsy Research Foundation	Epilepsy Research Foundation and Fund for Epilepsy registered.
	Pulse	17/11/03 NICE recommend cheaper drugs
	Regulator	Patients informed that risk of Major Congenital Malformation with Valproate was higher than with other AEDs and/or epilepsy in general.
	Regulator	EU review, SPC and PIL updates, discuss risk with patient, Neurodevelopmental delay, Autistic Spectrum Disorders.
	Pulse	12/1/04 VPA still has a place in pregnancy
	Pulse	19/1/04 Questions on NICE advise on epilepsy drugs
2004	Epilepsy Action	February, Valproate can affect male fertility

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	MISSED OPPORTUNITY	What research was done on male fertility and the reason for infertility?
2004	Hansard	04/02/04, HoL debate. Medicine Regulatory System. Lord Clement-Jones asks When Government intends to conduct a full independent and open review. Lord Warner responds that National Audit Office and Public Account Committee published a review in 2003. (13/01/03 & 26/06/03) http://bit.ly/308xtiS
	Pulse	22/3/04 Long wait to see specialist (neurologist)
	Pulse	29/3/04 NICE in new clash on epilepsy drugs
	Pulse	02/05/04 Epilepsy care dilemma
	Legal	October. Irwin Mitchell solicitors file Epilim 3 cases to the High Court using Consumer Protection Law to pursue Compensation.
	BBC	01/10/04. FAC Litigation. Legal Basis, with Deborah Mann, Karen Buck, David Body. http://news.bbc.co.uk/1/hi/health/3705384.stm 'The case is unusual because, rather than accusing the companies of negligence, the families are bringing their case under consumer protection laws introduced after the thalidomide scandal so that patients had a way of claiming compensation, even if negligence on the part of the drug company could not be proved.'
2004	NICE	NICE publish Guidance on Epilepsy management in pregnancy.
	Research	Epilepsy and Pregnancy register published and show Valproate risk many times higher than other treatments.
	Epilepsy Action	Article about Epilepsy Pregnancy register
	Wikipedia	Sodium Valproate page added.
	Legal	FAC Litigation granted Claimants' lawyers Irwin Mitchell £4million in Legal Aid.
2005	Science et Avenir	01/10/05. Journal article in France. Antiepileptique sous surveillance. https://www.apesac.org/presse/annee-2008-a-2012/265-antiepileptique-sous-surveillance.html
	MISSED OPPORTUNITY	Absence of discussion in medical journals about the Litigation and implications on the medical practice.
	Pulse	25/5/06 Article on Court Action
	National Newspapers	Irwin Mitchell give closing date for FAC Litigation Claimants.
	Legal	July. Legal Aid funding withdrawn by Legal Services Commission.
	ANSM	French PIL include risk of Autism Spectrum Disorders
2006	BMJ	Teratogenicity of AEDs – Epilepsy pregnancy register – VPA congenital abnormality 6.2% Responses – Deepak Srivastava Consultant neurologist Delhi. Unnecessary concerns. Women get anxious and even avoid pregnancy. Andrew Kelso, Clinical research fellow and honorary specialist registrar, St Georges – listed interests: Sanofi Epilim, GSK Lamictal. Valproate is not a demon drug – considerable negative publicity.

#FACsaware chronology of events to add to IMMDS review timelines

		<p>Phil Harrison-Read. Consultant Psychiatrist, Royal Free. NICE clinical guideline 38(3) ,9/2006 advises against routinely prescribing to women with Bipolar who may become pregnant. Dr Prakash, Assistant Professor Kasturba medical college – quotes Meador. Comparative risk VPA at 20%.</p> <p>Andrew Al-Adwani. Consultant Psychiatrist. Lincolnshire. Little solid evidence that folate reduces neural tube defects and is a pro convulsant. AEDs reduce oral contraceptive action.</p>
2007	Epilepsy Research UK	Epilepsy Research Foundation and Fund for Epilepsy merge to become Epilepsy Research UK.
	Epilepsy Action	Lobby politicians for a QOF for Preconception counselling and sit on expert panel.
	BNF	March. Pregnancy does not feature as contraindication.
	Epilepsy Action	24/04/07. Legal Action Epilim. Online article. https://www.epilepsy.org.uk/news/legal-action-over-epilim
	APPG Epilepsy	Report issued. Wasted money, Wasted lives
	Epilepsy Action	Article about Wasted money, wasted lives report.
	Court	10/05/07. Judicial Review. Reinstate Legal Aid funding for FAC Litigation.
	Legal	31/05/07. Cut off date to register as a Claimant in FAC Litigation.
	Legal	Claimant request for Forensic Accountant to give expert evidence for FAC Litigation on Epilim Sales, profits and pricing structures rejected.
2007	Pulse	13/9/07 Questions on investigations, contraception and driving.
	BBC	Panorama, Interview with Linda Hamilton, mother with affected child.
	Legal Services Commission	Legal Aid withdrawn for FAC Litigation.
	Courts	Judicial review reversed Legal Aid funding withdrawal from FAC Litigation.
2008	La Nouvelle Republique	24/09/08. Newspaper article in France. Le Medicament est – il a l’origine du handicap? Reference given to OACS charity. https://www.apesac.org/presse/annee-2008-a-2012/148-le-medicament-est-il-a-l-origine-du-handicap.html
	MISSED OPPORTUNITY	Mainstream Media, Medical Journals, Regulator, Politicians did not discuss and question risks.
2009	Hansard	02/03/09 Mr Wallace, asks what benefits have been awarded to those with FACS and valproate syndrome. Mr Shaw responds, no estimates have been made and children may be able to claim Disability Living Allowance.
	Hansard	03/03/09. Mr Wallace asks how many children and adults have a diagnosis of Fetal Anti Convulsant Syndrome. Dawn Primarola quotes Epilepsy and Pregnancy Register showing increased risk of Congenital malformation in live births. Risk 5-9%. http://bit.ly/2VRMCjT
	MISSED OPPORTUNITY	Inadequate data collection on numbers of those affected. Lack of scrutiny of the validity of Epilepsy Pregnancy register data. No apparent data collection of prevalence of miscarriage and still birth.
	Pulse	21/5/09 Fetal exposure may affect IQ in early childhood.
	DoH	QOF for Preconception counselling to come into effect in 2010/11 due to greater risk of neurological and physical disorders and Autism and Spina Bifida.
2010	Regulator	Statement on malformations and Autistic Spectrum Disorders

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2010	Hansard	26/02/10 Mr Syms asks about negative effects of valproate on embryos and under 18s. Compensation payments to those affected. What advice is given to NHS. Mr Mike O'Brien responds, MHRA responsible for medicine safety. Association with Spina Bifida and Myelomeningocele. Children liver damage and pancreatitis. Specialist should prescribe to females weighing up risk to fetus. NHS Litigation Authority have compensation details but disproportionate cost due to database set up so no figures available.
	Hansard	26/02/10 Mr Syms asks how many prescriptions issued to under 18s. Ann Keen responds information is not available. NHS Prescription Service unable to provide data from 2007 as process has changed.
	Hansard	26/02/10 Mr Syms asks what research is being undertaken on use of Epilim for other indications. Gilliam Merron responds National Institute for Health Research is not funding any research.
	Irish times	Settlement in Irish court against Health professionals for Epilim birth defects. https://www.irishtimes.com/news/birth-injuries-court-case-settled-1.853013
	Sirnyler Youtube	16/04/10. Documentary about Helenor Bye. https://youtu.be/yLvsi0Vfj-Y
	Legal Services Commission	26/10/10. Decision to withdraw Legal Aid funding from FAC Litigation.
	Families	Families of children in the FAC Litigation contact their local and national media and their MPs about the withdrawal of Legal Aid.
	Guardian	https://www.theguardian.com/society/2010/nov/08/epilim-anti-epilepsy-drug
	Guardian	https://www.theguardian.com/society/2010/nov/08/legal-aid-anti-epilepsy-drug
	Independent	https://www.independent.co.uk/news/uk/home-news/legal-aid-withdrawn-from-epilepsy-drug-families-2128432.html
	Hansard	08/11/10 Sir Menzies Campbell wrote to Lord Chancellor Kenneth Clarke criticising withdrawal of Legal Aid.
	BBC	08/11/10. Legal Aid withdrawal. Online article with Karen Buck. https://www.bbc.co.uk/news/uk-11707386
	IBB solicitors	08/11/10. Legal Aid withdrawal.
	The Pharma letter	08/11/10. Legal aid withdrawn. https://www.thepharmalatter.com/article/uk-families-denied-legal-aid-for-epilepsy-drug-sodium-valproate-court-case-against-sanofi-aventis
	Facebook	09/11/10. Justice for FACS Kids (Valproate Victims UK) group set up by Susan Cole.
	IBB Solicitors	15/11/10 Legal Aid withdrawal. Online article
	Hansard	17/11/10 Teresa Pearce MP. EDM Withdrawal of Legal Aid. 80 Signatures.
	Teresa Pearce	19/11/10. Teresa Pearce MP. Online article. Withdrawal of Legal Aid. https://www.teresapearce.org.uk/2010/11/hello-world/
	The Guardian	29/11/10. Newspaper and online. Flaws in Legal Aid. Interview with Emma Friedmann and David Body. https://www.theguardian.com/law/2010/nov/29/epilim-legal-aid-flaws
2010	BMJ	November. Article about withdrawal of Legal Aid. https://www.bmj.com/content/341/bmj.c6384

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2010	Emma Friedmann	November. Website set up about Epilim Litigation. www.emmafriedmann.com
	Hansard	30/11/10 Baroness Ford http://bit.ly/2O5oJDC House of Lords. Valproate, FAC Litigation, Legal Aid
2010	OACS Charity	07/12/10 Press Release. Petition submitted by parents and young people affected to 10 Downing Street.
2011	Epilepsy Society	National Society Epilepsy became Epilepsy Society
	Epilepsy Society	Sir William Gowers Centre – Clinical trials unit at Chalfont working with pharmaceutical industry and regulatory agencies.
	MISSED OPPORTUNITY	Chalfont had the facilities and expertise to answer the questions regarding Epilepsy or AEDs causing birth defects, was any research conducted?
	Legal	20/01/11. Irwin Mitchell press release about pending Discontinuance of FAC Litigation.
	BBC	20/01/11. Online. Legal action to be discontinued. Interview with David Body. https://www.bbc.co.uk/news/health-12242857
	The Times	21/01/11. Epilepsy drug families to drop case. Online article
	BBC	23/01/11. File on 4. Bitter Medicine. Vioxx and Epilim, Legal Aid in UK and Scotland. Interview with Emma Friedmann. https://www.bbc.co.uk/programmes/b00xhh70
	Courts	28/01/11 FAC Litigation Discontinuance first hearing.
	Press Association Getty Images	28/01/11. Photographs. Janet Stockley Pollard, Susan Cole, Samantha Scott Edgar, Janet Williams, Emma Friedmann. https://www.gettyimages.co.uk/detail/news-photo/susan-cole-janet-williams-samantha-scott-janet-stockley-news-photo/839185794
	BBC	28/01/11. Online. Litigation discontinuance. Interview with Janet Stockley Pollard and David Body. https://www.bbc.co.uk/news/uk-england-sussex-12303464
	Daily Mail	28/01/11. Online. Litigation discontinuance. https://www.dailymail.co.uk/health/article-1351390/Epilim-Families-think-epilepsy-pill-caused-birth-defects-forced-drop-case-legal-aid-withdrawn.html
	South Wales Argus	28/01/11. Online article with video of Emma Friedmann. https://www.southwalesargus.co.uk/news/national/8820663.interview-with-emma-friedmann-one-of-the-mothers-who-allege-that-the-drug-sodium-valproate-also-known-as-epilim-caused-a-range-of-birth-defects/
	Sanofi	30 th January. Update PIL to include full list of physical and neurodevelopmental birth defects.
	Research	February. 39.6% risk of neurodevelopmental delay with Valproate exposure. Cummings et al
	The Justice Gap	February. Online article by Emma Friedmann. Mother of test case in FAC Litigation. https://www.thejusticegap.com/2011/10/no-happy-ending/
2011	Online form press release	February. Consumer Justice Foundation online article about Epilim Litigation and Depakote. Interviews with Janet Stockley Pollard and Emma Friedmann.

#FACSAware chronology of events to add to IMMDS review timelines

		https://www.onlineformpressrelease.com/201195391/Lawsuit-For-Fetal-Valproate-Syndrome-Birth-Defects-From-Epilim-A-Form-of-Depakote-Put-On-Hold/news.html
2011	Hansard	07/03/11 Teresa Pearce asks for MHRA to review safety of Valproate. Simon Burns responds that MHRA update SPC and PIL when necessary. Treatment advice also available from National Institute of Health and Clinical Excellence and BNF.
	Mutual Shoots Ltd	01/05/11. May Day. Justice for Special needs kids speech by Emma Friedmann. https://youtu.be/KMrNf0879IM
	Courts	06/05/11. FAC Litigation Discontinued. Costs holiday granted by Sanofi on the condition that Claimants do not pursue Litigation against Sanofi or Third Party in the future.
	Yorkshire Post	06/05/11. Discontinuance of FAC Litigation. Online article. https://www.yorkshirepost.co.uk/news/latest-news/legal-aid-withdrawal-stops-birth-defects-case-1-3358589
	Yorkshire Post	07/05/11 Legal Aid withdrawal stops birth defects case. Online article https://www.pressreader.com/uk/yorkshire-post/20110506/282995396442776
	L'Independant	11/05/11. Newspaper article and interview with Marine Martin. https://www.apesac.org/presse/annee-2008-a-2012/149-un-nouveau-scandale-autour-d-un-medicament.html
2011	FACT	Fetal Anti Convulsant Trust launched by Janet Williams, Janet Stockley Pollard, Steve Pollard.
2012	MHRA	January. Paediatric Medicines and Medicines in pregnancy seminar – Emma Friedmann asked Question about Valproate and requested Caution in Use issued. MHRA response – Not defective.
	NICE	Guidelines update
	UK Human Rights	01/03/12. Legal Aid reforms and questions arising from changes to Clinical Negligence. Potential for a Human Rights challenge for birth injury. https://ukhumanrightsblog.com/2012/03/01/legal-aid-government-backs-down-on-clinical-negligence-and-domestic-violence/
	BBC	Interview with Janet Stockley Pollard. https://www.bbc.co.uk/news/uk-england-sussex-17095490
	Epilepsy Research UK	20/02/12. Online article. Interview with Janet Stockley Pollard about £10,000 lottery grant and petition. https://www.epilepsyresearch.org.uk/new-campaign-launched-over-epilepsy-drug-side-effects/
	The Justice Gap	08/03/12. Online article by Janet Williams and Emma Downes Murphy as officers of Organisation for Anti Convulsant Syndrome. https://www.thejusticegap.com/a-bitter-pill-the-epilim-families-fight-for-justice/
	Epilepsy Research UK	12/03/12. Online article. Women reassured about AED risk in pregnancy. https://www.epilepsyresearch.org.uk/women-reassured-of-anti-epileptic-drugs-risks-during-pregnancy/
	FDA	Issue Dear doctor letter warning of possibility of Litigation if Depakote prescribed during pregnancy
	Court	Individual claims lodged with French Civil Court. https://www.apesac.org/
2012	Epilepsy Action	Editorial, Valproate congenital malformation and dosage
2012	Pulse	8/5/12 NICE Epilepsy Guidance

#FACSAware chronology of events to add to IMMDS review timelines

	NICE	June. Publish CG142. Economic Cost of Autism. ASD with no Learning Disability = £3.1million. ASD with Learning Disability = £4.6million.
	Legal Aid, Sentencing and punishment of Offenders Act	01/05/12. LASPO Act passed into Law. https://www.legislation.gov.uk/ukpga/2012/10/contents/enacted
	Access to Justice Act	01/05/12. Access to Justice Act repealed.
	UK column	The death of Helenor Bye https://www.ukcolumn.org/ukcolumn-news/uk-column-live-special-paediatric-drug-company-abuse
	Journal of Personal Injury	Article by David Body. Product Liability under Consumer Protection Act 1987, Some practical problems.
2012	Health and Social Care Act	27/03/12. Health and Social Care Act passed into Law. http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted
	MISSED OPPORTUNITY	The Health and Social Care Act included: Pharmaceutical services expenditure, Monitor and their responsibility to review regulatory burdens and carry out impact assessments. Licensing providers. Primary Care Services responsibilities in relation to Pharmaceutical needs assessments. Control of entry on pharmaceutical lists. Responsibilities of Professional Standards Authority to advise regulatory bodies, investigate complaints, appointments to regulatory bodies and establishing voluntary registers. Schedule 3 Pharmaceutical remuneration and Secretary of State may 'direct the Board that an element of pharmaceutical remuneration specified in the direction is not to be included in a determination under sub paragraph 1. The MHRA has not been discussed. Dissemination of Patient safety information has not been discussed. Regulators who assess services that use pharmaceutical products have been discussed and specific duties are listed. Eg Monitor, Care Quality Commission, National Institute for Health and Care Excellence, Professional Standards Authority. Why hasn't the MHRA been included? Was a decision made to exclude the MHRA or did no one consider the relevance of the MHRA in the economic viability and legal responsibilities of providing Health and Social Care Services?
2012	Hansard	26/06/12. Mrs Moon asks How are people with FACS being monitored as they transition to adulthood.

#FACSAware chronology of events to add to IMMDS review timelines

		Anne Milton responds No estimate, no monitoring, Local services and CCGs responsibility to provide services. [113232]
2012	Rxisk	05/09/12. Online article by Janet Stockley Pollard with comments by Data based medicine Americas Ltd about other pharmaceutical products with increased risk of birth defects. https://rxisk.org/facts-about-facs/
	Hansard	18/09/12 Mr Anderson What guidance is available to doctors to provide preconception counselling, what support is available to those adversely affected. Norman Lamb responds MHRA review safety and update SPC and PIL, should only be started on Valproate by specialists, NICE guidance available, Andrew Lansley MP has set up Children and Young People's Health Outcomes Forum to recommend outcome measures of support provided.
	APESAC	September. APESAC set up and launched in France.
	La Cantarane	01/10/12. Interview with Marine Martin about APESAC Launch in France. https://www.apesac.org/presse/annee-2008-a-2012/150-une-nouvelle-association.html
	FACSA	November. FACS Syndrome Association set up by Janet Williams and Emma Murphy nee Downes.
	INFACIT	November. Independent Fetal Anti Convulsant Trust set up by Janet Williams and Emma Murphy nee Downes.
	Facebook	07/12/12. The FACS Syndrome Association group set up by Emma Murphy.
	Hansard	17/12/12 Kate Green asks what advice is available to women of childbearing age on the NICE recommendations, what advice is given to women regarding effect of Epilim on mental health. Dan Poulter responds guidance available on NHS Choices website and PIL and SPC. Women should be advised of risk of baby developing less quickly or have autistic disorders.
	OACS	December. Contact list, correspondence and other data lost.
2012	FACT	December. Contact list, correspondence and other data lost.
2013	Pulse	23/1/13 Pregnant women more likely to discontinue AEDs – Pre conception counselling and referral advised.
	Pulse	27/1/13 Valproate exposure reduces cognitive ability – GPs to identify women and refer to specialist.
	Clinical Neurology & Neurosurgery	Effect of long term exposure to disease – modifying drugs during pregnancy.
	Journal of Neurology neurosurgery and psychiatry	Study on pregnant women 2000-2004 show VPA exposed are 6 times more likely to have Neurodevelopmental delay. (no reference to paper, authors or date published).
	Epilepsy Action	5/2/13 6-10 times more likely to have Neurodevelopmental Delay – reference 2009 study in USA that led to warning by FDA. https://www.epilepsy.org.uk/news/news/epilim-and-pregnancy
	Epilepsy Action	Write up about BBC Documentary
2013	Hansard	05/02/13 David Anderson, EDM 1021, Fetal Valproate Syndrome, Request for Independent Inquiry. 33 Signatures.

#FACSAware chronology of events to add to IMMDS review timelines

2013	Facebook	10/02/13. FACSaware facebook group set up by Janet Stockley Pollard, Emma Friedmann and Deborah Mann.
	Mail on Sunday	26/02/13. Newspaper and online article. Interviews with Karen Buck, Emma Murphy, Janet Williams, Emma Friedmann. https://www.dailymail.co.uk/health/article-2284425/Epilepsy-The-drug-thats-harmed-children-Thalidomide.html
	Citizens Eye	26/02/13. Audioboom interview with Emma Friedmann. https://audioboom.com/posts/1234036-emma-friedmann
	Hansard	14/03/13 Paul Flynn, EDM 1197, MHRA, Reform of MHRA to remove dependence on pharmaceutical industry. 15 Signatures.
	Hansard	26/03/19 Anas Sarwar MP – Westminster Hall Debate – http://bit.ly/2O6aFK8
	FACT	Petition to Stephen Dorrell MP calling for a Public Inquiry. By Janet Stockley Pollard. https://you.38degrees.org.uk/petitions/public-inquiry
	FACT	March, Briefing for MPs regarding Public Inquiry by David Body. Published and shared widely with parents, media and MPs.
	#facsaaware	March, #facsaaware set up by Fetal Anti convulsant Trust as an online awareness campaign.
	FACSaware	Became formal supporter of All Trials a Sense about Science campaign.
	Sunday Mail Scotland	Article about Valproate birth defects
	Medical News Today	24/04/13. Online article by Joseph Nordqvist about Christensen population based study in Denmark. https://www.medicalnewstoday.com/articles/259597.php
	Tony Topping	26/04/13. Online radio interview with Jo Cozens. https://www.blogtalkradio.com/thetonytoppingshow/2013/04/26/a-cover-up-that-is-the-new-thalidomide
	MHRA	May. Email to FACSaware – There is no need to issue new warnings.
	CM & MCUH Trust	May. Education Letter written by Professor Jill Clayton Smith and Dr Rebecca Bromley for OACS Charity.
	OACS FACSaware	May. Publish Education letter and distribute to parents and professionals.
	Hansard	20/05/13, Jon Ashworth asks What are the implications on the DWP benefits system for women who took Valproate and children with Valproate syndrome. Mr Hoban responds We do not record causation. [155920]
	Hansard	21/05/13, Jon Ashworth asks Will DoH ask MHRA to issue regular Valproate Caution in Use to GPs. Dr Poulter responds MHRA and predecessor have issued 3 warnings. MHRA issue warnings, update PIL and SPC when necessary. Women shouldn't be prescribed unless necessary and other treatments are ineffective or not tolerated. [155921]
2013	Hansard	21/05/13, Jon Ashworth asks Has DfE considered teaching teratogens in National Curriculum. Elizabeth Truss responds Proposals exist for key stage 3 in Science and it is for teachers to decide what to teach. There is scope for teratogens to be taught in PSHE lessons. [155919]

#FACSAware chronology of events to add to IMMDS review timelines

2013	Hansard	03/06/13, Lyn Brown asks what is DoH doing to ensure doctors are aware of risk and are following NICE guidelines, what is the estimate of number of children affected. Dr Dan Poulter responds Information on children affected is not held centrally, MHRA update PIL and SPC and they have issued 3 warnings in the past. DoH expect Doctors to adhere to NICE guidelines.
	Jo Cozens	June 2013. Jo Cozens wordpress blog. https://jocuz1971.wordpress.com/jo-cozens-biography/
	Hansard	03/07/13 Naomi Long asks How many children have diagnosis of FVS and other associated conditions, how many children diagnosed with FACS from 1989-2012. Dr Poulter responds, this data is not held centrally and due to no ICD 10 codes it is not available.
	BBC	06/07/13. Panorama. https://youtu.be/waQDkz7pR5s
	DES Daughter	06/07/13. Blog about Pills and Pregnancy Panorama. https://desdaughter.com/2013/07/06/the-truth-about-pills-and-pregnancy-video-on-youtube/
	OACS/FACT/ #facsaaware	14/07/13. OACS newsletter http://www.oacs-uk.co.uk/web/files/OACS_Newsletter_Quarterly_Monthly_14.07.2013-1.pdf
	Epilepsy Society	August, Leaflets printed, available for purchase and distributed advising women of management of epilepsy in pregnancy.
	Facebook	21/07/13. Organisation for AntiConvulsant Syndrome set up by Jo Cozens.
	BBC	02/08/13 East Midlands Today news, interview with Emma Friedmann. https://www.youtube.com/watch?v=XmZdzJljZc
	FACSAware	August – FACSAware launch with demonstration at MHRA HQ
	FACSAware Youtube	06/08/13 Compilation of pictures from campaign. https://youtu.be/_GmhTRYk00g
	BBC	11/08/13. BBC Wales Report. Interviews Jo Cozens. https://youtu.be/HqVV4H-Pp8g
	DES Daughter	11/08/13. Blog about the FACSAware demonstration and promoting the BBC Wales Report and interview with Jo Cozens. https://desdaughter.com/2013/08/11/watch-the-wales-report-dangers-of-epilim-in-pregnancy/
	INFACT/FACSA	16/08/13. Private MHRA meeting
	Epilepsy Action	Article, Study links Valproate to Autism.
	Mikey Argy	2013. Mikey Argy set up 38 degrees petition calling for compensation from Sanofi and Grunthal. https://you.38degrees.org.uk/petitions/make-pharmaceutical-companies-pay-for-their-mistakes
	DES Daughter	02/09/13. Blog about FACSAware Demonstration at MHRA promoting BBC interview with Emma Friedmann. https://desdaughter.com/2013/09/02/epilim-sodium-valproate-in-pregnancy-watch-emmafriedmann-interview/
	FACSAware OACS	03/09/13. Meeting with Norman Lamb cancelled. Meeting held with Yassar Abbas. Information given to Mr Gray at DoH.
	FACSAware	29/09/13, Meeting with Alec Shelbrooke in Manchester
2013	FACSAware	29/09/13. Parents join NHS demonstration in Manchester

#FACSAware chronology of events to add to IMMDS review timelines

2013	MHRA	14/10/13, Article 31 submitted to EMA PRAC to review Valproate
	MHRA	16/10/13, Email to FACSaware confirming that November Drug Safety Update will include item on Valproate and links to guidance.
	DoH	29/10/13, Anas Sarwar MP organised meeting at DoH with Norman Lamb, Alec Shelbrooke, Anas's Constituent and FACSaware, OACS, FACSA, INFACT, Young person affected.
	FACSaware	01/11/13. Parliament FACT file published and shared with parents, media and MPs.
	MHRA	04/11/13, email to FACSaware to confirm Dr Sarah Branch will liaise with EMA PRAC.
	FACSaware	15/11/13. Published Press release about film preview and shared with parents, media and MPs.
	Daniel Leach	18/11/13, Preview of Sodium Valproate – The Cost at London College of Communication. Attended by Mothers and their children who featured in the documentary film. Trailer: https://youtu.be/w6_Yz05--yE Film: https://youtu.be/Mi89I7qkCJ8
	MHRA	19/11/13, Drug Safety Update including Valproate warning and links to guidance and research papers.
	Hansard	18/12/13. DoH send letter to Alec Shelbrooke advising MHRA have issued drug safety update and initiated EMA review.
	Questionnaire	Epilepsy Action report third of women not aware of risk in pregnancy.
	Epilepsy Action	Response to Regulatory Action
	Epilepsy Action	Report on new guidance about switching AEDs
2013	Epilepsy Action	Article on MHRA referral to EMA PRAC
2014	DES Daughter	14/02/14. Blog promoting Sodium Valproate The Cost film with Emma Friedmann, Karen Buck and David Body. https://desdaughter.com/2014/02/14/sodium-valproate-the-cost/
	FACSaware	24/02/14 Email to MHRA. Suggest harmonising Yellow Card and care.data / CPRD would save £billions in care costs and provide funding to MHRA which would address power of pharmaceutical industry in regulation. Need for a tick box on Yellow Card form for women who took medicine during pregnancy and for men who took medicine during conception process. Need for link between biological parent records and their offspring.
	MHRA	25/02/14 Email to FACSaware. Thank you. Excellent points regarding interworking between Yellow Card and care.data.
	Epilepsy Research UK	26.02/14. Online article quoting estimates of 20,000 children affected in the UK. https://www.epilepsyresearch.org.uk/nearly-20000-children-harmed-by-epilim-sodium-valproate/
	DES Daughter	08/03/14. Blog about 38 degree petition by Fetal Anti Convulsant Trust calling for Public Inquiry. https://desdaughter.com/2014/03/08/sign-the-petition-public-inquiry-into-disabilities-caused-by-antiepileptic-medication-in-pregnancy/
2014	Children and Families Act	13/03/14. Children and Families Act passed into Law. http://www.legislation.gov.uk/ukpga/2014/6/contents/enacted

#FACSAware chronology of events to add to IMMDS review timelines

	MISSED OPPORTUNITY	The Children and Families Act could have included responsibilities for schools, social care and other agencies to provide training to staff around drug safety and the responsibility to provide updated information to the parents/carers of children with medical needs.
2014	FACSAware	04/04/14. Liaison with European patient groups (OACS, APESAC, ABVSV). FACSAware sent emails to all members of PRAC requesting patient groups have opportunity to give evidence to PRAC.
	MHRA	April, Update to Yellow Card and issue guidance on it's use.
	FACSAware	05/04/14. Publish template letter and list of email addresses for EMA PRAC members for individuals to send urging them to take action and providing link to documentary Sodium Valproate the Cost. https://youtu.be/Mi89I7gkCJ8 Summary - 40% risk. Ban for use in pregnancy. Child's quality of life should be considered before women's desire to have a child. Adoption, fostering and surrogacy should be considered as alternative parenting options.
	EMA	7-10 April. PRAC take evidence
	Leicester Mercury	April. Newspaper and online. Mom of the year finalists. Article about Emma Friedmann, Epilepsy, FACS, Campaign, Disabled child.
	Epilepsy Network	26/04/14. Article about Emma Friedmann, FACS and Mom of the year finalist. http://theepilepsynetwork.com/mom-of-the-year-2014-so-proud-of-tireless-emma/
	Facebook	27/04/14. Association belge des Victimes du Syndrome Valproate group set up by Nathalie Raemdonck. Belgium.
	Facebook	29/04/14. Epilepsy, Pregnancy and Pills group set up by Emma Murphy.
	Legal	May. US Depakote Claimants take pharmaceutical company to court in Illinois
	DES Daughter	03/06/14. Blog about the 38 degree petition by Mikey Argy. https://desdaughter.com/2014/06/03/grunenthal-and-sanofi-pharmaceutical-companies-must-face-their-obligations/
	INFACT	06/06/14 INFACT registered with Companies House – Emma Murphy, Saffron Palmer, Janet Williams. https://beta.companieshouse.gov.uk/company/09075755
	FACSAware	16/06/14. Press release published on Facebook group for parents to send to their media contacts.
	Branwen Mann	27/06/14. Give evidence to EMA PRAC.
	OACS	27/06/14. Give evidence to EMA PRAC.
	FACSAware	27/06/14. Give evidence to EMA PRAC.
	APESAC	27/06/14. Give evidence to EMA PRAC
	ABVSV	27/06/14. Give evidence to EMA PRAC.
	INFACT/FACSA	27/06/14. Give evidence to EMA PRAC.
	FACT	30/06/14. Fetal Anti Convulsant Trust (FACT) change Facebook group name to FACSAware.
	Emma Murphy	Emma4facs webpage updated with FACS Syndrome Association (FACSA) and Independent Fetal Anti Convulsant Trust campaign achievements. https://emma4facs.wordpress.com/epilepsy-pregnancy-and-pills-campaign/campaign-achievements/
2014	NICE	QOF retired – Preconception counselling

#FACSAware chronology of events to add to IMMDS review timelines

2014	Questionnaire	Epilepsy Action report percentage of women unaware had risen to almost half.
	FACSAware	June, Press release to all media contacts. Basic established facts and planned meetings.
	FACSAware	18/06/14 APPG information pack sent to Alec Shelbrooke MP
	APPG Thalidomide	18/06/14 Alec Shelbrooke hosts FACSAware, OACS, FACSA, INFACT
	Epilepsy Action	Article, EMA PRAC to recommend restrictions
	FACSAware	01/07/14. Valproate report for Jon Ashworth. Published and shared widely with parents, media, politicians.
	DES Daughter	10/07/14. Blog about 20,000 harmed promoting links to other news sources. https://desdaughter.com/2014/07/10/20000-children-harmed-by-epilim-antiepileptic-drug-in-the-uk/
	Richard Goldberg	Medicinal Product Liability and Regulation. Published book referencing Epilim and Seroxat.
	Mise en Garde	October, Mise en Garde. French news item about EMA PRAC featuring APESAC, OACS, FACSAware.
	Hansard	13/11/14, Individuals, charities and campaign groups meet at DoH to discuss what information should be given to patients, by who and in what format.
	EMA	21/11/14, CMDh endorse EMA PRAC recommendations. https://www.ema.europa.eu/en/medicines/human/referrals/valproate-related-substances
	Facebook	05/12/14. Fetal Valproate Syndrome Support Australia group set up by Grant Sparkes.
	Epilepsy Ireland	10/12/14. Article. EMA PRAC recommendations.
2014	Faye Waddams	23/12/14. Faye Waddams blog on epilepsy and pregnancy. https://fairfaye1986.weebly.com/blog/does-epilepsy-matter-now-that-i-have-two-blue-lines
2015	Facebook	09/01/15. Epilepsy, Pregnancy, Motherhood and Me group set up by Faye Waddams.
	OACS Charity	15/01/15. Meeting with Norman Lamb MP.
	MHRA	22/01/15. Strengthened warnings in Dear Doctor letter to Healthcare professionals and patient groups/charities. Resources made available – NHS Choices, DoH Social Care blog, Black Triangle, Patient Information, Health care professional information, PIL update and Consent forms. https://www.gov.uk/drug-safety-update/medicines-related-to-valproate-risk-of-abnormal-pregnancy-outcomes
	BBC	25/01/15. BBC London News. Interview with Karen Buck. https://youtu.be/TRR0JHppiXc
	DES Daughter	26/01/15. Blog about strengthened warnings from the MHRA. https://desdaughter.com/2015/01/26/medicines-related-to-valproate-risk-of-abnormal-pregnancy-outcomes/
	Hansard	02/02/15 House of Lords, Epilepsy New Treatments, http://bit.ly/303XXmh
2015	Facebook	02/02/15. FACS New Zealand group set up by Denise Astill.
2015	INFACT FACSA	10/02/15. FACS awareness week promotion.

#FACSAware chronology of events to add to IMMDS review timelines

2015	Hansard	26/02/15 Epilepsy Debate http://bit.ly/2O8dIXJ
	Dept of Health	26/02/15. Social Care Blog. Alert about the importance of advising women to visit Doctor for advice on Valproate. https://socialcare.blog.gov.uk/2015/02/26/taking-the-right-medicine/
	MISSED OPPORTUNITY	Social Care blog did not mention 30-40% risk. Did not mention details of how Fetal Valproate Syndrome can present in those affected. If Social Workers knew the symptoms of FVS they would be able to suggest parents seek diagnosis to ensure appropriate support and treatments for children/adults affected.
	Epilepsy Action	Article on new guidance from MHRA.
	MHRA	Drug safety Update. Up to 30-40% risk developmental delay, up to 10% malformations.
	Epilepsy Research UK	Online article. Personal story by Emma Friedmann https://www.epilepsyresearch.org.uk/about-epilepsy/real-stories/emma-friedmann/
	International League Against Epilepsy	March, Online article about Valproate
	Supreme Court	11/03/15. Montgomery v Lanarkshire Health Board judgement on Informed Consent. https://www.supremecourt.uk/cases/docs/uksc-2013-0136-judgment.pdf
	FACSAware	13/03/15, VPA: Roles and Responsibilities. Report published and shared with parents, media, MPs and regulators.
	Facebook	13/04/15. APESAC group set up by Marine Martin.
	Youtube EF	02/05/15. International Workers Day, May Day. Justice speech by Emma Friedmann. https://youtu.be/AmivN51DroI
	APESAC	20-21/06/15, Conference with parents, medical and legal speakers.
	Hansard	24/06/15, House of Commons, Engagements, Teresa Pearce MP, PM Cameron responds agreeing to ask Secretary of State for Health to meet Teresa Pearce and parents. http://bit.ly/31t6Suh
	MISSED OPPORTUNITY	OACS Charity and FACSAware not invited or informed of further meetings at DoH.
	France IGAS	22/06/15. Fact finding report commissioned in France. Published February 2016. www.igas.gouv.fr/spip.php?article522
	OACS, FACSAware	30/08-02/09/15, OACS, OACS Ireland tour West Coast from Wales to Scotland visiting families from OACS and FACSAware.
	Morning Star	28/10/15. Article by Faye Lipson. Interviews with Janet Williams, Emma Murphy, Catherine Cox. https://morningstaronline.co.uk/a-fa99-mothers-demand-an-end-to-epilepsy-drug-cover-up-1
2015	Times	13/12/15. Article by Nicholas Hellen.
2016	Rose Thompson	01/01/16. Vimeo interview with Janet Stockley Pollard. https://vimeo.com/150489569
	MHRA	08/01/16, Stakeholder engagement meeting at MHRA to discuss Valproate warnings and resources.
	ITV	18/01/16. Central News interview with Emma Friedmann.

#FACSAware chronology of events to add to IMMDS review timelines

		https://youtu.be/LYrgflcRQZs
2016	MHRA	29/01/16, Valproate Stakeholder Network meeting to discuss the Valproate Toolkit.
	FACSAware	January, 5,000 leaflets printed.
	ITV	18/01/16 Central News. Interview with Emma Friedmann. https://youtu.be/LYrgflcRQZs
	FACSAware	03/02/16, Local Offer Live exhibition in Leicester. MHRA Yellow Card representative joins FACSAware to inform visitors about medicines in pregnancy, valproate and importance of Yellow Card reporting. Distributed Yellow Card promotional materials and FACSAware leaflets.
	MHRA	08/02/16, Drug Safety Update, Central Alerting System – Valproate toolkit
	France IGAS report	February. IGAS publish report in France. http://www.igas.gouv.fr/IMG/pdf/2015-094R.pdf
	Sanofi	Update packaging to include written warning on outside of Epilim Box
	MISSED OPPORTUNITY	Sanofi spelt Pregnant and Contraception wrongly in written warning on outside of Epilim box. Non English speakers would not have been able to use translation software to receive warning.
	Epilepsy Action	Article about Valproate Toolkit and MHRA warnings.
	NICE	Epilepsy Guideline update
	FACSAware	09/02/16. Leaflet published for parents to print off.
	DES Daughter	14/02/16. Blog about Valproate Toolkit. https://desdaughter.com/2016/02/14/better-understanding-of-the-risks-of-valproate-medicines-and-pregnancy/
	WHO	09/03/16. Director General, Dr Margaret Chan commends the MHRA Valproate Toolkit at MHRA Lecture. https://youtu.be/t-73olsei8Q
	ITV	15/03/16.ITV Central news. Interview with Emma Friedmann https://www.youtube.com/watch?v=sUo1Zf6T44A
	FACSAware Youtube	15/03/16. ITV interview and compilation of photos. https://www.youtube.com/watch?v=QW_JBlgETQQ
	Welfare Reform Act	16/03/16. Welfare Reform Act passed into Law. http://www.legislation.gov.uk/ukpga/2016/7/contents/enacted
	MISSED OPPORTUNITY	The Welfare Reform Act could have included a request to include 'causation' of health need where known or suspected in Education Health & Care Plans, Work Capability Assessments and Personal Independence Payment assessments. Assessors could have received training on Adverse Drug and Devices reactions to inform their decision making process.
	APPG Epilepsy	March, Discuss epilepsy registry and MPs welcome Valproate Toolkit
	Epilepsy Action	Article about Epilepsy APPG
	Epilepsy Action	April, survey launch to establish understanding of levels of awareness of risk to women taking valproate.
	Research	Cochrane review of Valproate monotherapy. Weston et al.
	Reuters	24/08/16. Online article about the soon to be published IGAS report in France. https://uk.reuters.com/article/us-sanofi-epilepsy/over-14000-women-took-sanofi-epilepsy-drug-despite-fetus-risk-ministry-idUKKCN10Z2AE
2016	BMJ	October. Women unaware of risk. Responses

#FACSAware chronology of events to add to IMMDS review timelines

		Alain Brailon. Senior Consultant, University hospital Amiens, France. Drug company, regulatory agencies and Doctors have grossly failed to do their job. Healthcare professionals must perform a root cause analysis to understand the causes of this systemic failure and apologise.
2016	Epilepsy Action	Article, Women should be better informed.
	Medicines Communication Charter	Educational resources for Doctors to aid discussions around Consent
	MISSED OPPORTUNITY	October. APPG Epilepsy did not have dissemination of Valproate Toolkit or impact of it on the agenda.
	France Government & APESAC	15/11/16. French Government confirms compensation fund will be established for those affected by Depakine. Updates available from APESAC. https://www.apesac.org/
	French Court	21/11/16. Criminal complaint lodged for Civil Party action. Updates available from APESAC. https://www.apesac.org/
	LCiL 24 news	03/12/16. UN International Day for persons with disability. Yellow Card, MHRA, FACS. Interview with Emma Friedmann https://youtu.be/83LQ7xdljsU
	French Court	13/12/16, Those affected by Depakine in France to pursue legal action against Sanofi. French Government commit to compensate French Claimants. Updates available from APESAC. https://www.apesac.org/
	APESAC	13/12/16, OACS, OACS Ireland attend APESAC press conference in Paris.
	ITV	14/12/16 Central News. Interview with Emma Friedmann https://www.youtube.com/watch?v=oXWAjsbQPzM
2016	Facebook	19/12/16. ASSAC group set up by Natascha Allenbach. Switzerland.
2017	FACSAware	02/01/17, Jon Ashworth sent question to DoJ on behalf of constituent regarding access to Justice
	FACSAware	12/01/17, Report submitted to MHRA on actions required by regulatory and professional stakeholders. Also includes general observations of professionals and regulators at MHRA VSN.
	OACS Charity	14/01/17, Meet up in Watford with APESAC, FACSAware and France TV Envoye Special.
	FACSAware	15/01/17, Interviews in Leicester and Sheffield with France TV Envoye Special.
	FACSAware	January. 5,000 leaflets printed.
	FACSAware	24/01/17, Local Offer Live exhibition Leicester with OACS and Yellow Card representative from MHRA.
	FACS NZ	13-17/02/17, Conference in New Zealand.
	ANSM	08/03/17, Article 31 submitted to EMA PRAC for further action.
	EMA	09/03/17. EMA start Valproate review process. https://www.ema.europa.eu/en/medicines/human/referrals/valproate-related-substances-0#overview-section
	Epilepsy Action	March, Article, EMA to reconvene PRAC
	France TV	16/03/17, Envoye Special broadcast featuring OACS, FACSAware, APESAC.
2017	APESAC	25/03/17, FACSAware attend Department of Health and APESAC conference at French parliament.

#FACSAware chronology of events to add to IMMDS review timelines

2017	Legal	30/03/17, French government, Department of Health set up medico legal team. 2004 Claimants registered in France.
	Legal	01/04/17, Swiss lawyers announce they are to represent Claimants in Switzerland.
	Legal	01/04/17, Mark Harvey of Hugh James solicitors confirm to FACSaware reasons why they are unable to represent Valproate Claimants in UK.
	MHRA	25/08/18. Publish Discussing Valproate video online https://youtu.be/MNv-BG-bgFO
	FACSaware	26/04/17, Choice Unlimited exhibition Leicester with Yellow Card representative from MHRA.
	Real Media	06/06/17. Big Pharma and Brexit. Interview with Emma Friedmann https://youtu.be/vecmZHQRiM https://youtu.be/OmEE4Hg9M8I
	Epilepsy Action	July, Article, EMA PRAC will hold a Public Hearing
	ASSAC	26-27/08/17, Conference in Switzerland, attended by FACSaware, OACS, OACS Ireland, APESAC, ABVSV.
	BBC	22/09/17. Breakfast news. Interview with Jo Cozens. https://youtu.be/zqd33C28SaM
	BBC	22/09/17. Victoria Derbyshire show. Interview with Branwen and Deborah Mann and Clare Pelham Epilepsy Society. https://www.youtube.com/watch?v=dWD8wKBbZD4
	BBC	22/09/17. Victoria Derbyshire show. Interview with Jo Cozens https://www.youtube.com/watch?v=P5C-9UxlgZ4
	BBC	22/09/17. Radio Norfolk. Interview with Julie Marjot https://www.youtube.com/watch?v=NAwOX6IM4zl https://www.youtube.com/watch?v=n9QU5N55Tks
	BBC	22/09/17. Radio 4, Today. Interview with Susan cole https://www.youtube.com/watch?v=uihRfw08O-I
	BBC	22/09/17, Sophie Hutchison, Nicki Stiastry interview FACSaware and OACS families for extended news report.
	BBC	22/09/17 News report, interview Julie Marjot https://www.youtube.com/watch?v=WlO_d_7rOyl
	BBC	22/09/17, Drivetime Scotland interview Ian McLachlan https://www.youtube.com/watch?v=xD8ow4dvCvY
	BBC	25/09/17. Radio Leicester. Interview with Emma Friedmann https://www.youtube.com/watch?v=APd8H6vpsE8
	SKY	26/09/17. News. Interview with Branwen and Deborah Mann. https://www.youtube.com/watch?v=UyEh_eODZQI
	BBC	26/09/17. Breakfast. Interview with Samantha Scott Edgar and Dr Rebecca Bromley. https://www.youtube.com/watch?v=98MzzU0yN08
	BBC	26/09/17. Breakfast. Interview with Ian and Lillias McLachlan. https://www.youtube.com/watch?v=-isck2Fua5w
	BBC	26/09/17. World service news. Interview with Emma Friedmann https://www.youtube.com/watch?v=6py2ddoNhAc
	BBC	26/09/17. World Service news. Interview with Janet Stockley Pollard. https://youtu.be/eElv9rUB6gM
	BBC	26/09/17. Radio Sussex. Interview with Janet Stockley Pollard https://www.youtube.com/watch?v=tR13283zuF8
2017	BBC	26/09/17. Radio Wiltshire, Interview with Natasha Mason

#FACSAware chronology of events to add to IMMDS review timelines

		https://www.youtube.com/watch?v=9FnMA2fWma8
2017	BBC	26/09/17. National News. Interview with Janet Stockley Pollard https://www.youtube.com/watch?v=HgwyPhwzvHc
	EMA	26/09/17, PRAC Valproate Public Hearing https://youtu.be/CzeJSzkrygM
	BBC	26/09/17. News at 6. https://www.youtube.com/watch?v=V8vJngwoH-E
	Telegraph	26/09/17 https://www.telegraph.co.uk/news/2017/09/26/medical-experts-complicit-letting-20000-children-develop-deformities/
	FACSAware	26/09/17, Social event in London attended by OACS UK, OACS Ireland, FACSAware, FACS Justice, ASSAC, APESAC, ABVSV.
	Leicester Mercury	27/09/17. Newspaper and online article. Interview with Emma Friedmann. https://www.leicestermercury.co.uk/news/health/leicester-mum-says-dangers-epilepsy-534356
	RTE	28/09/17 One Prime Time. Interview with Karen Keely https://www.youtube.com/watch?v=Tv_2KH-Np1Y
	BBC	28/09/17. Wales news. Interview with Jo Cozens. https://www.youtube.com/watch?v=n9QU5N55Tks
	Spirit FM	28/09/17. Radio News. Interview with Janet Stockley Pollard. https://www.youtube.com/watch?v=IDZ3hD708QI
	Spirit FM	28/09/17 https://www.spiritfm.net/news/sussex-news/2389698/felpham-mum-claims-epilepsy-drug-caused-birth-defects/
	BBC	28/09/17. Radio Essex. Interview with Mary Toms https://www.youtube.com/watch?v=MYK-Gd-xD40
	Bognor news	28/09/17 Newspaper and online article. Interview with Janet Stockley Pollard. https://www.bognor.co.uk/news/felpham-family-welcomes-drug-risk-review-1-8172872
	EMA	04/10/17, Publish summary of Public Hearing.
	Daily Record	06/10/17. Interview with Samantha Russell about her baby that died and her other children affected by Valproate. Includes 28/01/11 Press Association video of Emma Friedmann. https://www.dailyrecord.co.uk/news/local-news/heartbroken-irvine-mum-demands-justice-11291573
	FACSAware	11/10/17, Choice Unlimited Exhibition Rutland
	HoC Hansard	19/10/17 Norman Lamb MP http://bit.ly/2vmOSDI Valproate and Fetal anti convulsant syndrome. Valproate debate suggests Public Inquiry https://www.youtube.com/watch?v=Tv_2KH-Np1Y
	The Sun	https://www.thesun.co.uk/news/5116290/mum-claims-epilepsy-drug-epilim-left-two-of-her-sons-battling-autism-aspergers-and-adhd/
	News Corp	October. Online article. Interview with Janet Stockley Pollard. http://dir.md/news/5116290/mum-claims-epilepsy-drug-epilim-left-two-of-her-sons-battling-autism-aspergers-and-adhd/?host=www.thesun.co.uk
2017	IB Law	24/10/17. Brief history of Valproate, warnings issued, summary of legal and regulatory action. Online article. https://www.lblaw.co.uk/blog/epilepsy-drug-epilim-and-its-potential-impact-on-pregnancy

#FACSAware chronology of events to add to IMMDS review timelines

2017	Epilepsy Ireland	Set up FACS Forum Ireland with Stakeholders from Health, Regulation, Government and charities.
	The Journal.ie	18/11/17. EMA PRAC & FACS Forum. Interview with Wendy McGarth and Karen Keely. https://www.thejournal.ie/epilepsy-drug-pregnancy-3703579-Nov2017/
	ANSM	Instruct manufacturers to put pictograms on outside of all epilepsy medication boxes. Pregnant woman in circle with strike through or Pregnant woman in triangle.
	MISSED OPPORTUNITY	MHRA did not request manufacturers put pictogram on outside of all AED boxes.
2018	FACSAware	22/01/18, Report submitted to MHRA on what patients require of regulation and the medical profession.
	BBC	22/01/18. Inside Out documentary. Interviews with Karen Buck, Warren Matthews, Janet Williams, Emma Murphy, Sue Jenkinson, Natasha Jenkinson, Tanya Hughes, Natasha Mason, Professor Turnpenny, Professor Gus Baker, Charles Joseph Oudin, Norman Lamb MP. https://www.youtube.com/watch?v=Rvf2-qvkeig
	The London Economic	09/02/18. Online article. Interviews with Janet Williams and Emma Murphy. https://www.thelondoneconomic.com/news/mums-expose-decades-long-cover-baby-defect-drug-still-prescribed-thousands-women-amid-calls-inquiry-national-scandal/19/10/?doing_wp_cron=1572301810.4716329574584960937500
	BBC	10/02/18. Inside Out world news. https://www.youtube.com/watch?v=6py2ddoNhAc
	DHSC Hansard	21/02/18, Jeremy Hunt MP Statement on Medicines and Medical Devices Safety Review. http://bit.ly/2J6oWQU https://youtu.be/kiGKly8_Vac
	BBC	21/02/18, Radio 5 live with Julie Marjot
	IBB Claims	https://www.ibbclaims.co.uk/site/blog/Medical-Negligence/epilepsy-drug-sodium-valproate-and-birth-defects
	Epilepsy Action	Article about IMMDS review
	MHRA	Pregnancy prevention programme, pictogram on outside of box and foil wraps, pharmacy cards, GP software updates.
	Manufacturers	Print pictogram and written warning on outside of Valproate box and pictogram on foil wraps.
	Epilepsy Society	27/02/18. Online article by Emma Friedmann about IMMDS review announcement. https://www.epilepsysociety.org.uk/emma-friedmann-and-sodium-valproate-announcement#.Xat_SehKiUk
	Epilepsy Action	Article, MHRA bans valproate and introduces PPP.
	NICE	Guidelines update
	UK Teratology Information Service	March. Bumps information update. http://www.medicinesinpregnancy.org/bumps/Medicine--pregnancy/sodium-valproate/
	Facebook	05/03/18. INFAC group set up by Janet Williams and Denise Astill.
	Pulse	29/3/18 Managing Migraine
2018	FACSAware	March. 5,000 leaflets printed

#FACSaware chronology of events to add to IMMDS review timelines

2018	FACSaware	11/04/18, Choice Unlimited exhibition Leicester with Yellow Card representative from MHRA.
	Legal	21/04/18. Joint submission by OACS, FACSaware, Leigh Day solicitors and David Body sent to IMMDS review.
	FSRH	23/04/18 MHRA issues PPP.
	MHRA	24/04/18 Drug Safety Update. Valproate only for women on PPP.
	Practical Neurology	April, Women and Valproate, what should neurologists do? Dr John J Craig.
	Practical Neurology	April, Valproate, childbearing potential and new regulations. Dr Sanjay Sisodiya
	Pulse	24/4/18 27,000 patients. GPs to review in months
	SKY	24/04/18. Online. Interview with Emma Murphy, Emma Friedmann, Karen Buck, June Raine about the Valproate Pregnancy Prevention Programme. https://news.sky.com/story/valproate-new-licensing-rules-for-controversial-epilepsy-drug-11344823
	BMJ	April. Open journal. Retrospective study on valproate prescribing to women with bipolar https://bmjopen.bmj.com/content/8/4/e020450
	BMJ	18/04/18. Article on Valproate restrictions and how a woman's Human Rights are being affected, exceptions need to be made. by Dr Heather Angus-Leppan and Dr Rebecca Liu. https://www.bmj.com/content/361/bmj.k1596.abstract
	MISSED OPPORTUNITY	Neurologists have repeatedly been obstructive at the MHRA Valproate Stakeholder meetings. They had an opportunity with a BMJ article on Valproate restrictions to reverse their obstructive nature and offer their support to patients whose voice has been listened to by the MHRA. Instead they didn't. They call for exceptions on the grounds of Human Rights. They fail to recognise how insulting this is to mothers and those personally affected with FVS. The neurology community has shown no desire to understand the view of women with epilepsy, no professional consideration that having a child with disability causes the mother to experience many of the triggers for her epilepsy eg Tiredness, stress, anxiety, irregular eating, lack of sleep. Open letter sent by Dr Angus Leppan and Dr Liu to the MHRA, signed by 62 individuals and high profile hospitals and departments.
	Channel 5	02/05/18. News. Interview with Susan and Hannah Cole. https://www.youtube.com/watch?v=nzrku88qMeE
	Morning Star	05/05/18. INFACT win Campaign of the week. Interview with Emma Murphy and Janet Williams. https://morningstaronline.co.uk/article/activists-win-three-year-battle-over-epilepsy-drug
	Channel 5	11/05/18. News report. Interview with Clare Pelham Epilepsy Society. https://youtu.be/JBGRLjU4038
2018	DES Daughter	11/05/18. Blog about the IMMDS review announcement. Promoting Leigh Day submission to the review on behalf of FACSaware and OACS. https://desdaughter.com/2018/05/11/submission-cumberlege-review-valproate/
2018	FACSaware	15/05/18, Local Offer Live exhibition Leicester with Yellow Card representative from MHRA.
	MHRA	24/05/18 PPP supporting resources distributed

#FACSAware chronology of events to add to IMMDS review timelines

	BMJ	Editorial – Angelika Wieck, Sarah Jones – Dangers of Valproate in pregnancy.
	ANSM & APESAC	June. Joint report. Updates available. apesac
	BMC	01/06/18 https://bmcpregnancychildbirth.biomedcentral.com/articles/10.1186/s12884-018-1842-x
	Company Chemist Association	June, Clinical Audit launched
	INFACT	05/06/18. Annual conference.
	MHRA	02/08/18 Published Pregnancy Prevention Programme online video https://youtu.be/VuBq2M1Me04
	BMJ	17/08/18 Responses to BMJ article by Dr Heather Angus Leppan & Dr Rebecca Liu. Includes 62 high profile Signatories in Medicine and Neurology supporting exceptions for women who wish to become pregnant to take Valproate. https://www.bmi.com/content/361/bmi.k1596/rapid-responses
	Connate Support CIC	25/08/18 Registered at Companies House by Deborah Mann and Karen Buck. https://beta.companieshouse.gov.uk/company/11537593
	GOV.UK	25/09/18 https://www.gov.uk/drug-safety-update/valproate-pregnancy-prevention-programme-actions-required-now-from-gps-specialists-and-dispensers
	NHS	25/09/18. Sodium Valproate advice to patients. https://www.nhs.uk/medicines/sodium-valproate/
	MISSED OPPORTUNITY	NHS Choices information does not feature a prominent written or pictogram warning.
	MIND	Online advice about Valproate. https://www.mind.org.uk/information-support/drugs-and-treatments/lithium-and-other-mood-stabilisers/valproate/#.Xat7juhKiUk
2018	Pharmacy Regulation	15/11/18 https://www.pharmacyregulation.org/regulate/article/focus-supplying-medicines-safely-sodium-valproate Used Epilepsy Society image and not the internationally recognised image.
2019	JAMA	04/01/19. Christensen. Prenatal exposure to Valproate & other anti epileptic drugs & ADHD. Association with Valproate but not other AEDs https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2720066
	FACSAware	January. 5,000 leaflets printed. 500 pens.
	FACSAware	23/01/19, Local Offer Live exhibition Leicester with Yellow Card representative from MHRA.
	HoL Hansard	28/02/19, Lord O'Shaughnessy, House of Lords, Safety of Medicines and Medical Devices. http://bit.ly/2VvY6bH https://youtu.be/IZAYGdfjppw
	Epilepsy Action	March, Article about HoL debate
	Leicester Mercury	17/03/19. Article about Loneliness. Interview with Emma Friedmann about community cafes and medicine safety.

#FACSAware chronology of events to add to IMMDS review timelines

		https://www.leicestermercury.co.uk/news/leicester-news/simple-way-people-leicester-helping-2644370
	Epilepsy Ireland	22/03/19. National conference in Dublin. FACS Forum, OACS Ireland, Health Service Executive, Trinity College. https://youtu.be/M20PnQ0VAtA
	Hansard	26/03/19 Cat Smith MP
	RCGP/ ABN/ RCP	29/03/19. Guidance document on Valproate use in women and girls of childbearing years, authors Dr Judy Shakespeare, Dr Sanjay Sisodiya. Endorsed by RCGP, RC Physicians, RC Psych Contributors: RC Paed and child health, RC Obs and gynae, R Pharmaceutical Society, RC Midwives, RC Nursing, Ass British Neurologists, British Paed Neurology Ass, Epilepsy Specialist Nurse Ass, Institute of Health Visiting, Faculty of Reproductive and Sexual Health, Nursing and Midwifery Council.
	RCOG	29/03/19 https://www.rcog.org.uk/en/guidelines-research-services/guidelines/valproate-use/
	RCGP	29/03/19 https://www.rcgp.org.uk/about-us/news/2019/march/thirteen-uk-healthcare-bodies-launch-pragmatic-guidance-on-valproate-use.aspx
	RCPCH	29/03/19 https://www.rcpch.ac.uk/news-events/news/thirteen-uk-healthcare-bodies-launch-pragmatic-guidance-valproate-use
	PSNC	29/03/19 https://psnc.org.uk/walsall-lpc/wp-content/uploads/sites/56/2019/03/ESCA-Valproate-use-for-women-and-girls.docx
2019	MHRA	30/03/19 Issued updated Acknowledgement of Risk form
2019	Women with epilepsy	01/04/19 https://www.womenwithepilepsy.co.uk/
	FSRH	Quoted by RCOG and others but nothing on website.
	MEDSCAPE	01/04/19 https://www.medscape.com/viewarticle/911124
	SPS.NHS	01/04/19 https://www.sps.nhs.uk/wp-content/uploads/2019/04/Prescribing-of-Valproate-in-line-with-the-Valproate-Pregnancy-Prevention-Programme-PREVENT-Policy.pdf
	Epilepsy Society	01/04/19 https://www.epilepsysociety.org.uk/news/royal-colleges-publish-new-guidance-around-use-of-valproate-for-women-and-girls-of-childbearing-age-with-epilepsy-01-04-2019#.XX-9bChKiUk
	RPHARMS	01/04/19 https://www.rpharms.com/resources/quick-reference-guides/dispensing-valproate-for-girls-and-women
	Epilepsy Action	April, History Epilepsy Action involvement in valproate campaign https://www.epilepsy.org.uk/involved/campaigns/sodium-valproate
	MHRA	11/06/19. How to report a side effect from a medicine – Patient guide to Yellow Card. Video uploaded. https://youtu.be/TrUHLhgVAE4
	MHRA	12/06/19. How to report a side effect from a device – Patient guide to Yellow Card. Video uploaded. https://youtu.be/U4btj0tJEP8
	GOV.UK	21/06/19 https://www.gov.uk/guidance/valproate-use-by-women-and-girls

#FACSAware chronology of events to add to IMMDS review timelines

	MISSED OPPORTUNITY	Department of Health and other Health bodies have not supported the MHRA promotional materials about the Yellow Card and Drug Safety.
	Better Care Together	05/07/19. Information Management and Technology teams in Leicester, Leicestershire and Rutland amend stakeholder IT systems to enable access to EHCP from NHS and Local authority systems.
	INFACT & FACS NZ	10/07/19. INFACT and FACS NZ meet with MHRA to discuss regulation.
	INFACT & FACS NZ	15/07/19. INFACT and FACS NZ meet with WHO in Geneva.
	PCWHF	11/07/19 https://pcwhf.co.uk/resource_type/clinical-guidelines/
	BBC	20/08/19. North West news about SEN provision. Interview with Samantha Scott Edgar https://youtu.be/5b_TCE-E3sg
	Wikipedia	16/10/19. Sodium Valproate page updated. https://en.wikipedia.org/wiki/Valproate
2019	Connate Support CIC	November. Professional Board members appointed. https://beta.companieshouse.gov.uk/company/11537593/officers
2020	Young Carers awareness day	30/01/20. #YoungCarersAwarenessDay #YoungCarers
	FACSAware	31/01/20. Local Offer Live exhibition Leicester.
	APESAC	04/02/20. French prosecutor lodged investigation into Sanofi regarding Depakine. https://www.reuters.com/article/us-sanofi-depakine/frances-sanofi-under-investigation-in-depakine-birth-defects-case-idUSKBN1ZY0NW
	Epilepsy Day	10/02/20. International Epilepsy Day. #EpilepsyDay
2020	Watford Observer	17/02/20. Interview with Branwen Mann about Young Carers https://www.watfordobserver.co.uk/news/18240740.disabled-south-oxhey-carer-took-care-disabled-mother/
	MHRA	21/02/20. Valproate Registry meeting with patient groups.
	Rare Disease Day	29/02/20. #RareDiseaseDay
	MHRA	17-23/02/20 Adverse Drug Reaction awareness week. Focus on polypharmacy and importance of reporting using the Yellow Card. #ADRAwarenessWeek #PolyPharmacy #YellowCard #MedSafetyWeek
	HoC Hansard	02/03/20. Medicines and Medical Devices Bill. Second reading. https://hansard.parliament.uk/Commons/2020-03-02/debates/FF798F53-ED6D-4AE5-B33A-780FBF45C151/MedicinesAndMedicalDevicesBill
	World Birth Defects Day	03/03/20. #WorldBDDay #WorldBirthDefectsDay
	Department of Work and Pensions	05/03/20. Meeting with patient groups to discuss DWP benefits, assessments and policies.
	MISSED OPPORTUNITY	IMMDS Review did not take Oral evidence from organisations that have a significant role in the use of Valproate and Regulatory working groups. Association of British Pharmaceutical Industries. International League Against Epilepsy. Epilepsy Research UK. Royal College of Midwives. UK Teratology Information Service.

#FACSaware chronology of events to add to IMMDS review timelines

		Royal College of Paediatric and Child Health. Royal College of Midwives. British Paediatric Neurology Association. Epilepsy Specialist Nurse Association. Institute of Health Visiting. Faculty of Reproductive and Sexual Health.
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Timeline Evidence

INFACT/FACSA

Journal paper by S R Meadows 14th December 1968 - Anticonvulsant Drugs and Congenital Abnormalities

This paper was in The Lancet under Letter to the Editor and noted :

“Folic –acid deficiency is relatively common in pregnancy, and anticonvulsant drugs, particularly primidone, are known to act as if antagonising folic acid. The epileptic moths of these 6 children took combinations of the following drugs:

Primidone, Phenytoin, toxidone and phenobarbitone.... It is easy therefore to postulate how anticonvulsants might be added to the list of factors that may cause hare-lip and cleft palate. However, before creating anxiety about useful drugs, it would be helpful to know if other people have encountered the association”

- 1975 OACS Oral Evidence session 20 November
Its important to remember here that if OACS Oral Evidence is noted in the Timeline then other groups should be also, however INFACT/FACSA fails to be noted against any evidence they have put forward.
- Oct 1982 USA Written evidence from Leigh Day (on behalf of FACSaware, OACS, OACS Ireland, Valproate victims. Please see note above.
- 1999 OACS Charity set up by **Janet Williams** to provide support and raise awareness....
- 2005 Written evidence from Leigh Day, on behalf of FACS aware, OACS, OACS Oreland, Valproate Victims Event notes 2005 guidance from NICE .

Due to continuous awareness on the topic of danger of valproate in pregnancy and issues being over Covered up and hidden from the media and the public, INFACT/FACSA feel it is important to also note in the Timeline the exposing evidence given through the media channels and brought to the attention by the work of INFACT and FACSA

- Nov 2012 FACSA formed to support parents with children affected by the Valproate crisis.
- 2013 BBC Inside Out Documentary by INFACT/FACSA
BBC Panorama Documentary by INFACT/FACSA
(Before archive documentation)
- 2017 Debate in House of Commons by APPG for Valproate and other AEDs in Pregnancy Chair Sir Norman Lamb with support and evidence given by Secretariat INFACT
- European Medicines Agency Review publicise through EMA You tube channel.
INFACT uncovered archive and important covered up evidence.
- Sky News full day report on INFACTs Archive Evidence and EMA Review

2017 Bearing in mind and in respect of the Review, INFACT first responded to former Health Minister, Mr Jeremy Hunt Remit sent to us on 14th April,2017. The questions asked in the remit were

- Build an evidence case for exceptional treatment by outlining the specific needs of both children/adults affected by sodium valproate and their subsequent care needs, and how they are different from those who suffer from mental/physical disabilities but are not affected by valproate.
- The case should also include evidence and information on the clinical, regulatory and commercial behaviours and any evidence of negligence or clinical malpractice, taking into account the existing evidence and standards at the time.

However, a response to the remit was never received by INFACT and the announcement of the Review shortly followed.

2018 2nd Inside Out Documentary uncovering possible transgenerational link and how new warnings were failing.





INFACT

Timeline of Events

Sodium Valproate

Valproate Key Points

- Sodium Valproate was reported to the Committee for the Safety of Medicines to be teratogenic when first licenced in 1973, in July 1973 CSM gave the right for Drs to have datasheet “but without the patients themselves seeing it”
- Valproate was not research during the first 5 years of licencing in order to calculate the implications especially after Thalidomide some 15 years earlier.
- No information given to the public from Sanofi until 1996 by a Patient Information Leaflet which stated ‘if pregnant please consult your doctor’ then in 2000 reporting ‘possible Spina Bifida’.
- The Medicines & Healthcare Products Regulatory Agency (MHRA) were aware of the outcomes when Valproate was prescribed to women of child bearing age and the effect of the drug neurodevelopmentally on the child from September 2000, but failed to release this information to the patient directly through the HCPs.
- The above resulted in hundreds of Women with Epilepsy, and other conditions unable to make an informed choice.
- Sodium Valproate now being prescribed also for Bipolar, migraine headaches and/or pain relief.
- In 2013 the Quality and Outcomes Framework changed its Indications therefore withdrawing from giving women Pre-Conception Counselling and not allowing women, once again to make that all important informed choice.
- MHRA agreed figures of those exposed to Valproate in pregnancy with 40% having Neurodevelopmental disorders and 1 in 10 having a major malformation such as Spina Bifida following the release of a journal paper by Bromley et al, meetings with INFAC and intervention taken by the European Medicines Agency in 2014/2015.

REFERENCES:

- 1) Journal of Neurol Neurosurg Psychiatry 2013;0: 1-7 Rebecca Bromley et al: The Prevalence of Neurodevelopmental Disorders in Children Prenatally Exposed to Antiepileptic Drugs
- 2) House of Commons Committee of Public Accounts: Services to People with Neurological Conditions: Progress Review. <http://www.publications.parliament.uk/pa/cm201516/cmselect/cmpubacc/502/502.pdf>

- New warnings on the dangers of Valproate in pregnancy went out in February 2016. These warnings were distributed to Healthcare Professionals such as prescribing specialist, dispensing pharmacists, primary care doctors, trust medical directors, HCP's working in field of Sexual Health. Yet this warning was not be given a Mandatory Status and therefore was not compulsory.
- The same warnings released by the MHRA to HCPs did not filter through to the female patient of child bearing age prescribed Valproate until May 2017 and became the Pregnancy Prevention Program in April 2018 following the intervention of Lord O'Shaunessy, INFACT and the APPG for AEDs in Pregnancy.
- Minister George Freeman MP stated in 2015 that Clinical Practice Research Datalink covering only 7-8% of population notes that 35,000 women between 14yrs old and 45 yrs old are pregnant each year. Only 30 (0.08%) have prescription for Valproate. Calculation of whole population in the UK taking this drug (420,000) using these figures show that 336 exposed each year, with 51% affected by valproate, this calculates to 172 affected each year with 7,368 affected since Valproate came onto the market in 1973 (43yrs).
- In a meeting on the 22nd February 2017 with Lord O'Shaughnessy the MHRA stated there had been approx. 400 babies affected by Valproate in utero between February 2016 (When the new warnings were released) to February 2017.
- On the 19th January 2018 INFACT receive confirmation of the Government remit to be answered on the 18th April 2018. However this was superseded by the announcement of the IMMDS Review in at the beginning of March 2018 with INFACT never receiving a response from the Ministers office.
- The PPP still fails to be used by GPs, specialists and other healthcare professionals, with NICE failing to make it clear in their Guidance, GPs contracts not updated swiftly enough to incorporate the PPP and MHRA and GMC failing to penalise those not using it.
- The Government must now consider a 'Statement of Regret' and reasonable compensation for those affected, taking into account the years of suffering some people have had due to lack of warnings from the beginning of Valproate's life on the market.

Major Events:

- Restricted license granted in the UK 1972 for Epilepsy Clinics only
- Full license granted and Introduced onto the UK market in 1973 by Reckett & Coleman
- Committee for Safety of Medicines (CSM) discussed and decisions made on the instruction given to Doctors in 1973
- A Datasheet was produced in 1974 by Reckett & Coleman explain the teratogenic effects of the drug
- Sanofi reported teratogenic effects in animals to the Association of the British Pharmaceutical Industry in 1979
- Medical research papers began to appear in the medical journals from 1980 (*See research data attached*)
- Current Problems Sheets released by the Committee on Safety of Medicines stating the teratogenic effects in human released in January 1983 – 2005
- Committee on Safety of Medicines Meeting Minutes where Valproate in pregnancy was discussed from 1999-2005
- Sanofi claim to have released product information to doctors in 1989
- Sanofi claim to have released patient information in 1989
- British National Formulary entry stating sodium valproate and the increased risk of Neural tube defects when taken in pregnancy in 1991
- First Patient Information leaflet (PIL) released by Sanofi Winthrop appeared in boxes of medication in 1995 stating '*If pregnant please consult your doctor*'
- National Institute of Clinical Excellence (NICE) issued guidelines concerning the warnings and pre-conception counselling for women of child bearing age taking Valproate in 2004

- Patient Information Leaflet (PIL) released by Sanofi stating *'Some babies born to mothers who took Epilim Chrono during pregnancy may develop less quickly than normal. These children may require additional educational support.'* In 2005
- Patient Information Leaflet (PIL) released by Winthrop Pharmaceuticals (but same address as Sanofi) stating *'Some babies born to mothers who took sodium valproate during pregnancy may develop less quickly than normal or have autistic disorders. These children may require additional educational support'* in 2010.



Major Research/Journal papers reporting Valproate and the Effects on the Foetus:

Time line: Key publications which altered the way we think about Valproate exposure.

1980- Dalens, B. Teratogenicity of valproic acid. *The Journal of Pediatrics* 1980; 97(2):p332-333. The first report of an infant with major congenital malformations thought to be linked to exposure to sodium valproate.

1982 –Rovet, E. & Guibaud, P. Maternal valproic acid and congenital neural tube defects. *The Lancet* 1982; 2(8304): p937. – Demonstrates the potential association between prenatal exposure to VPA and spina bifida.

1988 –Ardinger, H., et al Verification of the Fetal Anticonvulsant Syndrome. *American Journal of Medical Genetics* 1988; 29:p171-185– the first group case series of children exposed prenatally to sodium valproate and highlights potential characteristics of the syndrome.

1995 – Clayton-Smith, Donna D. Confirmation of Fetal Valproate Syndrome. *Journal of Medical Genetics* 1995; 32: p724-727 – The first paper to confirm the affects of Valproate in pregnancy and that of Fetal Valproate Syndrome.

1996 – King, P.B., et al. Spina bifida and cleft lip among newborns of Norwegian Women. *American Journal of Public Health* 1996; 86(10):p1454-1457. Demonstrated that changes in anticonvulsant use across the country lead to an alteration in the type of birth defects seen in the children.

1997 – Samren, E.B., et al. Maternal use of antiepileptic drugs and the risk of major congenital malformations: a joint European prospective study of human teratogenesis associated with maternal epilepsy. *Epilepsia* 1997; 38(9): p981-990. This collaboration of a number of different research groups highlights the importance of the dose of the drug.

2000- Moore, S., et al. A clinical study of 57 children with fetal anticonvulsant syndromes. *Journal of Medical Genetics* 2000;37:p489-497. The first study into a group of children diagnosed with fetal anticonvulsant syndromes.

2001 –Adab, N., et al. The longer term outcome of children born to mothers with epilepsy. *Journal of Neurology, Neurosurgery and Psychiatry* 2004; 75:p1575-1583. The first study to include a large group of children exposed to sodium valproate and to find that they require increased levels of educational support.

2004- Gaily, E., et al. Normal intelligence in children with prenatal exposure to carbamazepine. *Neurology* 2004; 62:p28-32. This large and well designed study found that the IQ of children exposed to carbamazepine was not significantly different from a group of un-exposed children.

2006-Hunt, S., et al. Levetiracetam in pregnancy: preliminary experience from the UK Epilepsy and Pregnancy Register. *Neurology* 2006; 67: p1876-1879. The first investigation into prenatal exposure to levetiracetam (Keppra) and birth defects.

2008 –Hunt, S., et al. Topiramate in pregnancy: preliminary experience from the UK Epilepsy and Pregnancy Register. *Neurology* 2008; 71: p272-276. The first paper to investigate prenatal exposure to topiramate.

2008 – Bromley, R., et al. Autism spectrum disorders following in utero exposure to antiepileptic drugs. *Neurology* 2008; 71: p1923-1924. The first prospective study to demonstrate an increased prevalence of autistic spectrum disorders in children exposed to sodium valproate.

2009- Meador, M., et al. Cognitive function at 3 years of age after fetal exposure to antiepileptic drugs. *The New England Journal of Medicine* 2009; 360(16): p1597-1605. The largest prospective study into sodium valproate and lamotrigine demonstrating that the first is associated with reduced IQ.

2011 –Shallcross, R., et al. Child development following in utero exposure: levetiracetam vs sodium valproate. *Neurology* 76; p383-389. The first study to investigate the rate of developmental delay in a group of children exposed to levetiracetam.

2011- Tomson, T., et al. Dose-dependent risk of malformations with antiepileptic drugs: an analysis of data from the EURAP epilepsy and pregnancy registry. *Lancet Neurology* 2011; 10: p609-617. The largest study to date which shows level of risk by dose of antiepileptic drug.

2013 – Bromley RL., et al. The prevalence of Neurodevelopmental disorders in children prenatally exposed to antiepileptic drugs. *Neurol Neurosurg Psychiatry* 2013; **0**: p1-7. In the context of already published work, suggests that the risks associated with VPA treatment during pregnancy include neurodevelopmental disorders.

We know though past events, since Valproate received its full licence in 1973, that procedures taken have avoided giving the female patient, in these circumstances, an informed choice and a fully transparent insight into the dangers, damages and side effects which can be caused when taking this drug in pregnancy.

Since this information was withheld in 1973 onwards, somewhere between 7,000 (figures given by MHRA and George Freeman MP in 2016) and 20,000 (figures calculated from the Man study 2012) babies have been harmed to varying degrees, with the majority suffering neurodevelopmental disorders such as Autism and around 11% suffering major malformation such as Spina Bifida.

There have been missed opportunities along the way, with Valproate never being discussed openly by the Chief Medical Officer, as she did with Ebola, Zika, antibiotics, HPV vaccine, Folic Acid, smoking and Alcohol in pregnancy. Neither has Valproate been noted openly through social media by the Health Minister, Chair of RCGP OR Royal Pharmaceutical Society yet other topics have.

INFACT have held meetings with all governing bodies such as General Medical Council, NICE, General Pharmaceutical Council to prompt and encourage them to openly, through social media, discuss the Valproate Pregnancy Prevention Program. This has never been achieved with the exception of the MHRA on the introduction of the toolkit in 2016 and the PPP in 2018.

Systems have to change to avoid this EVER happening again, and without a similar re-occurrence caused by the effects of another prescribed medication.

Mesh Ireland

Campaign founder: Mary McLaughlin

Background

In 2008 I was implanted with a transobturator mesh implant. My campaigning activity started in 2016. What commenced as a personal quest for truth, gradually evolved into a public campaign to articulate the plight of the mesh injured and the need to address dysfunctional aspects of existing institutional frameworks.¹ My educational background in the disciplines, Law, Politics and Education has assisted me.

Mesh Ireland is a grass roots, one-woman campaign which started in late 2016. I went public on my campaign in 2017. I was the first woman to alert the public authorities in Northern Ireland of the lack of mesh removal services for local women². I paved the way for others in the fight to be transferred to NHS England mesh removal services.³ My journey moved to the USA to avoid becoming part of what became known as the #notafullremoval scandal. I had my mesh implant fully removed in January 2019 in the USA by mesh removal expert, Dr Dionysios Veronikis, Mercy Hospital, Missouri.

In August 2018 I launched the 'Offer of Dr Veronikis campaign'. The main success of this campaign has been in Scotland. I have played a major role in the advanced of this campaign.⁴ The First Minister, Nicola Sturgeon has spoken to Dr Veronikis⁵. Scottish surgeons have visited Dr Veronikis in the USA and Dr Veronikis scheduled visit to Scotland in Spring 2020 is now delayed due to the Covid situation. In June 2020, the campaign to bring Dr Veronikis to the UK and Ireland reached a political impasse in Scotland. The "hostile environment" which the campaign faces reflects Mesh Ireland's strong view of a race to the bottom ethics of self-regulation in the context of mesh removal services.

The situation of our women

In November 2017 I formed the Mesh Ireland Facebook group. I wanted to use my skill set to improve the existing systems and to share my experiences with women in a similar situation. I also needed a group to have a place at the table of decision makers.

¹ Extensive emails and FOI correspondence regarding data, coding of surgeries and medical devices regulatory regime.

² Contact with Dr Brid Farrell, Public Health Agency, 17 July 2017 and article in Belfast Telegraph by David Young, PA, July 29, 2017 <https://www.belfasttelegraph.co.uk/news/northern-ireland/vaginal-mesh-implant-sufferers-demanding-removals-on-the-nhs-35978977.html>

³ <https://www.bbc.co.uk/news/uk-northern-ireland-40898220> Vaginal mesh campaigners welcome 'major development' By Marie-Louise Connolly BBC News NI Health Correspondent 11 August 2017

⁴ http://www.parliament.scot/parliamentarybusiness/report.aspx?r=11976&mode=html#iob_108295

⁵ <https://www.sundaypost.com/fp/first-minister-calls-us-mesh-surgeon-to-invite-him-to-scotland/> Marion Scott, Sunday Post, November 3, 2019.

The Mesh Ireland members are from the North and South of Ireland. They are informed by my campaign and I support them by articulating their problems or signposting avenues of assistance. The membership ceiling is 100 members and membership is open to women impacted by vaginal incontinence mesh implants who live on the island of Ireland or have a nexus to the geographical region. Exceptions are made from time to time.

The Mesh Ireland group have sadly had one member who died in 2018. This lady's health deteriorated after a sling procedure, mesh erosion and the development of squamous cell carcinoma in her bladder. Although she survived for some years, her quality of life was severely impaired. She died in 2018.

Mesh Ireland has many members facing the problem of stagnated health treatment. They are currently without real hope that their situation will improve. We have booked some successes such as the procurement of a specialist scanner and highlighting gaps in services to Ministers, but real progress is slow. Many women have lost their opportunity to take legal redress.

Market exploitation of mesh women's vulnerability

By the time Mesh Ireland participated in the IMMDS Review Evidence session, clarity around "mesh myths" were emerging. Local clinicians had led women to believe that mesh was fully removed and the shortness of the explant could be explained by shrinkage. The presence of Dr Veronikis' mesh removal photos and surgical videos on social media refreshed the debate on the truthfulness of the medical community and patients' medical records.

Women from Mesh Ireland were shocked by this new knowledge. Like their mesh sisters around the globe their trust in clinicians was shaken once again by the emerging scandal within the mesh scandal – the #notafullremoval scandal. I highlighted this scandal in my evidence sessions at the IMMDS Review.

Campaign vision and goals

Against this background and journey, the Mesh Ireland campaign has focused on obtaining and maintaining access to healthcare justice for mesh injured women. It acknowledges that mesh is a global issue and is part of a global advocacy community. It supports in principle campaigns to ban mesh implants.

Mesh Ireland's focus is on improving the functionality of the existing systems. Its focus is on women who have been implanted with vaginal mesh implants used as treatments for urinary incontinence.

The Mesh Ireland campaign advocates for:

- Autonomy of choice for mesh implanted women
- Informed consent on the nature of surgeries and risks
- Provision of full and safe removal services on public healthcare systems
- Support from international mesh removal expert, Dr Veronikis
- Access to justice in the legal arena and just compensation for the injured.

In the North and South of Ireland we have been particularly supported by Sinn Féin, and their two women's healthcare parliamentarians, Orlaithi Flynn, MLA,⁶ and Louise O'Reilly, TD, and local media outlets which have covered our campaign.

Advocacy activities

As a campaigner I have briefed leading key policy makers on the mesh issue either in initiated meetings or as an invited attendee. A non-exhaustive list includes:

Public Bodies - the Public Health Agency NI, the Patient Client Council NI, the Department of Health, the Department of the Communities NI, the Commissioner for Older People, the Office of the Attorney General Northern Ireland

Politicians – *Sinn Féin* (Michelle O'Neil, Deputy First Minister, Orlaithi Flynn MLA, Dr. Caiomhe Archibald MLA, Pat Sheehan MLA, Deirdre Hargey MLA, Louise O Reilly TD), *Alliance* (Paula Bradshaw, MLA), *Greens* (Clare Bailey MLA), *SDLP* (Dolores Kelly MLA , Mark H. Durkan MLA, Nichola Mallon MLA)

Scotland – as part of the campaign to bring Dr Veronikis to Scotland - Neil Findlay MSP, Jeane Freeman, Minister of Health, CMO Calderwood.

England – IMMDS Review - Private meeting in September 2018., Oral Evidence Session Mesh Ireland 19th March 2019,⁷ Final Say Oral Evidence Session, 20 May 2019,⁸ Timeline meeting in September 2019.

⁶ <https://www.bbc.co.uk/news/uk-northern-ireland-46810171> Vaginal mesh: Northern Ireland centre progress 'frustrating' By Marie-Louise Connolly BBC News NI Health Correspondent 10 January 2019

⁷ <https://www.youtube.com/watch?v=nVf9uKu2Xu4> Mesh Ireland Oral Evidence, with Patient Testimony.

⁸ <https://www.youtube.com/watch?v=NyNJ8N0aZQ0> Mesh Ireland Final Say IMMDS Channel, YouTube

Mesh UK – sent as part of email

Thank-you for your e-mail. For the question regarding key moments in our campaigning activities: -

We initially started as Mesh UK on the 22/02/2017 to start a parliamentary march down at the houses of parliament. It was only going to be a temporary group for this march but then it turned into a support group to offer positive support and awareness for mesh injured patients, their carers and loved ones. It was important for us to make this a public group so anybody could engage with us, and they didn't need to join to participate, and anyone can see what was really going on at a glance.

We held a UK mesh meet and greet in Torquay 07/07/2017 and also meet with Dr Sarah Wollaston, MP for Totnes.

We then registered Mesh UK Charitable Trust as a Charitable Incorporated Organisation with the Charity Commission on the 06/01/2018. We launched publicly the charity on Good Friday, Friday 30th March 2018.

We met John Wilkinson at a trade show in Coventry [REDACTED] on regulatory issues [REDACTED] we challenged this information [the information John Wilkinson was presenting] [REDACTED].

We met with John Wilkinson at the MHRA to discuss with him and his colleagues the problems of mesh on the 22/06/2018

We held an International mesh Meet and Greet in Florida on the 3rd October 2018 and are planning another one in London in April 2020.

Candia McCullough and Joanne Davies were invited to Sky News on the 9th October 2018 to discuss Mesh UK Charitable Trust and to give our opinion on NICE guidelines being published and promoting the use of surgical mesh as a last resort.

We created a documentary called True Insight with presenter Benjamin Leonides Morgan and Big Rich Productions. It is a feature length film about the effects of surgical mesh implants and was published on youtube in December 2018.

We held a photoshoot of mesh injured victims showing where their mesh was placed and what injuries and pain they have suffered from it and these were published on social media to raise awareness during 2018.

From a charity fundraiser point of view we have done car boot sales and held several fundraising events. The next fundraiser is on the 29th February 2020 which is a down to earth evening promoting health through plant based foods.

We have sent 2 families on respite breaks this year.

We are the leading group in the UK with true data/figures, and it is important to us to have a true reflection of what is going on. Our numbers are real numbers and not artificially inflated, i.e. by not buying followers.

We have many countries attached to our group and we have global support offering support 24/7. We have inspired other to find the strength to stand up and support others.

Scottish Mesh Survivors Group Campaign Timeline

2011	<ul style="list-style-type: none"> • Scottish Mesh Survivors (SMS) group is formed. Research and information gathering on the mesh scandal begins.
2013	<ul style="list-style-type: none"> • Women speak out and meet with Health Secretary Alex Neil. • Scottish Mesh Survivors campaign is launched. • Dakota woman Linda Gross awarded £8million against Johnson & Johnson firm Ethicon over mesh device used in Scotland. • 2013 – 2017 Scottish Government sets up mesh Short Life Working Group (SLWG), Transvaginal Mesh Working Group (TMWG), Expert Working Group (EWG) and 'Independent' Review Group (IRG) – Elaine Holmes and Olive McIlroy participate in all four as SMS patient representatives.
2014	<ul style="list-style-type: none"> • Campaigners Elaine Holmes and Olive McIlroy lodge petition demanding mandatory reporting by doctors of mesh complications, an implant register and fully informed consent. • Health Secretary Alex Neil calls for a mesh suspension and launches a safety review but NHS Glasgow and Lothian refuse and continue implanting mesh in hundreds of women. • American Medical Systems agrees £750million US payouts. • Thalidomide Campaigners support SMS and correctly predict the scale of the mesh scandal will surpass Thalidomide. • Scotland's PIL AND CONSENT BOOKLET (version 1): Synthetic vaginal mesh mid urethral tape procedure for the surgical treatment of stress urinary incontinence in women was adopted by the whole of the UK. • Elaine Holmes and Olive McIlroy win Sunday Mail 'Unsung Heroes Award' for Scottish Mesh Survivors 'Hear Our Voice' Campaign.
2015	<ul style="list-style-type: none"> • New Health Secretary Shona Robison pushes the Independent Review. Journalist Marion Scott reveals that every TVM surgeon appointed in the Review has financial links to mesh manufacturers. • Delaware woman Deborah Barba awarded almost £100million against Boston Scientific – later adjusted to £10m because of local compensation limit rules. • US mesh Attorney Adam Slater gives evidence in the Scottish Parliament to the Public Petitions Committee and he describes mesh as a "car crash" – a "social cancer". • Campaigners launch Scottish Mesh Survivors website. • Interim Report is published and raises safety concerns about obturator and POP mesh implants. • SIMS trial patient recruitment 'voluntarily' stopped in Scotland after robust SMS campaign. • Teleconference meeting with Dr Dan Poulter and MP George Freeman. • Marion Scott wins 'Journalist and Reporter of the Year Award' for her campaigning work. • CMO and Health Secretary Shona Robison give evidence to Public Petitions Committee.
2016	<ul style="list-style-type: none"> • Former Health Secretary Alex Neil demands Scotland hosts a global mesh conference as compensation in US reaches £3billion.

Scottish Mesh Survivors Group Campaign Timeline

	<ul style="list-style-type: none"> • SMS stage a peaceful demonstration at Scottish Pelvic Floor Network (SPFN) Annual Conference in protest [REDACTED] SIMS offering a trip to Brazil and laptops to the centre who recruited the most women to the controversial SIMS trial. • US firm Endo is axed after mesh legal costs hits £1billion. • Boston Scientific denies using counterfeit mesh from China. • US Attorney Steve Mostyn holds press conference at Scottish Parliament regarding counterfeit mesh.
2017	<ul style="list-style-type: none"> • More than 100 MSPs sign Scottish Mesh Survivors 'No Mesh Whitewash' pledge poster. • Three members of the IRG: Lead Urogynaecologist Dr Wael Agur, Elaine Holmes and Olive McIlroy resign ahead of the Final Report being published [REDACTED]. • Scotland's mesh safety review branded a 'whitewash' as Health Secretary Shona Robison faces condemnation over failure to stop mesh use. • Lead Urogynaecologist Dr Wael Agur gives mesh evidence to the Public Petitions Committee, it is described as 'some of the most compelling evidence heard'. • Elaine Holmes and Olive McIlroy give evidence in Australian Senate Mesh Review. • Over 400 mesh cases in Scottish court.
2018	<ul style="list-style-type: none"> • Britton Report: Review of Mesh Safety Review reveals systemic failings by Scottish Government. • IMMDSR suspends pelvic mesh use [REDACTED] • Holyrood's new Health Secretary Jeane Freeman follows UK Government and halts mesh. • Edinburgh mesh victim [REDACTED] • Scottish gran Eileen Baxter, 78, is first to have mesh listed on her death certificate. • MSPs call for a mesh ban. • Podcast by Public Petitions Committee Convener MSP Johann Lamont and MSP Brian Whittle. • Our 'Three Meshketeers'; Neil Findlay MSP, Alex Neil MSP and Jackson Carlaw MSP win joint 'Political Hero of the Year Award' for supporting SMS and indeed mesh victims everywhere. • Immediate halt on the use of mesh in Scotland as we become the first country to suspend mesh use twice. • Oral Evidence Submission to IMMDSR from Elaine Holmes and Olive McIlroy on behalf of SMS.
2019	<ul style="list-style-type: none"> • US mesh manufacturer Bard withdraws mesh as compensation in the US reaches £10billion. • Elaine Holmes and Olive McIlroy win No.1 Magazine 'Amazing Woman Lifetime Inspiration Award'. • Journalist Marion Scott wins 'Campaign of the Year Award' for Scottish Mesh Survivors 'Hear Our Voice' Campaign. • Missouri mesh expert Dr Veronikis offers to help Scottish mesh-injured women. • Oral evidence submission to IMMDSR from Elaine Holmes and Olive McIlroy on behalf of SMS.

Scottish Mesh Survivors Group Campaign Timeline

<ul style="list-style-type: none">• UK medical watchdog NICE faces backlash after announcing proposals to re-introduce mesh and are forced into a turnaround [REDACTED].• Situation, Background, Assessment and Recommendation (SBAR) management of pelvic mesh complications in Scotland.• 500+ mesh cases in Scottish court.• Elaine Holmes and Olive McIlroy participate in IMMDSR meeting at Church House Building, Westminster.• Cabinet Secretary Jeane Freeman announces the creation of a Complex Case Review Unit. She confirmed: “NO PROSPECT OF THE HALT I LIFTED BEING LIFTED”.
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The Mesh suspension you have recommended in the UK must remain for the following reasons:

- The risks from mesh cannot be mitigated. Clinicians and clinical societies have continuously failed to reassure us how they will mitigate the risk. Better training of surgeons doesn't work as the risk is with the mesh device, regardless of surgical skill.
- The risks from mesh cannot be predicted. Clinicians are unable to identify which patients are high risk of developing chronic pain and disability and which are not, it is Russian roulette.
- The risks from mesh are lifetime. There are reports where after several years of the good outcome surgeons talk about, women can start developing serious injuries later in life.
- Not all the risks of mesh are known. There are more reports of auto-immune diseases and cancer but the clinicians continue to deny them.
- The risks from mesh are irreversible. No woman goes back to her normal, even if the mesh device is completely removed. Clinicians continue to tell us the improvement rate after mesh removal is 50%. This is not good enough.
- The risks from mesh are entirely avoidable. The present alternative continence procedures, colposuspension and autologous fascial sling, are not associated with the irreversible adverse events of mesh, this makes mesh procedures entirely avoidable. If no mesh is used, a woman cannot develop mesh-related injuries.

“Mesh is an avoidable risk – it is a lifetime risk”



The Voices Today on Messed up Mesh

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To: Independent Medicines and Medical Devices Safety Review

Email: reviewteam@kcl.ac.uk

Date: 27 September 2019

From: Lorraine Evans, Founder and ICS Committee Member Patient Representative

Email: [REDACTED]@tvt-messed-up-mesh.org.uk

Subject: Timeline of Events Year 2008 to Present Day

Reference: A37303

We're submitting our timeline of events as requested in your email dated 14th September 2019.

May we take this opportunity to say a massive thank you to everyone on the review team panel for providing this review for all the mesh injured, you've shown us you care with an empathic approach to everyone, and with so much understanding on what we have been through in our health plus the sheer devastation it has caused to our families and careers plus the insecurity of financial loss through no fault of our own.

TVT Mum provides help and support to men and women experiencing severe health problems and complications from the medical devices Trans-vaginal Tension Free Tape (TVT), Tension Free Vaginal Tape Obturator (TVT-O), TransObturator (TOT) and other medical devices using surgical polypropylene synthetic mesh for hernia's, prolapse, stress urinary incontinence and rectopexy.

We have a huge database of research with only a fraction showing on the website.

You're more than welcome to arrange a visit to see a full insight on how much work was and still is produced on the mesh scandal or if you need clarification on any items within the timeline of events, please do not hesitate to contact us.

*'It's very disturbing to know the mesh injured are disabled not only from the synthetic mesh implant medical device surgical procedure but **also** left infirm and disabled when the mesh is excised and removed'*

Today surgeons recognise there's a critical status to have more experienced synthetic mesh removal surgeons to help with mesh complications for SUI, POP, Hernia and Rectopexy. Campaigners and support groups fought hard throughout the years for Multi-Disciplinary Teams (MDT) centres, if we didn't do this at the beginning where would we be now?

1. 2005, Lorraine is at the beginning of her dreadful mesh journey, TVT surgery was performed by an obstetrician, next day nearly died, Pulmonary Embolism, suffered ongoing ill health plus other complications. It was not known publicly about mesh complications.
2. 2008, discovered something not right, appointment with GP, could see mesh poking through, didn't know who to contact, was asked to research, couldn't find anyone in the UK. Found in the USA Dr. [REDACTED], Professor of Urology and [REDACTED], MD Professor of Urology [REDACTED]
3. During 2008, found a USA support group ([REDACTED]) shared difficult times with the members, extremely helpful, there was no support group in the UK at the time. The members increased in the UK and around the world.
4. During 2008, emailed Dr [REDACTED] and Prof [REDACTED], asked who can help me in the UK, was given contact details for Professor [REDACTED] BSc, MD, FRCS (Urol), FEBU, made a private consultation appointment, travelled in severe pain during the 4 hours journey there and back. Confirmed mesh has gone through the vaginal wall.
5. 2008-2009, Professor [REDACTED] could not help further, not in his NHS catchment area, gave two more surgeons (UK) to contact the first surgeon was very dismissive, then contacted Professor [REDACTED] BM, BCh, MA(Cantab.), DM (Oxon.), FRCS(Urol) an experienced and highly respected surgeon, he helped me over the years and saved my life.
6. 2009, the mesh journey begins for the UK, The Voices Today on Messed up Mesh (TVT MUM) website is published with a message board for all the members, it was during this time we all helped each other, shared experiences, shared valuable information, increased support groups, and found more surgeons, for years it was and still is difficult to find an experienced mesh removal surgeon.

Key Projects

2019-Present

- Submitted feedback on the IMMDS review FF mesh timeline, plus our timeline of events from 2008 to Present Day
- Appointed ICS Committee Member for the International Continence Society (ICS) Consensus Document on the Diagnosis and Treatment of Mesh Complications
- NHSE Registered Stakeholder for Patients/Public Specialised Women's Services
- TVT MUM Oral Hearing for IMMDS review with Baroness Julia Cumberlege CBE, DSG, DL

2018-2019

- Mesh work recommenced July 2018, progress for mesh-injured community/campaign
- October 2018 submitted personal TVT mesh implant surgery experience to IMMDS review
- November 2018 submitted evidence on surgical synthetic mesh implant medical devices to Baroness Julia Cumberlege CBE, DL and IMMDS review

2015-2018

- Employment ceased end of 2015
- Continued with some mesh work during 2015-2016 then Charity ceased mid 2016
- Timeout from employed work and support/mesh campaign to give priority help for my son [REDACTED]

2014-2015


- January 2014 employed part-time work
- Appointed NHS England Patient and Public Voice Representative, processes for NHSE Mesh Working Group Interim Report, recommendations published Dec 2015. The Mesh Oversight Group ensured that those recommendations were implemented, final report 2017

2010-2014

- Patient membership registrations, support, help and advice by telephone, email and forum
- Registered charity 2012 under HMRC paragraph 1 of Schedule 6 Finance Act 2010
- Correspondence to Prime Minister, MHRA, FDA, Clinicians, Solicitors and Press

2008-2009

- Designed and published website for a patient support group and campaign
- Joined Truth in Medicine (USA) support group, research on surgical synthetic mesh implant medical devices

YEAR	ACTIVITY AND EVENT	DOCUMENTS/LINKS
2008	Joined Truth in Medicine Support Group in the USA to have and find support, help, research on mesh kits	http://www.truthinmedicine.us.com/
2009	No other support groups available and decided to open a patient support group for the UK. Designed and published a website launched May 2009 for patient support, help, advice, information, and to start the mesh campaign	https://www.tvt-messed-up-mesh.org.uk/
	Evaluate running a charity and did an enormous amount of reading to ensure things run as smoothly as possible.	
	A message board was designed and provides forums for everyone to post and reply to each other. The message board is really good for members to share their stories and experiences plus to view updates on any news. Currently Closed.	https://www.tvt-messed-up-mesh.org.uk/phpbb/index.php Currently Closed.
	Provided support, advice and information to patients by telephone, email, newsletters, and through networking most days through available online forums and social media	June 2009 opened Twitter account https://twitter.com/TVTMMum
2010	Medicines and Healthcare Regulatory Agency (MHRA) website and realized this is where we need to contact and complete our adverse event report. Plus contacted about serious health concerns with synthetic mesh kits, ongoing corresponding for many years since 2010.	Email correspondence sent to the MHRA (see Item 1 for the string of email correspondence)
	TVT Mum became a member of the National Council for Voluntary Organisations (NCVO)	
	Produced our own Videos for YouTube, and there were new web pages added to the site including feedback from the mesh injured, with regular latest news items from 2009 – Present day	TVT MUM YouTube Channel https://www.youtube.com/user/TVTMMum/ https://www.tvt-messed-up-mesh.org.uk/feedback-comments.html https://www.tvt-messed-up-mesh.org.uk/latest-news.html

		<p>ARCHIVED: NEWS Please click to view each Year From 2009 to 2018 January 2015 - December 2018 >>> January - December 2014 >>> January - December 2013 >>> April - December 2012 >>> January to March 2012 >>> January - December 2011 >>> January - December 2010 >>> January - December 2009 >>></p>
	<p>TVT Mum in Focus DATE 10 MAY 2010 It is a Matter on Safety and Urgent Action</p>	<p>https://www.tvt-messed-up-mesh.org.uk/tvt-mum-in-focus.html</p>
2011	<p>Started the draft document for the Prime Minister it took months and months to prepare I added every concern I could think of at the time regarding TVT, TVT-Secur, TVTO & TOT Medical Devices and Flat Graft Surgical Mesh used for Prolapse and Hernias. The document was the start of all the current investigations and is in the hands of hundreds of experts within the medical world, regulatory bodies and the legal system around the United Kingdom.</p>	<p>https://www.tvt-messed-up-mesh.org.uk/parliament-10-downing-street.html</p>
	<p>Continued during the year 2011 to write more articles and also created the online petition on 23rd January 2011 and it's still open today.</p>	<p>https://www.tvt-messed-up-mesh.org.uk/articles-tvt-mum.html</p> <p>https://www.thepetitionsite.com/1/an-urgent-review-is-required-on-the-medical-devices-tvt-tvto-tot-and-the-use-of-mesh-graft-for/</p>
	<p>During the year 2011 the MHRA have launched an investigation. Full details are on the website.</p>	<p>https://www.tvt-messed-up-mesh.org.uk/latest-news-from-the-mhra.html</p> <p>https://www.tvt-messed-up-mesh.org.uk/worldwide-registers-reporting-adverse-incidents-for-medical-devices.html</p> <p>https://www.tvt-messed-up-mesh.org.uk/mhra-archive.html</p> <p>https://www.tvt-messed-up-mesh.org.uk/mhra-alerts.html</p>

		https://www.tvt-messed-up-mesh.org.uk/our-thoughts-on-the-mhra.html
	Our Medical Condition is recognized as a 'Hidden Disability' 'Chronic TVT/Mesh Implant Inflammation'.	https://www.tvt-messed-up-mesh.org.uk/hidden-disability-chronic-tvt-mesh-implant-inflammation.html
2012 And the year 2013	12th January 2012 The document to the Prime Minister and Health Secretary was sent in the post. Urgent Review on TVT, TVT-Secur, TVTO & TOT Medical Devices and Flat Surgical Mesh used for Prolapse and Hernias Sent to: The Rt Hon David Cameron MP, Prime Minister - 10 Downing Street, London Andrew Lansley CBE MP Member of Parliament for South Cambridgeshire Secretary of State for Health	https://www.tvt-messed-up-mesh.org.uk/pdfs/Urgent-Review-on-TVT-TVT-Secur-TVTO-and-TOT-Medical-Devices.pdf
	January 2012 The Department of Health replied We received a letter from the Department of Health answering all the concerns within the document sent to the Prime Minister. TVT Mum is mentioned in the DH letter - 'Websites such as TVT-MUM can also help to increase awareness. The recent increased awareness of this problem is resulting in an increase in the number of reports, helping the MHRA with their assessment'	Document has been submitted as evidence to the IMMDS Review
	February 2012 Email received from the MHRA Copy of email can be submitted if requested.	'In February 2012, the MHRA commissioned an independent review of all current and up-to-date evidence on the use and potential problems associated with both vaginal tapes and mesh for stress urinary incontinence and pelvic organ prolapse. This is expected shortly. We will publish the findings of this research as quickly as possible so that surgeons and doctors can give the best information possible to patients about the benefits and risks of this type of surgery.'
	21st February 2012 Trustee profiles and TVT Messed up Mesh known as	

	<p>TVT Mum non-profit voluntary organization and support group is registered as a small charity with the HM Revenue & Customs registration number XT32413</p> <p>Registered charity under HMRC paragraph 1 of Schedule 6 Finance Act 2010</p> <p>Copy of HMRC letter can be submitted if requested</p>	
	<p>20th March 2012</p> <p>TVT Mum is offered a Meeting with the MHRA The Prime Minister document was passed to Dr Susanne Ludgate BSc (Hons) MB ChB DMRT FRCR FRACR Clinical Director, Devices at the Medicines and Healthcare products Regulatory Agency (MHRA)</p> <p>Copy of email can be submitted if requested.</p>	
	<p>5th April 2012</p> <p>Email sent to the MHRA from TVT Mum I asked - Can they MHRA issue a medical device alert on Vaginal Tape/Mesh? They responded:</p> <p>On 18th April 2012 - We are not considering issuing a Medical Device Alert on vaginal tapes and mesh as we do not have enough evidence to indicate the problem is with the mesh devices being unsafe, as opposed to a failure of the surgical procedural involved in implanting them. Although as you are aware we continue to review this situation and to investigate all incidents and clinical evidence with the tape and mesh manufacturers.</p> <p>Copy of email can be submitted if requested</p>	
	<p>12th April 2012</p> <p>All day Group Meet for a possible Documentary, we tried to do a documentary for three students to go towards their journalist degree, unfortunately after spending a whole day they lost the film!</p> <p>24th May 2012</p> <p>I was contacted again by the students and they decided they only wanted to do another with myself for their documentary, I have a copy on CD, and they achieved a high pass for their journalist degree.</p> <p>CD film can be submitted if requested</p>	<p>https://www.tvt-messed-up-mesh.org.uk/tvt-mum-support-group-meetings.html</p>
	<p>From January 2012 to Present day</p> <p>A huge amount of email correspondence with the MHRA throughout the whole year</p>	
	<p>During the year 2012 there was a lot of campaign work in the USA, FDA PHN since the Year 2008 and plus formation of Worldwide support groups</p>	

	<ul style="list-style-type: none"> • Designed patient membership registration forms, gave support, help and advice by telephone, email and forum • Correspondence to MHRA, FDA, Clinicians, Solicitors and Press 	
2014 And the year 2015	We had a TVT/Mesh Support Group Meet and Greet Location: The Manor House Golf Club, Castle Combe	
	<p>In July 2014 NHS England confirmed Lorraine Evans and Hayley Martin are appointed to the working group as Patient and Public Voice (PPV) representatives, full details are on the website.</p> <p>NHS England Full Working Group Face to Face Meetings in London: All the meetings are chaired by Professor Keith Willett 16th July 2014 - Attended meeting - Minutes of the meeting received 3rd November 2014 (unfortunately Lorraine and Hayley couldn't make this date in London due to ill health) - Minutes of the meeting received 2nd February 2015 - Attended meeting - Minutes of the meeting received 27th April 2015 - Attended meeting - Minutes of the meeting received 23rd June 2015 - Attended meeting - sub working groups recommendations submitted and also the Minutes of the meeting received 19th August 2015 - Attended meeting - sub working group recommendations to be submitted 24 August - September 2015 - Awaiting minutes of the meeting from 19 August and also we send regular correspondence via email and telephone October and November 2015 - Final Draft received on NHS England Mesh Working Group Interim Report October 2015 - Currently reading with more email correspondence throughout October and November until the next NHS England full working group meeting in London TBA 3 December 2015 - NHS England Mesh Working Group Report - https://www.england.nhs.uk/ourwork/qual-clin-lead/mesh/</p> <p>PLUS NHS England Sub Working Group Teleconference's: 2nd December 2014 - Teleconference and corresponding via email 10th December 2014 - Teleconference and corresponding via email 8th January 2015 - Teleconference and corresponding via email plus TVT Mum proposal has been submitted 28th January 2015 - Teleconference and corresponding via email 5th February 2015 - Teleconference and corresponding via email</p>	<p>https://www.tvt-messed-up-mesh.org.uk/NHS-England-Patient-Public-Voice-Members.html</p> <p>https://www.england.nhs.uk/mesh/</p>

	<p>24th February 2015 - Teleconference and corresponding via email March 2015 - Corresponding via email 15th April - Teleconference and corresponding via email May 2015 - Corresponding via email 18th June 2015 - Teleconference and corresponding via email 16th July 2015 - Teleconference cancelled not needed this month only corresponding via email August 2015 - Corresponding via email - Recommendations finalized for submission on 19th August for the NHS England full working group meeting (see dates as above)</p>	
	<p>22 August 2014 ██████████ contacted to say she is visiting the FDA in the USA, and she needed a supporting article from TVT Mum Subject: Synthetic Mesh Medical Devices used for the Surgical Treatment of Stress Urinary Incontinence, Prolapse and Hernias</p>	Document submitted to the FDA
	<p>25th October 2014 Support Group Meet up Location: St. Joseph's Church Hall, Aldershot, Hants, GU11 3JB</p>	
2015	<p>MHRA An email sent to the MHRA in November 2015 and did not receive a reply, this is very important and needs actioning by the MHRA and the FDA.....</p> <p>TVT/Mesh medical devices CE directive and Modification</p> <ol style="list-style-type: none"> 1. When the synthetic TVT/Mesh medical device products are passed with the CE directive does this mean they are passed never to be modified? 2. Was there any clinical RCT's on synthetic mesh implanted both as a fully intact mesh product and also as a modified mesh? <p>We have reason to believe and probably the surgeons are unaware the TVT/mesh medical device products have a sealed edge and if modified it could be viable factor with the ongoing problems with synthetic meshes. When some patients have the TVT/Mesh surgical procedure and the surgeon decides to modify the flat graft mesh for POP by cutting it before implanting and also for TVT/TVTO medical devices the mesh is cut after implantation it could well be causing the mesh products to fray/and fragment into the surrounding tissue.</p> <ol style="list-style-type: none"> a) CE marked mesh products are cut and modified - Is it possible the modified TVT/mesh could be acting like a 'wick' a capillary for bacteria to enter and travel through the pores of the mesh? This could be causing a foreign body reaction and for the mesh to shrivel, harden, plus chronic pain, urinary tract infections, yeast infections and inflammation. b) When the mesh is cut and modified it no longer has a sealed edge when implanted - Could the make-up of the product with an unsealed edge cause toxins to travel within the body? This could be the link to the various autoimmune diseases people are experiencing from synthetic mesh implants. <p>Please also consider it's not just modification of the mesh that's</p>	

	<p>concerning but also the sealed edges. The mesh edges are very sharp and when the thick plastic sheath is pulled through it might leave tiny specks of plastic in the body this could be causing a foreign body reaction, plus the intense irritation, abscesses, itching and inflammation too.</p> <p>We believe when the modified mesh is in situ and also removed even a small piece of mesh left in the body plus any plastic from the sheath will break down into minuscule debris, we believe this is causing a foreign body reaction hence the reason for constant chronic infections including UTI and possibly the onset of Lichen and Chronic thrush.</p>	
	<ol style="list-style-type: none"> 1. The Final NHS England Interim Report was published December 2015 and then the Mesh Oversight Group was formed but without the PPV Members. 2. July 2017 - The Oversight Mesh Group have to implement the NHS England Interim report recommendations, they published their final report in July 2017, the link to view current status on the Mesh work is https://www.england.nhs.uk/mesh/ 	
2016	Timeout	
2017	Timeout	
2018	Mesh work recommenced July 2018, to see progress for mesh-injured community/campaign	Contacted various patient support groups and gave some help to MeshUKCT – after a few months decided to leave
	November 2018 submitted evidence on surgical synthetic mesh implant medical devices to Baroness Julia Cumberlege CBE, DL and IMMDS review	Evidence submitted
2019	Attended the IMMDS review in Exeter with Baroness Cumberlege and met Valerie Brasse (Review Secretary), review team and patients from our mesh group	
	NHSE Registered Stakeholder for Patients/Public Specialised Women’s Services	Webinar feedback submitted
	TVT MUM Oral Hearing for IMMDS review with Baroness Julia Cumberlege CBE, DSG, DL	IMMDSReview https://www.immndsreview.org.uk/Evidence.html
	International Continence Society (ICS) Committee Member – Patient Representative	Consensus Document on the Diagnosis and Treatment of Mesh Complications
	The IMMDS Review FF mesh timeline, plus our timeline of events from 2008 to Present Day	Submitted feedback and our timeline of events
	Patient support group meeting on the 15 th October 2019 in Tetbury	Venue and time arranged

Additional information

- Thousands of emails received and replied from patients, regulators, official organisations
- Numerous telephone calls, although not logged
- Numerous postings on social media and forums
- 2010-2017 - Medical Expert ██████████ FRCOG Consultant Gynaecologist
- 2011 – Contacted numerous solicitors for legal advice, possible lawsuit, personal mesh claims. Many patients were badly let down for many years, approached 13 Solicitors. Solicitors were oblivious to what was going on, no education, no research, no data to hand, and more, if you need further information this can be discussed at a later date. Through promises of a claim the patients lost significant amounts of money requested by Solicitors to pursue their claims and then to be let down with no case, now find their statute of limitations has run out. Currently most mesh injured feel very let down and would like compensation.
- 2009-present day – Searching for experienced surgeons to help us all, in the earlier years there wasn't anyone to help, but through searching we eventually found some. Most patients were treated as an experiment for the best surgical procedure to remove the mesh.
- Our gratitude and thanks to all the medical professionals, patient mesh support groups and individual campaigners, plus all the relevant organizations for their help, care and compassion given to the mesh injured
- Throughout the years we also contacted the press and media, but there was not much interest due to no one really acknowledging there's serious health concerns until Kath Sansom at Sling the Mesh highlighted patient's mesh experiences and the APPG campaign.
- Website Sitemap to all the webpages links within the site: <https://www.tvt-messed-up-mesh.org.uk/website-sitemap.html>

All documents submitted to the IMMDS review

1. Ref A37303 item 1 TVT MUM Timeline submission for IMMDSR FF Mesh Timeline
2. Ref A37303 item 2 TVT MUM Feedback for IMMDSR FF Mesh Timeline
3. Ref A37303 item 3 APRIL-2019-TVT-MUM-NEWS
4. Ref A37303 Item 4 Correspondence with MHRA
5. Ref A37303 item 5 MHRA-PUBLIC-NOTICE-september 2011
6. Ref A37303 item 6 august-2011-synthetic-vaginal-tapes-for-stress-incontinence
7. Ref A37303 item 7 fda july 2011 phn
8. Ref A37303 item 8 VT-Workshop-Agenda
9. Ref A37303 item 9 FDA SURGICAL MESH

**The Medical World Allowed
Medical Marketing to Overtake Medical Science
and Stifled Scientific Innovation**

Welsh mesh survivors

Time-line of Welsh Campaign:

Welsh Mesh Survivors Support Group Campaign.

(I've written a little about my decision to set up the Facebook Welsh Mesh Survivor Support Group)

Mesh Implant:

2002: TAH Sacrocolpopexy and colposuspension Mercilene mesh 30x30 cms

2003: Mesh revision/repair - snipping off and sewing back using mesh graft

2005: 2 separate open abdominal mesh removal operation months apart and removal of ovaries due to suspicious "changes"

2007: Abdominoplasty/repair of diastases and hernia seen back in 2001

2011: I became ill again, whilst convalescing googled and researched "Mesh Problems" I was absolutely horrified and shocked. I discovered and joined TVT-MUM Lorraine Evans and some American Groups - Mesh Medical Newsdesk and Fighters and Survivors of all surgical mesh implants.

>I found out about the reporting of adverse events via TVT-MuM - I reported and started writing to the MHRA - resulting in many emails.

I was so angry that I decided to sue (I sent the Expert Witness Report to Review Team) My case was dropped after being sent to three different law firms. The reason given was that Medical Defence would fight due to Time-Bar after being sent from one law firm to another. (I was told by solicitor I was not out of time when I started proceedings! I was just within the ten years/Tort Law limit)

2011/12/13: I became very ill, could not use bowel or bladder.

Two separate Laparoscopic mesh removal and division of bowel and bladder adhesions. They found multiple problems and injuries (I've sent medical notes to demonstrate and also photographs of operation)

I was angry for myself and became very angry that more and more people were coming forward with Mesh injuries.

I wrote to Jeremy Hunt, knocked on all of the wrong doors. Devolved Government was fully explained to me. I wrote to Mark Drakeford to which I had a generic replies.

Jane Hutt AM (my Assembly Minister) has been highly supportive, [REDACTED]

I was interviewed by my local newspaper a few times.

2013: I joined the original Scottish Mesh Survivors founded by Karen Neil.

Den and I flew up to Scotland to meet everyone and to support their "Hear Our Voice Campaign" at Holyrood, Scottish Parliament.

Karen Neil gave me all help to explain how to set up group on Facebook.

25th June 2013: I founded Welsh Mesh Survivors Support Group and have had to learn so much about Mesh issues and Facebook!

I began to write in earnest to Welsh Government. Some of the Welsh Group came onboard and also started to work. We mostly had generic replies and were fobbed off.

We wrote everywhere I could think of.

2014: I was asked to be interviewed by The Times newspaper in connection with Carl Heneghan's "Fruit Netting Scandal"

Welsh Mesh Survivors have since worked alongside Scottish, English, Irish and Global Campaigners, researching, sharing and collating evidence.

Many of our Welsh AMs have been particularly supportive, Jane Hutt, Angela Burns Owen Smith and Carl Sergeant have been wonderful.

2015/16 I became extremely ill. I was told that a defunctioning colostomy was needed due to my bowel and bladder problems as I was in danger of sepsis, due to residual mesh, despite all of the Mesh removal operations.

I was also referred to the disgraced Bristol Surgeon and he insisted that I needed his special Mesh otherwise I would not get well. I said that I would think about it.

TVT-MuM members contacted me when they heard and asked me to a meeting. They showed me their colostomy bags and Urostomy bags and warned me not to have his special Mesh.

My spine started to deteriorate very badly. I was offered surgery to fit spinal rods and screws and sterilised cadaver bone.

Immunologist colleague of my husband's advised me that it would be disastrous, as I had already had surgical implant rejection involving titanium.

2016: Welsh Mesh Survivors continued our Email Campaign with Government.

Many of the Welsh Group joined the mass English Group STM. I also joined for a short time.

1/08/2017: I set up an on-line petition. I sent it to UK Governments.

2017: Global Mesh Alliance was set up by a number of us.

>>28/11/2017 With the work of Welsh Mesh Survivor Support Group Admin, Nicola Hobbs and myself - UNISON and [REDACTED] and [REDACTED] - UNITE

The TWO great UNIONS in Wales wholeheartedly agreed to support the Surgical Mesh Campaign:-

Cardiff and Vale UNISON Health Branch

AND

UNITE Wales Labour Party Liaison.

Welsh Mesh Survivors were told that the Members of these two Unions in Wales, would be supported at any of their work related tribunals .

>> Many Welsh Mesh Survivors had joined Sling the Mesh and and one of our Welsh Group Members, [REDACTED], went to meet Owen Smith MP. He gave full support to UK Mesh Survivors and he became fully involved in the UK Mesh Campaign.

Everyone worked to support the very successful English Campaign at Westminster, which included Mesh Survivors from all over the UK.

>>Dennis and I were then asked to go to represent Welsh Mesh Survivors at the meeting in London with Lord Oshaughnessy, as arranged by Sling The Mesh Group. Dennis and I were the only Mesh Campaigner Advocates to arrive at his London Office, due to bad weather conditions. The Irish, Scottish and English Mesh Campaigners took part by teleconference.

Dennis and I were snowed in for four days. It was a very productive meeting, culminating in Jeremy Hunt's decision to set up the IMMDS Review.

>>Monday 22nd January 2018

Meeting to discuss Complications of Surgical Mesh Devices

Welsh Cabinet Health Secretary for Health and Social Services

Vaughan Gething

Jane Hutt AM

Ty Hywel building

Welsh Cabinet Health Secretary Vaughan Gething agreed to meet Welsh Mesh Survivors. Jane Hutt AM arranged and facilitated the meeting at the Welsh Assembly.

Nicola Hobbs and myself. We insisted that our Male Hernia Mesh-injured Advocate was also present, but he was refused entry, despite the fact that previous to the meeting, we had given his name to Admin staff. The Assembly Staff said it was a discussion about "Women's issues"

We refused to split Pelvic and Hernia Mesh-injured people into two separate groups, Richard was allowed into the room after we protested, but he was symbolically made to sit in the corner, apart from us all.

As a direct result of this meeting, Vaughan Gething decided to set-up the Task and Finish Working Group, looking into Pelvic Mesh issues. Welsh Mesh Survivors were invited to join the Group, but were only sent the remit and documents four days before the Committee met and the Welsh Group were also horrified to find that the appointed Chair was one of the leads of the Welsh MDT whom many Mesh Survivors felt had ruined their

lives. Nicola Hobbs and I met our AM Jane Hutt for advice, We invited Richard Cox Hernia Mesh Advocate, too.

Nicola and I wrote to as many Members as we could, telling them of our disgust at this treatment and our reasons for declining the invitation to join the Task and Finish Working Group.

We wrote to Vaughan Gething and explained what had happened, we told him that though we would not meet with the Committee, we would work to produce research and patient profiles to demonstrate Pelvic Mesh complications.

Global Mesh Survivors shared all of their work.

7th May 2018: Welsh Assembly Plenary Meeting: Welsh Mesh Survivors went to hear the The Task and Finish Working Group Report on Pelvic Mesh - Welsh Cabinet Health Secretary Vaughan Gething set up a new Government body called the "Women's Health Implementation Group" He announced to the Assembly that "though Welsh Mesh Survivors had been invited to join the Committee, they declined"

Jane Hutt AM stood in our defence and explained our reasons for not attending.

Vaughan Gething set aside £1 million a year, in order to fund the Health-care Pathways put forward by the WHIG.

Vaughan Gething also promised to "Look into Hernia Mesh"

>> End of May 2018: [REDACTED]

[REDACTED] We parted company with them [Sling the Mesh] and also with one of our Welsh Members whom had set up another Welsh Mesh Group under STM umbrella. This group also interacts Welsh Government in order to raise awareness and make changes. The division is very sad, but we are all human and have differing opinions.

>> July 2018 Welsh Mesh Survivors Support Group set up a "Core Working Group" and we have made a commitment to meet WHIG every two months to work and discuss a way forward, in order to treat the already Mesh-injured people of Wales and to protect future patients from harm. We have shared that work with the Review Team.

We have almost come to the end of the first year.

At the insistence of Welsh Mesh Survivors Core Working Group, a 'Review' was made into Hernia Mesh, culminating in the Welsh Mesh Hernia Report published by Welsh Deputy CMO.

He was invited along to present it to the Welsh Mesh Survivors CWG after a copy was sent to us a few days before, for our perusal. It is very short and NOT acceptable to Welsh MeshCWG, at all.

Welsh Mesh Survivors wrote our comments all over the Hernia Mesh Report in red pen, as a protest. We also sent some up-dated research.

Welsh Mesh Survivors have demanded that the Deputy CMO re-consider the report and publish once more.

We also await the release of FDA Alternative Summary Reporting of Hernia Mesh - 20 years of hidden Adverse Events!

The most offensive statement written within this Welsh Hernia Report was that only five women had written in to Government to complain about Hernia Mesh "and they were all from the Women's Group" Welsh Mesh Survivors felt that this statement was offensive, sexist and we felt that it was untrue.

All Governments must remember that Mesh Campaigners represent many hundreds of Mesh-injured people

>> July 2019 WHIG set up a programme The Mapping of Patient Health-Care Pathways

We have, with the permission of WHIG, given the documents to the Review Team

>>WHIG Meeting 9th Sept 2019: Tracy Myhill, Chair of WHIG Announced to the Welsh Mesh Survivors Core Working Group their intention to invite Dr Veronikis and others to a Health Conference to take place in Wales in 2020

THIS INVITATION WILL BE SENT TO DR VERONIKIS AS A DIRECT CONSEQUENCE OF THE WORK SET UP BY MESH IRELAND'S MARY MCGLAUGHLAN AND SCOTTISH MESH SURVIVORS, OLIVE MCILROY AND ELAINE HOLMES

WITH GREAT APPRECIATION TO MARION SCOTT FOR HER RELENTLESS SUPPORT OF GLOBAL MESH SURVIVORS, WITHOUT WHOM NONE OF THESE CAMPAIGNS WOULD EVER HAVE TAKEN ROOT WITHIN THE WALLS OF UK GOVERNMENT

Many Thanks to ALL Global Mesh Survivors...For WE are MANY.

Words will never be enough to express our full appreciation of the work shared with Welsh Mesh Survivors.

WE CARRY ON THE BATTLE TO RAISE AWARENESS AND FOR JUSTICE, IN TRIBUTE AND HONOUR OF THE DEAD AND THE SUFFERING.

THERE ARE SO MANY EVIL PEOPLE WITH BLOOD ON THEIR HANDS -
GWAED AR EU DYWLO.

WELSH MESH SURVIVORS SUPPORT GROUP WISH TO THANK BARONESS JULIA CUMBERLEGE, SIR CYRIL CHANTLER AND ALL OF THE IMMDS REVIEW TEAM, WHOSE TASK, WE ALL KNOW, HAS NOT BEEN EASY.

WE HOPE THAT THE IMMDS MESH REVIEW REPORT WILL SOON BE PUBLISHED AND THAT, IN THE WORDS OF OUR CHILDREN, "YOU DO THE RIGHT THING"

DENNIS AND JEMIMA WILLIAMS - REPRESENTING WELSH MESH SURVIVOR SUPPORT GROUP.