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RESEARCH ARTICLE

Vaccine damage schemes in the US and UK reappraised: making them fit for purpose in the light of Covid-19

Richard Goldberg*†

Durham University, Durham, UK
* Author e-mail: richard.goldberg@durham.ac.uk

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Abstract

Vaccines have continued to play a crucial global role in preventing infectious diseases in the twenty-first century. The Covid-19 pandemic has underlined their importance, with vaccines seen as the best way to protect the public from coronavirus. A longstanding problem of governments has been the extent to which they should assume responsibility for the compensation of those injured by vaccines. This paper reappraises the vaccine damage schemes currently available in the US and UK in the light of the Covid-19 pandemic. It argues that any improvements to both US and UK schemes should be included in a revised national vaccine policy which takes into consideration their respective long-term national vaccine strategies to prepare for future pandemics. It supports the adoption of a UK-wide National Vaccine Injury Compensation Programme, similar to the one in the US, to be administered by the Secretary of State for Health and Social Care. To balance the need for rigorous criteria to determine causation with the need for fairness, the programme should adopt the US practice of allowing negotiated settlements between parties in circumstances where review of the evidence has not concluded that the vaccine(s) caused the alleged injury but there are close calls concerning causation.

Keywords: tort; product liability; vaccines; medicinal products; compensation; Covid-19

Introduction

Vaccines have continued to play a crucial global role in preventing infectious diseases in the twenty first century.[1] The Covid-19 pandemic has underlined their importance, with vaccines seen as the best way to protect the public from coronavirus.[2]

A longstanding problem of governments has been the extent to which they should assume responsibility for the compensation of those injured by vaccines. This paper provides a timely reappraisal of the vaccine damage schemes currently available in the US and UK in the light of the Covid-19 pandemic. While the US and UK have different legal systems, there are of course many similarities in their Anglo-American tort law heritage, as well as in their shared experiences of the controversies concerning the pertussis and the Measles Mumps Rubella (MMR) vaccines.[3] It seeks to argue that any

†I am grateful to Peter Todd, Hodge Jones & Allen Solicitors and Professor Elizabeth Miller, Department of Infectious Disease Epidemiology, London School of Hygiene & Tropical Medicine for helpful discussions.

[1]US Senate *The Importance of Vaccines* (22 January 2021), https://www.rpc.senate.gov/policy-papers/the-importance-of-vaccines (accessed 16 February 2022).

[2]*UK Covid-19 Vaccine Uptake Plan* (13 February 2021), https://www.gov.uk/government/publications/covid-19-vaccination-uptake-plan/uk-covid-19-vaccine-uptake-plan (accessed 16 February 2022).

[3]PA Offit *Deadly Choices: How the Anti-Vaccine Movement Threatens Us All* (Basic Books, 2011) pp 13–23, 25–44, 85–104.

improvements to both the US and UK schemes should be included in a revised national vaccine policy which takes into consideration their respective long-term national vaccine strategies to prepare for future pandemics.

Part 1 explores development of the US National Childhood Vaccine Injury Compensation Act of 1986 (NCVIA), and the establishment of the National Vaccine Injury Compensation Programme (VICP), in the light of increased litigation costs, the rise in prices of vaccines and the instability and unpredictability of the childhood vaccine market subsequent to the Swine Flu Act 1976. While acknowledging criticisms of the NCVIA, it considers that there is much to be said for the success of the VICP. It examines the role of the Public Readiness and Emergency Preparedness Act of 2005 (PREP), which offers 'targeted liability protection'[4] to the manufacturers of drugs, vaccines and medical devices used in declared public health emergencies. This Act is controversial in that, through broad immunity and limitations on compensation, recourse for victims is extremely limited. The issuance of a Covid-19 Declaration has triggered the broad immunity provisions of the PREP Act and has provided that a 'Covered Countermeasure Process Fund' will cover serious injuries or death as a direct result of Covid-19 vaccines.[5]

Part 2 examines the UK Vaccine Damage Payments Act 1979, which was enacted to provide an ex gratia payment for vaccine-damaged persons for death or severe disablement[6] proved on a balance of probabilities to have been caused[7] by vaccination. The determination of causation continues to be a major source of difficulty in Tribunal appeals and the paper explores concerns about determining the causation issue in favour of applicants using biologically plausible theories, despite the absence of independent scientific evidence supporting a causal association. The decision to extend the 1979 Act to those vaccinated against the Covid-19 virus, as opposed to the creation of a bespoke Covid-19 vaccines compensation system in the UK, is appraised.

Part 3 argues that any improvements to the US and UK schemes should be included in a revised national vaccine policy which takes into consideration the countries' respective long-term national vaccine strategies to prepare for future pandemics. This policy must promote public health by incentivising innovation in the design of new vaccines, whilst encouraging public confidence in vaccines through transparent and fair decision-making that is soundly based on scientific evidence.

This paper supports the adoption of a UK-wide National Vaccine Injury Compensation Programme to be administered by the Secretary of State for Health and Social Care, similar to that in existence in the US. Learning from previous controversies over the determination of causation, a new programme must define the criteria used to determine causation, giving sufficient weight to scientific evidence. To balance the need for rigorous criteria to determine causation with the need for fairness, the programme should adopt the US practice of allowing negotiated settlements between the parties where there are close calls concerning causation.

1. Vaccine compensation schemes in the US

(a) Swine Flu Act of 1976

In February 1976, isolates of virus taken from two recruits at Fort Dix, New Jersey, who had influenza-like illnesses, included a new strain – A/New Jersey/76 (Hsw1n1) (H1N1) – similar to the virus believed to be the cause of the 1918 pandemic, known as 'swine flu'. These findings were reviewed by the Advisory Committee on Immunisation Practices of the US Public Health Service (ACIP), who recommended the launch of an immunization programme to prevent the

[4]Public Readiness and Emergency Preparedness Act, 42 USC §247d-6d.
[5]85 FR 15198, 15201, 15203; 42 USC §247d-6e.
[6]Vaccine Damage Payments Act 1979, s 1(1).
[7]ibid, s 3(5).

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effects of a potential pandemic.[8] The National Influenza Immunization Program (NIIP) was then initiated.[9] Due to concern over vaccine manufacturers' liability when insurers declared they would end coverage for vaccine manufacturers,[10] the Swine Flu Act 1976 was passed, transferring the manufacturer's liability for injuries to the US Government.[11] By virtue of its 'unique role in the initiation, planning and administration of the swine flu program',[12] an exclusive remedy was provided against the US government 'for personal injury or death arising out of the administration of swine flu vaccine under the swine flu program and based upon the act or omission of a program participant'.[13] The programme adopted a no fault approach to the provision of compensation, requiring a determination as to whether the plaintiff's injuries were in fact caused by the vaccine's administration.[14] The results of a Center for Disease Control (CDC) study suspended the programme after establishing an apparent temporal association between the onset of Guillain-Barré Syndrome (GBS) within 10 weeks of vaccination and the vaccination itself, which was sufficient to presume causation.[15] The government limited its liability under the 1976 Act to cases where a causal link could be shown between GBS and the vaccination. This was a heavy burden of proof to overcome since there was at the time (and there remains to this day) no understood causal path between the vaccination and the syndrome.[16] A 'vast field'[17] of litigation commenced, with experts attributing many injuries to the vaccine. Cases in which GBS occurred within 10 weeks of the vaccination were all deemed compensable,[18] and virtually all other cases where GBS occurred outside the 10-week period were deemed uncompensable.[19] However, it is apparent that the uncertainty in respect of proof of causation in specific cases resulted in several courts providing compensation irrespective of causal link.[20] By 1985, $90 million had been paid out by the government to those who developed GBS and this led to increasing governmental reluctance to assume such financial risks with vaccination programmes in the absence of scientific evidence.[21]

[8]For a detailed account of the swine flu experience and how it was addressed by the US Government see RE Nestadt and HV Fineberg *The Swine Flu Affair: Decision-Making on a Slippery Disease* (US Department of Health, Education and Welfare, 1978).

[9]DJ Sencer and JD Millar 'Reflections on the 1976 swine flu vaccination program' (2006) 12 Emerging Infectious Diseases 29, at 29–30.

[10]The decision of insurers to decline liability coverage was primarily due to the 5th Circuit Court of Appeals' decision of *Reyes v Wyeth Laboratories* 498 F2d 1264 (5th Cir 1974), which held the defendants liable for failing to warn the plaintiff's parents directly of the vaccine's unreasonably dangerous condition and small risk that the vaccine could cause polio, even where they had been provided in package inserts: at 1277–1278. The real concern of insurers was apparently not so much the duty to warn imposed by *Reyes* and consequent court awards but overhead costs and further lawsuits: Nestadt and Fineberg, above n 8, pp 44–48.

[11]National Swine Flu Immunization Program of 1976, Pub L No 94–380, § 2, 90 Stat 1113, 1114–15 (codified as amended at 42 USCA § 247b).

[12]Ibid, § 247b(k)(1)(A)(ii).

[13]Ibid, § 247b(k)(2)(A).

[14]*In re Swine Flu Immunization Product Liability Litigation. Unthank v United States* 533 F Supp 703, 718 (1982).

[15]LB Schonberger et al 'Guillain-Barré Syndrome following vaccination in the National Influenza Immunization Program, United States, 1976–1977' (1979) 110 American Journal of Epidemiology 105; see also the Institute of Medicine's *Vaccine Supply and Innovation: Report of the Committee on Public-Private Sector Relations in Vaccine Innovation* (Washington, DC: National Academy Press, 1985) p 98. The decision was subsequently made to reinstate the immunisation of high-risk populations such as the elderly and those with chronic lung disease: Nestadt and Fineberg, above n 8, pp ii, 63–64.

[16]See M Petráš et al 'Is an increased risk of developing Guillain-Barré Syndrome associated with seasonal influenza vaccination? A systematic review and meta-analysis' (2020) 8(2) *Vaccines (Basel)* 150.

[17]M Greenberger 'The 800 pound gorilla sleeps: the federal government's lackadaisical liability and compensation policies in the context of pre-event vaccine immunisation programs' (2005) 8 Journal of Health Care Law & Policy 7, at 13.

[18]See eg *Titchnell v United States* 681 F2d 165, 169 (1982); *Benedict v United States* 822 F2d 1426, 1430 (6th Cir 1987).

[19]See eg *Lima v United States* 708 F2d 502, 509 (1983); *Gates v United States* 707 F2d 141, 1142–1143, 1146–1147 (1983); *Kennedy v United States* 815 F Supp 926, 936 (SDW Va 1993).

[20]See eg *In re Swine Flu Immunization Product Liability Litigation. Unthank v United States* 533 F Supp. 703, 722, 729 (1982), *aff'd* 732 F2d 1517, 1520 (1984); *Hockett v United States* 730 F2d 709, 712–713 (1984) and, further, *Institute of Medicine* (1985), above n 15, pp 93–114.

[21]Greenberger, above n 17, at 13.

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(b) National Childhood Vaccine Injury Act of 1986

(i) Background

Extending the scope of strict liability and litigation costs,[22] the rise in prices of vaccines[23] and the instability and unpredictability of the childhood vaccine market,[24] together with increasing concern over the uncertainties of obtaining compensation for injuries due to vaccines, all led to Congress passing the NCVIA in 1986.[25] The central achievement of the Act was the establishment of the National VICP, under which compensation may be paid for a vaccine related injury or death.[26] It is administered by the US Claims Court[27] and claims for compensation for a vaccine-related injury or death are initiated by a petition.[28]

(ii) Limitations on awards

The increasing governmental reluctance to accept financial risks with vaccine programmes resulted in the NCVIA capping certain types of awards.[29] Thus the petitioner can recover actual unreimbursable expenses and reasonable projected unreimbursable expenses which are for diagnosis and medical care or for rehabilitation,[30] but 'actual and projected pain and suffering, and emotional distress' is limited to $250,000.[31] Awards for a vaccine-related death are capped at $250,000.[32] For those injured by a vaccine after attaining the age of 18, compensation for loss of earnings is limited to 'actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections'.[33] In addition, compensation awarded under the NCVIA – unlike under the Swine Flu Act – is secondary to any payment made under any state compensation programme, under an insurance policy or under any Federal or state health benefits programme, or by an entity providing health services on a prepaid basis.[34] Importantly, in awarding compensation the NCVIA authorises payment of reasonable attorney fees and other costs incurred in any proceeding.[35]

(iii) Criticisms

Stakeholders have reported the perception of an adversarial environment, due to the onus on petitioners to show that a covered vaccine caused the injury when there are no associated injuries on

[22]Due to concerns in the 1980s that vaccines against diphtheria, pertussis and tetanus (DPT) resulted in disabilities and developmental delays in children, a 'massive increase in vaccine-related tort litigation' (*Bruesewitz v Wyeth LLC* 562 US 223, 227 (2011)) was generated, culminating in more than 200 suits each year. Increased accountability of vaccine manufacturers reached its zenith through liability for failing to develop and make available a safer vaccine that had received no FDA approval: *Toner v Lederle Laboratories* 732 P 2d 297, 310–311 (Idaho 1987), affirming 779 F2d 1429, 1433 (9th Cir 1986).

[23]Changing liability rules from negligence to strict liability increased the wholesale price of the DTP vaccine 'by well over 2,000 percent' and approximately 96% of the price went towards litigation costs; the wholesale price of the OPV was more than 300% higher than under traditional negligence rules: see RL Manning 'Changing rules in tort law and the market for childhood vaccines' (1994) 37 Journal of Law & Economics 247, at 273.

[24]*Bruesewitz v Wyeth LLC*, above n 22, at 227.

[25]42 USC § 300aa-1. See HR Rep No 99–908 at 4–7 (1986); and, further, JB Apolinsky and JA Van Detta 'Rethinking liability for vaccine injury' (2010) 19 Cornell Journal of Law & Public Policy 537, at 550–551.

[26]42 USC § 300aa-10(a).

[27]42 USC § 300aa-12(a).

[28]42 USC § 300aa-11(a)(1), (9), 11(c). The Act defines the term 'vaccine-related injury or death' as 'an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine': 42 USC § 300aa-33(5).

[29]Greenberger, above n 17, at 14–16.

[30]42 USC § 300aa-15(a)(1)(A), (B).

[31]Ibid, § 300aa-15(a)(4).

[32]Ibid, § 300aa-15(a)(2).

[33]Ibid, § 300aa-15(a)(3)(A). Cf those injured *before* attaining the age of 18, who could recover lost earnings in anticipation of turning 18, calculated 'on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy': ibid, § 300aa-15(a)(3)(B).

[34]Ibid, § 300aa-15(g), (h).

[35]Ibid, § 300aa-15(e).

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the Table.[36] In addition, there has been widespread criticism of the failure to expedite adjudications. Between 1999 and 2014, VICP claims filed have taken on average five and a half years to adjudicate.[37] However, for the more than 1,400 claims filed since 2009, the average time to adjudicate a claim reduced to 1.6 years. It is thought that one of the reasons for this was that the majority of autism claims were filed prior to 2009 and that these claims may have taken longer as they were part of the Omnibus Autism Proceeding (OAP) (2002–2010), denying claims that autism was a vaccine injury.[38] In its most recent statistics report published on the VICP (January 2021), the Division of Injury Compensation Programs (DICP) noted that on average it now takes 2 to 3 years to adjudicate a petition after it is filed.[39] Further, since its inception in 1988, 19,538 petitions have been adjudicated, with 7,807 determined to be compensable and the other 11,731 dismissed. The total compensation paid over the life of the programme is approximately $4.5 billion.[40] Significantly, by far the majority (about 60%) of all compensation awarded by the VICP results from negotiated settlements between the parties for which the US Department of Health and Human Services' (HHS) review of the evidence has not concluded that the vaccine (s) caused the alleged injury.[41] With over 3.7 billion doses of vaccine distributed in the US from 2006 to 2018, approximately one individual for every one million doses was compensated.[42] Of the 3.7 billion doses since 2006, 1.67 were influenza doses (over 45%).[43] By far the majority of all pending claims (67%) involve influenza vaccines.[44] Table 1 provides a detailed account of the cases adjudicated since the inception of the VICP. Of the 19,538 cases adjudicated, 7,807 (40%) have been deemed compensable. However, the success rate of the programme has risen considerably over the last seven years, with the special masters deeming approximately 77% of the cases adjudicated to be compensable.

(iv) Table claims, off-table claims and causation

The person who suffered such a vaccine-related injury or died must have been administered a vaccine listed in a vaccine injury table and have suffered an injury covered by the Act and occurring within a specified time listed in the table (the so-called 'Table claim').[45] If a petitioner demonstrates a compensable injury within this time, causation is presumed.[46] Alternatively, petitioners may claim that they have suffered injuries not of the type covered in the Table, but that they can show by a preponderance of evidence that their injuries were 'caused-in-fact' by the vaccination in question (the so-called 'off-Table claim').[47] Since 2009, more than 98% of new claims filed

[36]GAO *Vaccine Injury Compensation: Most Claims Took Multiple Years and Many Were Settled through Negotiation*, GAO-15-142, November 2014, pp 30, 33. Yet in many respects this is inevitable. See NF Engstrom 'A dose of reality for specialized courts: lessons from the VICP' (2015) 163 University of Pennsylvania Law Review 1631, at 1711–1715.

[37]GAO, ibid, p 9.

[38]Ibid, p 10. The OAP was established by the Chief Special Master of the US Court of Federal Claims: see Autism General Order # 1 2002 WL31696785, 2002 US Claims LEXIS 365 (Fed Cl Spec Mstr 3 July 2002).

There were court rulings in 2009 and 2010 for two sets of three test cases for the petitioners' theories of causation. See further A Kirkland *Vaccine Court: The Law and Politics of Injury* (New York University Press, 2016) pp 172–197 and R Goldberg *Medicinal Product Liability and Regulation* (Hart Publishing, 2013) pp 119–128.

[39]Department of Health and Human Services HRSA *Data & Statistics* p 7 https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/data-statistics-report.pdf (accessed 16 February 2022).

[40]Ibid, p 1. The latest figures indicate that total awards amount to $4.14 billion, producing an average compensation figure of $532,700: ibid, p 9.

[41]Ibid, p 1.

[42]Ibid, p 1.

[43]Ibid, p 2.

[44]KM Thompson et al 'Performance of the United States Vaccine Injury Compensation Program (VICP): 1988–2019' (2020) 38 Vaccine 2136, at 2138, 2140.

[45]42 USC § 300aa-11(c)(1)(C)(i).

[46]HR Rep No 908; 99th Cong 2d Sess 6, 15.

[47]42 USC § 300aa-11(c)(1)(C)(ii)(I); § 300aa-13(a)(1)(A).

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Table 1. Claims adjudicated since the inception of VICP

Fiscal Year	Compensable	Dismissed	Total	% Success
FY 1989	9	12	21	43
FY 1990	100	33	133	75
FY 1991	141	447	588	24
FY 1992	166	487	653	25
FY 1993	125	588	713	18
FY 1994	162	446	608	26
FY 1995	160	575	735	22
FY 1996	162	408	570	28
FY 1997	189	198	387	49
FY 1998	144	181	325	44
FY 1999	98	139	237	41
FY 2000	125	104	229	54
FY 2001	86	88	174	49
FY 2002	104	104	208	50
FY 2003	56	100	156	36
FY 2004	62	247	309	20
FY 2005	60	229	289	20
FY 2006	69	193	262	26
FY 2007	82	136	218	38
FY 2008	147	151	298	49
FY 2009	134	257	391	34
FY 2010	180	330	510	35
FY 2011	266	1,742	2,008	13
FY 2012	265	2,533	2,798	9
FY 2013	369	650	1,019	36
FY 2014	370	193	563	66
FY 2015	519	142	661	78
FY 2016	698	185	883	79
FY 2017	696	202	898	77
FY 2018	544	199	743	73
FY 2019	641	181	822	78
FY 2020	707	198	905	78
FY 2021	171	53	224	76
TOTAL	**7,807**	**11,731**	**19,538**	

Source: Department of Health and Human Services HRSA: Data & Statistics

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alleged off-Table injuries, which required the petitioner to prove their injury was caused by the vaccine they received.[48]

By comparison with the relaxation of the burden of proving causation for injuries which are Table claims, the burden of proof on the petitioner in an off-Table claim is a heavy one.[49] As Engstrom has observed: causation questions are problematic in the context of vaccine injuries since they are 'not traumatic or observable', nor do they trigger 'signature diseases', so that adverse effects caused by vaccines may be caused by other mechanisms, and since vaccines are administered to young infants and children, many neurological disorders are 'merely coincidental, temporal associations'.[50] Such facts have complicated the determination of causation under the VICP.[51] However, one should be cautious of using the existence of 'elemental scientific uncertainty at the root of the causal inquiry'[52] as a stick to beat the VICP with. Indeed, it should not be forgotten that the 'vaccine court was the sole institution in the world to conduct full and public hearings'[53] of the claims that autism was a vaccine injury, and that '[t]he OAP was a tremendous effort to bring closure to one of the most controversial causation questions of our day'.[54] The OAP test cases have reaffirmed the settled legal position that while there is no requirement on petitioners to produce supporting epidemiological evidence in a causation-in-fact claim,[55] in the instance in which general causation *has* been the subject of published epidemiological studies, such evidence should be given appropriate weight, along with the other evidence of the record.[56] This has reduced the dangers of elevating lower ranking hierarchical evidence[57] of biologically plausible mechanisms to connect vaccines to adverse events over published contrary epidemiological studies (at the top of the hierarchy),[58] though criticism remains that the VICP 'should more rigorously define the criteria' to determine causation.[59] Others have argued that in view of the difficulties in proving causation-in fact cases, the preponderance of evidence standard should be modified to a more generous 'benefit-of-the doubt standard', resolving close cases in favour of the petitioner.[60] A radical approach to causation has been suggested, which is to shift the burden of proof to the government in vaccine injury proceedings to prove by a preponderance of evidence that the

[48]GAO, above n 36, pp 20–21, 33. Nine new vaccines were added to the schedule of federally recommended childhood vaccines since the NCVIA: https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf (accessed 16 February 2022).

[49]*Grant v Secretary of Dept of Health & Human Services* 956 F 2d 1144, 1148 (Fed Cir 1992); *Hodges v Secretary of Dept of Health & Human Services* 9 F 3d 958, 961 (Fed Cir 1993); *Stevens v Secretary of HHS*, No 99–594 V, 2001 WL 387418 (Fed Cl Mar 30, 2001) at *7, per Chief Special Master Golkiewicz; HR Rep No 99–908, 13. For criticism of the problems of proving off-Table claims, see KE Strong 'Note: proving causation under the Vaccine Injury Act: a new approach for a new day' (2007) 75 George Washington Law Review 426 at 442–446; MS Holland 'Liability for vaccine injury: the United States, the European Union, and the developing world' (2018) 67 Emory Law Review 415, at 429.

[50]Engstrom, above n 36, at 1699.

[51]Ibid.

[52]Ibid.

[53]Kirkland, above n 38, p 172.

[54]Ibid, p 196.

[55]*Capizzano v Secretary of Health & Human Services* 440 F 3d 1317, 1325–26 (Fed Cir 2006). Indeed, causation can be demonstrated under the programme without any support from medical literature: *Althen v Secretary of Health & Human Services* 418 F 3d 1274, 1281 (Fed Cir 2005).

[56]*Cedillo v Secretary of Health & Human Services*, 2009 WL 331968 (Fed Cl Feb 12, 2009) at *92; *King v Secretary of Health & Human Services*, 03-584V, 2010 WL 892296 (Fed Cl March 12, 2010) at *74.

[57]Kirkland, above n 38, pp 164–171.

[58]This elevation of the use of biologically plausible mechanisms was arguably enhanced by the decision in *Althen v Secretary of Health & Human Services*, above n 55, at 1278, 1281. It has been seen in cases involving damaged nerves and autoimmune reactions after vaccination: see, eg, the hepatitis B claim for multiple sclerosis in *Werderitsh v Secretary of Department. of Health & Human Services* 2006 WL 1672884, *21, 25–26. For trenchant criticism of these decisions see PA Offit 'Vaccines and autism revisited – the Hannah Poling case' (2008) 358 New England Journal of Medicine 2089; and see further PA Offit 'Inoculated against facts' *The New York Times*, 31 March 2008.

[59]Offit, 'Vaccines and autism revisited – the Hannah Poling case', above n 58, at 2091.

[60]Strong, above n 49, at 452, 456–459 (2007); PH Meyers 'Fixing the flaws in the federal Vaccine Injury Compensation Program' (2011) 63 Administrative Law Review 785, at 845–847, 851.

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petitioner's injury was not caused by a vaccine.[61] Yet these more generous approaches to petitioners may result in undermining the need to be on the side of science in the resolution of cases and in so doing set an unhelpful precedent in increasing vaccine hesitancy. Asking the Secretary of HHS to prove a negative is an impossible burden to overcome, and one that upsets the balance between the interests of manufacturers, government and petitioners. '[S]cience can never demonstrate the absence of hazard' and it 'can only place an upper limit on risk'; confusion 'will always remain …at the lower margins of risk'.[62] Moreover, as Chief Special Master Golkiewicz has noted, protecting the vaccine's integrity, 'that is that vaccine[s] do [ ] not cause every injury that follows immunization',[63] remains critical to public confidence in vaccines.

Overall, there is much to be said for the success of the VICP despite these controversies, especially in its promotion of 'wide acceptance of vaccination as a public good that is also humane to those who perceive that they have been injured by this public good'.[64]

(v) Additions to the Table and proposal to remove SIRVA and vasovagal syncope

The majority of claims in the first decade of National VICP (1988–1998) were those alleging injuries on the vaccine injury Table. However, in 2014, the US Government Accountability Office (GAO) reported that the addition of six new vaccines, especially influenza vaccines, to the Table without covered injuries associated with these vaccines, had resulted in the majority of claims filed involving off-Table injuries. Subsequent to the 2014 GAO report, new injuries were added to the Table in March 2017.[65] These were: anaphylaxis within four hours of administration of hepatitis B vaccines, seasonal influenza vaccines, varicella vaccines, meningococcal vaccines and human papillomavirus (HPV) vaccines, intussusception between 1 and 21 days of administration of rotovirus vaccines, GBS within 3 and 42 days of administration of seasonal influenza vaccines, disseminated varicella vaccine-strain viral disease within 7 to 42 days of administration of varicella vaccines (if the strain determination is not done or the laboratory test is inconclusive), shoulder injury related to vaccine administration (SIRVA) for all injectable vaccines within 48 hours,[66] and vasovagal syncope within one hour after the administration of several vaccines.[67]

While this has helped counter some of the criticism of a migration away from the Table,[68] a recent controversial proposal by the Secretary for HHS has been to remove the additions of SIRVA and vasovagal syncope from it.[69] This has now become an important funding issue, as over 54% of petitions filed in the last two fiscal years are SIRVA claims,[70] and of these 99.2% were filed by adults.[71] The

[61]Apolinsky and Van Detta, above n 25, at 624–625.

[62]KR Foster et al (eds) *Phantom Risk: Scientific Inference and the Law* (MIT Press, 1993) p 435; and, further, DE Bernstein 'Getting to causation in toxic tort cases' (2008) 74(1) Brooklyn Law Review 51, at 70–71.

[63]LA Binski 'Balancing policy tensions of the Vaccine Act in light of the omnibus autism proceeding: are petitioners getting a fair shot at compensation?' (2011) 39 Hofstra Law Review 683, at 706.

[64]HC Meissner et al 'The National Vaccine Injury Compensation Program: striking a balance between individual rights and community benefit' (2019) 321 JAMA 343, at 344. Engstrong concedes that the shielding of manufacturers from liability has revitalised the vaccine marketplace and vaccine prices have partly stabilised: transaction costs are much lower than those of tort liability and the VICP is on a firm financial footing: Engstrom, above n 36, at 1715–1716.

[65]82 FR 6300, 21 March 2017. The Secretary of HHS can modify the Table by adding to or deleting from the list of injuries, conditions and deaths for which compensation may be provided or may change the time periods by which the onset of symptoms must transpire: 42 USC § 300aa-14(c).

[66]Ibid.

[67]Vaccines containing tetanus toxoid, pertussis bacteria, measles, mumps and rubella virus or any of its components (eg MMR, MM, MMRV), inactivated poliovirus, hepatitis B virus, haemophilius influenzae type b (Hib), varicella virus, hepatitis A virus, seasonal influenza virus and human papillomavirus (HPV); and pneumococcal conjugate or meningococcal vaccines: 82 FR 6300, 21 March 2017.

[68]See Engstrom, above n 36, at 1702–1706.

[69]85 FR 43794, 20 July 2020.

[70]T Overby 'The National Vaccine Injury Compensation (VICP) division of injury compensation programs (DICP) program update', The Advisory Commission on Childhood Vaccines (ACCV), 6 March 2020.

[71]85 FR 43794, 20 July 2020.

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essence of the legal argument presented by the HHS is that since the Act defines the term 'vaccine-related injury or death' as 'an illness, injury, condition, or death *associated with* one or more of the *vaccines* set forth in the Vaccine Injury table',[72] the programme covers injuries 'associated with the vaccine itself'. SIRVA is not a vaccine and is not an injury caused by a vaccine antigen, but one caused by negligent *administration* of the vaccine by a health provider. Neither SIRVA nor vasovagal syncope meet the 'associated with the vaccine' requirement, as neither set of injuries are associated with the vaccine itself, since if the vaccine is administered properly, these injuries will not occur. As the Table should include only 'injuries caused by a vaccine or its components, not the manner in which the vaccine was administered',[73] both SIRVA and vasovagal syncope should be removed from the Table.[74]

However, the Advisory Commission on Childhood Vaccines (ACCV) unanimously opposed the implementation of the changes to the Table, with three of the four members concluding that, while rare, both SIRVA and vasovagal syncope are injuries that *can* be caused by vaccination and thus should be compensable under the VICP.[75] They also considered that removing SIRVA and vasovagal syncope would not provide liability protection to health care professionals who administer them, and thus could lead to potential exposure of vaccine administrators to civil law suits: this in turn could be a disincentive to administering vaccines, resulting in lower vaccination rates.[76] Notwithstanding the concerns of the ACCV, the rule amending the Table was made final on 21 January 2021.[77] However, subsequent to a review by the new Democratic administration, the final rule was rescinded by a further final rule on 21 April 2021 for both procedural and policy reasons.[78] As a policy matter, HHS concluded that the rule would have a negative impact on vaccine administrators, and would be at odds with the Federal Government's efforts to increase confidence in vaccinations in the US, especially the Covid-19 campaign, as well as other campaigns such as annual influenza vaccination efforts.[79] It was also noted that a further reason for rescission of the rule was to allow HHS sufficient time to consider the state of the science concerning SIRVA.[80] It is submitted that HHS's rescission was correct: a careful and methodical consideration of the science regarding the definition is essential to the success of the VICP. A coherent vaccine policy which includes compensation must be based on the latest and most accurate peer-reviewed evidence. While the creation and amendment of decision aids involving compensation are 'politically charged',[81] that must not be allowed to undermine the need for their review as science evolves, but this must be undertaken in a considered manner.

(c) Public Readiness and Emergency Preparedness Act of 2005 (PREP)

(i) Scope of immunity

As a result of concern emerging in 2006 about the spread of avian influenza (H5N1),[82] 'targeted liability protection',[83] known as the PREP Act, was offered to the manufacturers of drugs, vaccines and medical devices used in declared public health emergencies.[84] The Act provides immunity to any

[72]42 USC § 300aa-33(5). Emphasis added.
[73]85 FR 43794, 43797 20 July 2020.
[74]Ibid.
[75]Recommendation from ACCV to Secretary of HHS, 20 May 2020.
[76]Ibid.
[77]86 FR 6249 (2021).
[78]86 FR 21209, 21210–21211 (2021).
[79]Ibid, 21211.
[80]Ibid, 21212.
[81]Engstrom, above n 36, at 1703–1706 (noting that decision aids attempting to crystallise scientific understanding must be susceptible to amendment as science evolves, but that such aids are 'manipulable' through their expansion or contraction).
[82]Apolinsky and Van Detta, above n 25, at 558–560.
[83]Public Readiness and Emergency Preparedness Act, 42 USC §247d-6d.
[84]This was of course prior to the emergence in 2009 of a new H1N1 influenza virus, resulting in the first global flu epidemic in 40 years: https://www.cdc.gov/flu/pandemic-resources/2009-pandemic-timeline.html (accessed 16 February 2022).

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'covered person', ie a manufacturer, distributor or administrator, with respect to 'all claims for loss caused by, arising out of, relating to, or resulting from' the 'administration to' or 'use by' an individual of a 'covered countermeasure', ie drugs, vaccines or medical devices, providing a declaration has been issued with respect to such a countermeasure.[85] The extent of the immunity is extremely broad. It applies to 'any type of loss', including: death, physical, mental, or emotional injury, fear of physical, mental or emotional injury, and loss of or damage to property,[86] where the loss 'has a causal relationship with the administration to or use by an individual of a covered countermeasure'.[87] This includes 'a causal relationship with the design… manufacture, labeling, … marketing, promotion, sale, purchase, … prescribing, administration, licensing, or use of such countermeasure'.[88] The sole exception to immunity from suit is for death or serious physical injury caused by wilful misconduct.[89]

(ii) Compensation

While immunising vaccine manufacturers from liability, the PREP Act provides for compensation for covered injuries directly caused by the administration or use of a covered countermeasure from an emergency fund designated the 'Covered Countermeasure Process Fund'.[90] The establishment of a compensation fund is contingent on the issuance of a declaration by HHS.[91] In implementation of the PREP Act, procedures have been established for the Countermeasures Injury Compensation Program (CICP) to provide medical and lost employment income benefits to those individuals who sustained a covered injury as the direct result of the administration or use of a covered countermeasure.[92] Only serious injuries or deaths are covered by the CICP.[93]

As with the NCVIA, injuries are eligible for compensation in two ways. First, petitioners can meet the preponderance of the evidence standard that the specified countermeasure probably caused the injury, on the basis of 'compelling, reliable, valid, medical and scientific evidence'.[94] Alternatively, if and when HHS establishes a table of injuries concerning the countermeasures, petitioners will be entitled to compensation if the injuries fall within the Covered Countermeasures Injury Table: these injuries are 'presumed to be directly caused' by the specified countermeasure, provided that the first symptom or manifestation of each onset of adverse effect occurs within a specified time period.[95] Stressing the need for the Table to be driven by scientific evidence of causation, the identification of covered injuries for inclusion in the Table must be based on 'compelling, reliable, valid, medical and scientific evidence that administration or use of the [vaccine] directly caused [the] covered injury'.[96] As from 8 September 2015, HHS has adopted a pandemic influenza countermeasures injury table, containing presumptive injuries from pandemic influenza vaccines, including the pandemic influenza 2009 H1N1 vaccine.[97] The Table creates presumption of causation in the event of anaphylaxis within four hours of the administration of pandemic influenza vaccines, and GBS within 3–42 days of the administration of the pandemic influenza 2009 H1N1 vaccine.[98] Again, as in the case of the NCVIA, if an injury does not fall within the Table, the claimant must prove 'that the injury occurred as the direct result of the administration or use of a covered countermeasure' by 'compelling,

[85]42 USC §247d-6d(a)(1), §247d-6d(b), §247d-6d(i).
[86]42 USC §247d-6d(a)(2)(A).
[87]42 USC §247d-6d(a)(2)(B).
[88]Ibid.
[89]42 USC §247d-6d(d)(1), as defined in §247d-6d(c).
[90]42 USC §247d-6e.
[91]See 42 USC §247d-6d(a),(b) and 42 USC §247d-6e(a),(b).
[92]42 CFR §110.1.
[93]42 CFR§110.20(a).
[94]42 USC §§239a(c)(2), 247d-6e(b)(4).
[95]42 USC §247d-6e(b)(5).
[96]Ibid; 42 CFR §110.20(b).
[97]42 CFR §110.100(a); 80 FR 47411 (2015).
[98]42 CFR §110.100(a).

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reliable, valid, medical and scientific evidence'.[99] Mere demonstration of temporal association between receipt of the countermeasure and onset of the injury is insufficient by itself to prove causation.[100]

The CICP provides expenses necessary 'to diagnose or treat a covered injury', and payments or reimbursements for the provision or future provision of 'reasonable and necessary medical services and items'.[101] There are no caps on these medical expense benefits.[102] The CICP also covers benefits for lost employment income,[103] and survivor death benefits are potentially compensable.[104] However, the CICP is significantly less generous than the NCVIA in that there are no damages awarded for pain and suffering.[105] In addition, no court may review any action of the Secretary for HHS taken under the PREP Act,[106] and no covered individual eligible for compensation may bring a civil action unless they have exhausted their remedies under the provisions.[107] Importantly, in contrast to the VICP,[108] the CICP does not authorise payment of reasonable attorney fees and other costs incurred in any proceeding.[109] This is likely to prove a major disincentive to claimants who will require the assistance of counsel and expert testimony to determine whether the vaccine caused the injury in off-Table claims.[110] Further, the limitation period for filing a claim under the CICP is one year from the date of the administration or use of the vaccine that is alleged to have caused the injury,[111] as opposed to three years after the date of the occurrence of a vaccine-related injury.[112] As of 1 July 2021, 1,657 claims have been filed under the CICP, of which 29 have been compensated.[113] All but one of the 29 concerned the H1N1 vaccine, the alleged injury in the overwhelming majority of cases being GBS.[114] It thus appears that with such broad immunity and limitations on compensation, recourse for victims is extremely limited.[115]

(iii) Covid-19 vaccines and immunity under the PREP Act

On 10 March 2020, the Secretary of HHS issued a Declaration under the PREP Act, effective from 4 February 2020, for certain medical products (covered countermeasures) to be used against Covid-19.[116] It comes as little surprise that such products include vaccines. Under the Declaration, covered countermeasures are: 'any antiviral, any other drug, any biologic, any diagnostic, any other device, or any *vaccine*, used to treat, diagnose, cure, prevent, or mitigate Covid-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product'.[117] A covered countermeasure must be a 'qualified pandemic or epidemic product', which is 'a drug … biological product

[99]42 CFR §110.20(c).
[100]Ibid.
[101]42 CFR §110.31. Cf 42 USC § 300aa-15(a)(1)(A),(B).
[102]42 CFR §110.80.
[103]42 CFR §110.30, §110.32.
[104]42 CFR §110.30, 42 CFR §110.33.
[105]42 USC §247d-6e(b)(2). Cf 42 USC § 300aa-15(a)(4).
[106]42 USC §247d-6e(b)(5)(C).
[107]42 USC §247d-6e(d).
[108]Ibid, § 300aa-15(e). See above, n 35.
[109]42 USC §247d-6e(b)(2); 42 CFR §110.44(d).
[110]This could be especially pertinent in cases requiring a determination of whether a Covid-19 vaccine caused a serious injury or death: PH Meyers 'The Trump administration's flawed decision on coronavirus vaccine injury compensation: recommendations for changes' (2020) Journal of Law and the Biosciences 1, at 5 doi:10.1093/jlb/lsaa082. See text to n 133.
[111]42 CFR §110.42.
[112]§ 300aa-16(a)(2). In the case of death occurring as a result of administration of a vaccine, the limitation period is one year from the date of death and four years after the date of the occurrence of the vaccine-related injury from which the death resulted: § 300aa-16(a)(23).
[113]*CICP Data* https://www.hrsa.gov/cicp/cicp-data (accessed 16 February 2022).
[114]Ibid, Table 2.
[115]Apolinsky and Van Detta, above n 25, at 560–562; Holland, above n 49, at 447–451.
[116]85 FR 15198, 15201–15203 (2020).
[117]85 FR 15198, 15202 (emphasis added).

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… or device [as] defined … [in] the Federal Food, Drug, and Cosmetic Act … that is … manufactured [or] used … to diagnose, mitigate, prevent, treat or cure a pandemic or epidemic; or … limit the harm such a pandemic or epidemic might otherwise cause' that the US Food and Drug Administration (FDA) has approved, cleared or authorised for emergency use.[118] The issuing of the Covid-19 Declaration triggers the broad immunity provisions of the PREP Act.

As previously noted, the Act provides broad immunity to any 'covered person', ie a manufacturer, distributor or administrator, with respect to 'all claims for loss caused by, arising out of, relating to, or resulting from' the 'administration to' or 'use by' an individual of a 'covered countermeasure', providing a declaration has been issued with respect to such a countermeasure.[119] Thus the broad immunity would preclude liability claims in negligence by a manufacturer in creating a vaccine, or negligence by a health care provider in prescribing the wrong dose.[120] An HHS Advisory Opinion has reaffirmed the broad scope of this immunity during the Covid-19 pandemic.[121] The Covid-19 Declaration provides that the CICP and 'Covered Countermeasure Process Fund' will cover serious injuries or death as a direct result of Covid-19 vaccines.[122] Since no table of injuries concerning Covid-19 countermeasures has been established, petitioners must meet the preponderance of the evidence standard that the Covid-19 vaccine probably caused the injury, on the basis of 'compelling, reliable, valid, medical and scientific evidence'.[123] As of 1 July 2021, there have been 1,165 Covid-19 countermeasure claims, 436 of which allege injuries/deaths from Covid-19 vaccines.[124] Two Covid-19 countermeasures (one of which concerned a Covid-19 vaccine), have been denied compensation since the standard of proof of causation was not met and/or covered injury was not sustained.[125] It has been predicted that in view of the limitations on compensation of the CICP, those who receive Covid-19 vaccinations during the life of the Declaration would be less likely to receive compensation than they would under the VICP, and that the process for pursuing compensation will be lengthier, more difficult and expensive in the absence of reimbursement of reasonable attorney fees.[126] In a highly critical assessment of the decision to place Covid-19 vaccine claims for compensation within the CICP,[127] describing it as 'an extremely restricted compensation scheme',[128] and one where decisions to grant or deny compensation are unpublished,[129] it has been submitted that a fairer compensation programme is needed, based on the best features of the VICP and the September 11th Victim Compensation Fund.[130] On the other

[118]42 USC §247d-6d(i)(1)(A), §247d-6d(i)(1)(A)(7). An emergency use authorisation for a Covid-19 vaccine may be issued by the FDA after it has determined that the requirements of section 564 of the Federal Food, Drug and Cosmetic Act (21 USC §360bbb-3) have been met. See further *Emergency Use Authorization for Vaccines to Prevent Covid-19: Guidance for Industry* (Department of Health and Human Services, Food and Drug Administration Centre for Biologics Evaluation and Research, October 2020).

[119]42 USC §247d-6d(a)(1), §247d-6d(b), §247d-6d(i).

[120]85 FR 15198, 15200.

[121]Department of Health and Human Services *Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration under the Act* (17 April 2020, as modified on 19 May 2020).

[122]85 FR 15198, 15201, 15203; 42 USC §247d-6e.

[123]42 USC §§239a(c)(2), 247d-6e(b)(4).

[124]*CICP Data*, above n 113, Table 1. The remaining 729 allege injuries/deaths from other Covid-19 countermeasures: ibid.

[125]Ibid, Table 5. One alleged countermeasure and alleged injury concerned a ventilator and death, the other a Covid-19 vaccine and swelling of the tongue and throat, difficulty speaking and dizziness.

[126]K Van Tassel et al 'Covid-19 vaccine injuries – preventing inequities in compensation' (2021) 384(10) New England Journal of Medicine e34(2).

[127]Meyers, above n 110, at 4.

[128]Ibid.

[129]Ibid; and, further, Meyers, above n 60, at 835.

[130]Meyers, above n 110, at 2, 7–11. For a new category of vaccines (in this case Covid-19 vaccines) to be added to the Vaccine Injury Table, Item XVII of the Table requires Congress to enact an excise tax on the vaccine, the CDC must recommend it for routine administration to children or pregnant women, and the Secretary must publish a notice in the Federal Register: see 42 CFR 100.3(a),(e)(8) and 86 FR 21209, 21211–12 (2021). It has been suggested that Congress amend the PREP Act by requiring that all vaccines recommended by the CDC to ameliorate a public health emergency be immediately added to the VICP, regardless of whether they are recommended for pregnant women or children. In addition, a 75-cent excise tax

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hand, manufacturers have argued that such broad protection is justifiable, given the expectation of government and the public that they develop and manufacture such vaccines as quickly as possible.[131] The difficulty remains that, viewed as a less generous scheme than the VICP with broad immunity and less accountability in the absence of judicial review of HHS decisions, the CICP may be seen as reducing the risk of vaccine manufactures at the expense of populist distrust about government, public health decision-makers and the safety of vaccines.[132] As Covid-19 vaccinations continue to be recommended by the CDC,[133] the pressure to mandate coronavirus vaccines continues to rise,[134] and society benefits through individual vaccination, the arguments in favour of inclusion of such vaccines in the VICP seem strong.

2. The UK's vaccine damage payments scheme

(a) Vaccine Damage Payments Act 1979

(i) Background

While the UK government initially resisted pressure generated by the Association of Parents of Vaccine Damaged Children for compensation, their hand was forced by several factors. The first was a rise in vaccine hesitancy in the early 1970s concerning the pertussis (whooping cough) vaccine. Vaccination rates had dramatically declined between 1971 and 1975 and by the summer of 1977 the national vaccine programme was in crisis.[135] Secondly, in its wide-ranging investigation of the question of compensation for vaccine damage,[136] the Pearson Commission concluded that since vaccination is recommended by the government, the government should be strictly liable in tort for serious and lasting damage suffered by anyone, whether adult or child, as a result of vaccination

could be applied for all vaccines for pandemic viruses in the US (as already the case for childhood vaccines) to finance the Vaccine Injury Trust Fund: Van Tassel et al, above n 126, at e34(3).

[131]Ibid. Cf the pre-existing UK *ex gratia* compensation system, the Vaccine Damage Payments Scheme (VDPS) (under the Vaccine Damage Payments Act 1979), which has been extended to those vaccinated against the Covid-19 virus (Vaccine Damage Payments (Specified Disease) Order 2020, SI 2020/1411, Art 2) and is without prejudice to the ability to pursue the alternative course of claiming compensation against the manufacturer of the vaccine in any civil proceedings in respect of disablement suffered: Vaccine Damage Payments Act 1979, s 6(4) (discussed below). Immunity from civil liability is conferred on manufacturers of medicinal products in the UK in specific circumstances, including the authorisation of a medicinal product on a temporary basis to manufacturers under reg 174 of the Human Medicines Regulations 2012: Human Medicines Regulations 2012, SI 2012/1916, reg 345 (as amended by the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020, SI 2020/1125, reg 29). Each of the current Covid-19 vaccines was initially supplied in the UK on a temporary basis under reg 174 prior to the subsequent issue of conditional marketing authorisations for sale and supply in Great Britain, pursuant to regs 50I(3)(b) and 58F. In respect of civil proceedings, if the government uses a tested, unlicensed vaccine against Covid-19, there will be *partial* immunity from civil liability, resulting in an exclusion of claims under contract, tort and breach of statutory duty. However, such immunity is not absolute and will be channelled towards a cause of action under s 2 of the Consumer Protection Act 1987. See Human Medicines Regulations 2012, SI 2012/1916, reg 345(3), (4) as amended by the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020, SI 2020/1125, reg 29. The 'central issue' would then be a determination of whether a Covid-19 vaccine is defective, which would be a very difficult obstacle to surmount in the context of rare adverse reactions to beneficial vaccines: see further R Goldberg 'Vaccine liability in the light of Covid-19: a defence of risk-benefit' (2022) Medical Law Review 1, at 21–24. available at https://academic.oup.com/medlaw/advance-article-abstract/doi/10.1093/medlaw/fwab053/6506562 (accessed 16 February 2022). There is no statutory exception equivalent to the wilful misconduct exception under the US PREP Act, 42 USC §247d-6e.

[132]WE Parmet 'Pandemics, populism and the role of law in the H1N1 vaccine campaign' (2010) 4 St Louis University Journal of Health Law & Policy 113, at 146, 152.

[133]https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html (accessed 30 July 2021).

[134]'New York City and California to require vaccines or tests for workers', *The New York Times*, 26 July 2021; 'Biden seeks to revive vaccine effort with new rules and incentives', *The New York Times*, 29 July 2021.

[135]See G Milward 'A disability act? The Vaccine Damage Payments Act 1979 and the British government's response to the pertussis vaccine scare' (2016) 30 Social History of Medicine 429, at 440–441.

[136]See the Royal Commission on Civil Liability and Compensation for Personal Injury, Cmnd 7054-1/1978, ch 25 (hereafter, Pearson Report).

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recommended in the community's interest.[137] While such a recommendation may seem entirely justifiable over 40 years later, this preferential treatment of vaccine damaged persons over other disabled children was questioned by commentators at the time and continues to be regarded by some as controversial.[138] It also sits uneasily with the report's statement that the compensation and care of severely handicapped children was based on the principle that they were to be treated alike, without regard to the cause of their condition,[139] an 'anomaly' said to have been agreed 'on the basis of the specific public health issues involved'.[140] Strict liability was to be subject to matters of cause and fact and without defences. Proof of causation was acknowledged as a longstanding difficult issue for the resolution of the courts since convulsions which may be symptomatic of whooping cough vaccine could also occur naturally[141] and the Commission was aware of 'no clinical tests which could distinguish the one from the other'.[142]

(ii) Scope of the 1979 Act

On the recommendations of the Pearson Commission, and to restore the public's confidence in the vaccination programme,[143] the Vaccine Damage Payments Act 1979 was enacted 'to provide a single tax-free payment'[144] for vaccine-damaged persons for death or severe disablement[145] proved on a balance of probabilities to have been caused[146] by vaccination against diphtheria, tetanus, whooping cough, poliomyelitis, measles, rubella, tuberculosis, smallpox, and any other disease specified by the Secretary of State by statutory instrument.[147] This became known as the Vaccine Damage Payments Scheme (VDPS). Over the years, several additional diseases have been specified, viz mumps, the haemophilus influenza type b infection (Hib), meningococcal Group C (meningitis C), pneumococcal infection and the human papillomavirus (HPV), pandemic influenza A (H1N1) to 31 August 2010,[148] rotavirus, influenza,[149] meningitis W and meningitis B.[150] The latest additional disease specified is Covid-19[151] and, as with H1N1, the conditions of entitlement have been modified to extend

[137]See Pearson Report, above n 136, ch 25, para 1408.

[138]G Dworkin 'Compensation and payments for vaccine damage' (1978/9) Journal of Social Welfare Law 330, at 332; P Cane and J Goudkamp *Atiyah's Accidents, Compensation and the Law* (Cambridge: Cambridge University Press, 9th edn, 2018) pp 94–95 and the inconsistency in the Pearson Report between para 1406 (vaccine-damaged children should be considered with other severely disabled children, irrespective of the cause of disablement) and para 1407 (a case for an additional remedy in tort for vaccine damaged children). As PS Atiyah put it at the time: 'It is hard to believe that these two paragraphs were written by the same person': PS Atiyah 'What now?' in DK Allen et al (eds) *Accident Compensation After Pearson* (Sweet & Maxwell, 1979) p 241.

[139]Pearson Report, above n 136, para 1489; Dworkin, above n 138, at 332.

[140]J Stapleton *Product Liability* (London: Butterworths, 1994) p 46.

[141]*Department of Health and Social Security, Whooping Cough Vaccine: Review of the Evidence on Whooping Cough Vaccination by the Joint Committee on Vaccination and Immunisation* (London: HMSO, 1977) para 47.

[142]Pearson Report, above n 136, para 1411.

[143]See Milward, above n 135, at 441.

[144]*Hansard* HC Deb, vol 352, col 719, Mr Alistair Darling, 27 June 2000. The scheme is not regarded as a compensation scheme: ibid, col 726. See also *Hansard* HC Deb, 24 March 2015, col 458 WH, Parliamentary Under-Secretary of State for Health (Jane Ellison).

[145]Vaccine Damage Payments Act 1979, s 1(1).

[146]Ibid, s 3(5).

[147]Vaccine Damage Payments Act 1979, s 1(2). Since 2014, the VDPS has been the responsibility of two Departments: the Department of Health and Social Care (DHSC) is responsible for the policy of the scheme and its legislation, while administration lies with the Department of Work and Pensions (DWP). Whilst severe disablement is assessed in accordance with social security regulations, the administration appears to sit awkwardly with the DWP, whose main emphasis is on the administration of working age, disability and ill-health benefits: https://www.gov.uk/government/organisations/department-for-work-pensions (accessed 16 February 2022).

[148]The Vaccine Damage Payments (Specified Disease) Order 2009, SI 2009/2516; the Vaccine Damage Payments (Specified Disease) (Revocation and Savings) Order 2010, SI 2010/1988.

[149]Except for influenza caused by a pandemic influenza virus: Vaccine Damage Payments (Specified Disease) Order 2015, SI 2015/47, Art 2.

[150]Vaccine Damage Payments (Specified Disease) Order 2016, SI 2016/454, Art 2.

[151]Vaccine Damage Payments (Specified Disease) Order 2020, SI 2020/1411, Art 2.

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the 1979 Act to those vaccinated against the Covid-19 virus at a time when they were 18 years or older.[152] The Secretary of State must be satisfied that a person was severely disabled as a result of vaccine damage, determined on the balance of probability.[153] If a causal link is established and disablement suffered is 60% (previously 80%) or more,[154] a lump sum of £120,000 is awarded.[155] In assessing whether the threshold is crossed for 60% disablement, it has been held in a significant breakthrough for applicants under the VDPS that a Tribunal should take into account an applicant's future prognosis on the balance of probabilities.[156] In *G (A Minor) v Secretary of State for Work and Pensions*,[157] which concerned the H1N1 swine flu vaccine, the Court of Appeal upheld the decision of the First-tier Tribunal that, notwithstanding the applicant did not cross the 60% disablement threshold as assessed solely at the date of the DWP decision refusing to accept severe disablement, further continuing disablement in the future was likely and should be taken into account: accordingly, the applicant was entitled to payment under the scheme.[158]

(iii) Claims experience

In contrast to the US VICP, success rates are extremely low: since the inception of the VDPS, there have been 6,799 claims, 946 of which have resulted in awards: a success rate of 13.9% (see Table 2). The number of accepted claims reached its height between 1979 and 1983 and has reduced to an average of 1.6 claims a year between 2010 and 26 August 2021.

By far the majority of claims to the VDPS that have been disallowed were on the basis that the vaccination did not cause the disability (a total of 4,349 claims, amounting to 79%). The other main reason for rejection was that claims were received outside the statutory time limit for making a claim,[159] with 629 rejected for that reason. Table 3 shows a breakdown of the claims that have been disallowed and the reason for the disallowance.

The scheme is without prejudice to the ability to pursue the alternative course of claiming compensation against the manufacturer of the vaccine in any civil proceedings in respect of disablement suffered, but in such proceedings any payment made[160] is to be treated as being paid on account of any

[152]Ibid, Art 3.

[153]Vaccine Damage Payments Act 1979, ss 1(1), (4), 3(5). Note that the onus of proof is not expressly discussed in the Act: R Goldberg *Causation and Risk in the Law of Torts: Scientific Evidence and Medicinal Product Liability* (Oxford: Hart Publishing, 1999) p 173.

[154]Vaccine Damage Payments Act 1979, s 1(4) as amended by the Regulatory Reform (Vaccine Damage Payments Act 1979) Order 2002, SI 2002/1592, Art 2. This concept of severe disablement derived from pre-WWII Industrial Injuries and War Pensions schemes: the choice of 80% was designed so that only the 'most in need' would receive benefit and was defended by improvements in disability policy: Milward, above n 135, at 443. Severe disablement is assessed 'as for the purposes of' s 103 of the Social Security Contributions and Benefits Act 1992: Vaccine Damage Payments Act 1979, s 1(4). Section 103(5) of the 1992 Act provides that 'assessed' means assessed in accordance with Sch 6, para 2 of which authorises the making of Regulations defining the principles of such assessment. Those Regulations are found in the earlier Social Security (General Benefit) Regulations 1982, SI 1982/1408, Sch 2 to which provides a lengthy list of injuries relating to specified degrees of disablement. The entire list of injuries set out are of a physical kind, most connoting permanent loss (eg loss of limb), and these may well not come into play in some vaccine damage cases; however, Sch 2 is to be taken into account in assessing the impact of the disability: see *G (A Minor) v Secretary of State for Work and Pensions* [2017] EWCA Civ 61, [2017] 1 WLR 1956, [45]–[46].

[155]Vaccine Damage Payments Act 1979, s 1(1), (1A); The Vaccine Damage Payments Act 1979, Statutory Sum Order 2007, SI 2007/1931, Art 2.

[156]*G (A Minor) v Secretary of State for Work and Pensions* [2017] EWCA Civ 61, [2017] 1 WLR 1956, [16], [43], [54]–[56].

[157]*G (A Minor) v Secretary of State for Work and Pensions* [2017] EWCA Civ 61.

[158]Ibid. While the claim was initially refused by the DWP on the ground that it had not been persuaded that the vaccination had caused the applicant's narcolepsy and cataplexy, it was in due course accepted for the purposes of the case that causation was established: ibid, [7].

[159]ie the later of: the date on which the disabled person attains the age of 21; and the end of the period of six years beginning with the date of the vaccination to which the claim relates: Vaccine Damage Payments Act 1979, s 3(1)(c).

[160]Under the Vaccine Damage Payments Act 1979, s 1(1).

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Table 2. Total number of VDPS claims and awards between 1977 and 26 August 2021

Year	Claims	Awards	Year	Claims	Awards
1977/78	6	0	1999/00	90	4
1978/79	1,712	36	2000/01	202	2
1979/80	874	317	2001/02	146	3
1980/81	121	256	2002/03	417	5
1981/82	72	68	2003/04	165	5
1982/83	98	38	2004/05	111	4
1983/84	101	40	2005/06	106	5
1984/85	111	36	2006/07	60	4
1985/86	64	24	2007/08	53	2
1986/87	76	17	2008/09	62	0
1987/88	66	10	2009/10	62	3
1988/89	38	3	2010/11	91	1
1989/90	51	3	2011/12	91	0
1990/91	34	1	2012/13	85	0
1991/92	43	7	2013/14	111	0
1992/93	49	13	2014/15	79	0
1993/94	54	3	2015/16	85	3
1994/95	78	7	2016/17	52	2
1995/96	70	6	2017/18	71	3
1996/97	69	5	2018/19	78	2
1997/98	202	3	2019/20	55	3
1998/99	135	0	2020/21	403	2
			TOTALS	**6,799**	**946**

Source: Department of Work and Pensions, FOI2020/76078, 11 December 2020; FOI2021/03388, 1 February 2021; FOI2021/61679 27 August 2021.

damages which the court may award for a disablement.[161] However, litigation remains a course attended by considerable difficulty.[162]

(iv) Tribunal appeals

Section 4(1) of the 1979 Act provides for appeal against any decision as to whether a person was severely disabled as a result of vaccination by reference to a First-tier Tribunal. In deciding an appeal, the Tribunal shall consider all the circumstances of the case (including any that did not obtain at the time when the decision appealed against was made).[163] The failure rates continue to be high. Since the inception of the VDPS, 2111 requests have been made for an appeal. Of those, 1402 were upheld, 502 were reversed, 203 were withdrawn and 4 remain outstanding.[164] Table 4 provides an analysis of the

[161]Ibid, s 6(4).

[162]See especially *Loveday v Renton* [1990] 1 Med LR 117 (pertussis vaccine) and the MMR vaccine litigation: see further, Goldberg, above n 38, pp 114–117.

[163]Vaccine Damage Payments Act 1979, s 4(4).

[164]FOI2020/76078, 11 December 2020; FOI2021/61679 27 August 2021.

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Table 3. Total numbers of VDPS claims disallowed and reasons for disallowance up to 26 August 2021

Reason for disallowance	Number disallowed
Duplicate claim or registered in error	**14**
Claim out of time	**629**
Child under age 2	**17**
Died prior to 9 May 1978/prior to age 2	**18**
Over age 18 when vaccinated	**105**
Disease not included in the Act	**90**
Not vaccinated in the UK/IOM	**16**
Vaccinated prior to 1948	**57**
Smallpox vaccination after 1971	**3**
Vaccination date before immunisation added to childhood immunisation program	**3**
Claim withdrawn	**14**
Invalid claim	**4**
Vaccination has not been verified	**45**
Payment already authorised	**2**
Causation not accepted	**4349**
Causation accepted, not severely disabled	**133**
TOTAL	**5499**

Source: Department of Work and Pensions: FOI2020/76078, 11 December 2020; FOI2021/03388, 1 February 2021; FOI2021/61679 27 August 2021.

most recent decisions of the Vaccine Damage Payments Tribunals in the years 1993–2021.[165] On the basis that:

Rate of reversal at tribunal	= No of decisions not to make a payment reversed by tribunal
	Total no of decisions at tribunal (excluding those withdrawn and outstanding)
	= R/U+R
	= 41/347
The rate of reversal at tribunal	= 12%

The determination of causation continues to be a major source of difficulty in Tribunal appeals. The matter is not helped by the fact that, unlike decisions of the VICP, where all decisions issued by the special masters are published (with appropriate redactions to protect private medical information concerning the petitioners),[166] the UK Vaccine Damage Payments Tribunal decisions remain unpublished.[167] In response to a request made by the author to obtain copies of the decisions, the author was informed that the DWP were unable to provide them.[168] It is, therefore, impossible for

[165]FOI2021/03388, 1 February 2021; FOI2021/61679 27 August 2021.

[166]Meyers, above n 110, at 6. Cf the position under the CICP, where the decisions to grant or deny compensation are kept secret and unpublished: see above text to n 136.

[167]Remarkably there is no legal requirement for a First-tier Tribunal to provide reasons for its decision. It may do so orally at hearing or in a written statement of reasons to each party; otherwise, a party may apply for such a written statement: Tribunal Procedure (First-Tier Tribunal) (Social Entitlement Chamber) Rules 2008, SI 2008/2685 (L 13), r 34.

[168]Response to FOI2020/76078 request, 11 December 2020, 2. The decisions 'are destroyed in line with Departmental document retention policy'. Those yet to be destroyed 'contain personal information which cannot be disclosed, in line with Data Protection Regulations': ibid.

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Table 4. Decisions of Vaccine Damage Payments Tribunal appeals by region, 1993–2021

Region	No of appeals	Upheld (U)	Reversed (R)	Withdrawn (W)	Outstanding (O)
Belfast	13	9	1	3	0
Birmingham	58	43	2	13	0
Cardiff	55	34	11	10	1
Glasgow	38	30	3	5	0
Leeds	33	24	5	4	1
Liverpool	30	23	4	3	0
London	55	44	5	6	0
Newcastle	24	20	1	2	1
Nottingham	39	32	3	4	0
Salford	37	28	1	8	0
Sutton	30	20	5	4	1
Totals	**412**	**306**	**41**	**62**	**4**

Source: Department of Work and Pensions: FOI2021/03388, 1 February 2021. FOI2021/61679 27 August 2021

the public and commentators to discern the reasoning behind the decisions made. Moreover, this does not help to generate any consistency in decision making, and the lack of transparency is unhelpful in the face of increasing vaccine hesitancy.

(v) Concerns over causation: use of biologically plausible theories unsupported by scientific evidence

A recent decision made by the Vaccine Damage Payments Tribunal raises concerns about determining the causation issue in favour of applicants, despite the absence of independent evidence supporting a causal association. This redacted First-tier Tribunal decision found that on a balance of probabilities vaccination with Fluenz Tetra (a seasonal flu vaccination) caused the daughter of the appellant to suffer narcolepsy between three and four months later, on the basis of a biologically plausible theory that was unsupported by scientific evidence.[169] While there is compelling epidemiological evidence of an increased risk of narcolepsy following vaccination with the H1N1 pandemic vaccine Pandemrix, especially in children, [170] and the Vaccine Damage Unit and the Secretary of State have previously accepted a causal link between the development of narcolepsy and Pandemrix,[171] there is an absence of any epidemiological study supporting an increased risk of narcolepsy following vaccination with Fluenz Tetra. The Secretary of State's four assessors relied on the absence of any such study to advise that the narcolepsy was not caused by the vaccine.[172] The Tribunal Judge ruled that the absence of an epidemiological study showing any causal link between the Fluenz tetra vaccine and narcolepsy did not render proof of causation fatal: in the Tribunal's view this was 'evidentially neutral'.[173] As we have

[169]First-Tier Tribunal Social Entitlement Chamber, 13 March 2020 (Judge Phillip Barber) paras 24, 34 (redacted decision, available at https://www.hja.net/wp/wp-content/uploads/Tribunal-decision-redacted.pdf?x17859 (accessed 16 February 2022)).

[170]J Stowe et al 'Reassessment of the risk of narcolepsy in children in England 8 years after receipt of the AS03-adjuvanted H1N1 pandemic vaccine: a case-coverage study' (2020) PLoS Med 17(9): e1003225.

[171]See Case No CV/5273/2014 *Secretary of State for Work & Pensions v [name redacted]*, Decision of the Upper Tribunal (Administrative Appeals Chamber) (Judge E Mitchell), 23 May 2015, paras 9–12; *G (A Minor) v Secretary of State for Work and Pensions* [2017] 1 WLR 1956, para 7. The susbequent litigation was confined to the issue of severe disablement. See n 157 above.

[172]First-Tier Tribunal Social Entitlement Chamber, 13 March 2020 (Judge Phillip Barber), para 25.

[173]Ibid, paras 24–25.

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previously noted from the decisions on the VICP, the absence of epidemiological evidence *in itself* is not fatal.[174] However, the Tribunal relied on the appellant's expert report which invoked an argument of molecular mimicry extrapolated from Pandemrix to Fluenz Tetra, in support of a biologically plausible mechanism in favour of establishing narcolepsy on a balance of probabilities.[175] Again, the invocation of such an argument is not unreasonable, provided it is supported by scientific evidence. In this case, however, the appellant's claim about molecular mimicry was not supported by any biological or epidemiological evidence. In the case of the proven increased risk of narcolepsy after Pandemrix, there is some evidence in support of molecular mimicry as a potential causal pathway.[176] Nevertheless, the molecular mimicry argument collapses when extrapolating it to Fluenz Tetra as the increased risk of narcolepsy was shown to be specific to Pandemrix and was not observed after vaccination with other pandemic vaccines containing the same H1N1 influenza antigen that was in Pandemrix (as well as in Fluenza Tetra). An association with other pandemic vaccines was looked for in epidemiological studies but was not found. Accordingly, while there is some evidence for the molecular mimicry argument, this appears to be specific to Pandemrix and possibly is related to the way the antigen was prepared for that particular vaccine or its co-administration with a powerful adjuvant that stimulates the immune system.[177] The Tribunal's ruling is flawed on several levels, all of which indicate it was not scientifically sound. General causation was not satisfied: there is no evidence that Fluenz Tetra can cause narcolepsy. The molecular mimicry argument is unsound as it is specific to Pandemrix. Secondly, on the specific causation issue, the Tribunal held that proof on a balance of probabilities was established by reference to the existence of a temporal sequence (ie vaccination then onset of narcolepsy within 3–4 months) and the absence of another 'trigger',[178] yet this has no probative value. At least one new case of narcolepsy occurs each year in every 100,000 children, and most have no obvious trigger.[179]

Since Fluenz Tetra is offered to all schoolchildren (under 13 years of age)[180] other temporally associated cases may arise in the future and this decision may well set an unhelpful precedent in increasing vaccine hesitancy.

(b) Covid-19 vaccines and the 1979 Act

The decision to extend the 1979 Act to those vaccinated against the Covid-19 virus is clearly correct. To have not done so could have had an effect on vaccine confidence by a failure to treat Covid-19 vaccines in the same way as other national vaccine programmes.[181] It is arguable that this has come at the expense of any attempt to address the need for changes to the scheme, particularly in the way the VDPS determines causation, which appears by no means clear or consistent,[182] and the Act's requirement of serious disability is a high hurdle to overcome. However, broader changes to the scheme would take time to agree and implement and there has been no appetite for such change from successive governments.[183] Nonetheless, the rollout of Covid-19 vaccines has now refocused

[174]See *Capizzano v Secretary of Health & Human Services*, above n 55, and further discussion in text to n 56.

[175]First-Tier Tribunal Social Entitlement Chamber, 13 March 2020 (Judge Phillip Barber), paras 24, 26, 34.

[176]See G Luo et al 'Autoimmunity to hypcretin and molecular mimicry to flu in type 1 narcolpesy' (2018) PNAS vol 115, no 52 E12323-E12332.

[177]Personal communication, Professor Elizabeth Miller, Department of Infectious Disease Epidemiology, London School of Hygiene & Tropical Medicine, 31 January 2021.

[178]First-Tier Tribunal Social Entitlement Chamber, 13 March 2020 (Judge Phillip Barber), para 24.

[179]European Medicines Agency 'European Medicines Agency reviews further data on narcolepsy and possible association with Pandemrix' (18 February 2011) https://www.ema.europa.eu/en/news/european-medicines-agency-reviews-further-data-narcolepsy-possible-association-pandemrix (accessed 16 February 2022).

[180]Public Health England *Guidance: Influenza Vaccines 2020–21 flu season* https://www.gov.uk/government/publications/influenza-vaccine-ovalbumin-content/influenza-vaccines-2020-to-2021-flu-season (accessed 3 February 2021).

[181]'Expansion of the Vaccine Damage Payments Scheme (VDPS) for Covid-19, IA No 9564, 2 December 2020, pp 2, 12.

[182]See above and Goldberg, above n 153, pp 174–176 (analysis of Vaccine Damage Tribunal Decisions in the years 1989–93).

[183]See *Hansard* HC Deb, 24 March 2015, col 461WH, Parliamentary Under-Secretary of State for Health (Jane Ellison).

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attention on this scheme, access to which will be important given the difficulties in establishing strict liability under the Consumer Protection Act 1987.[184] An impact assessment of the effect of adding Covid-19 to the list of specified diseases covered by the VDPS on the costs of business, the voluntary sector and the public sector estimated that total payments to the public could range from £0 in the scenario where there are no successful VDPS claims, between £3.2 million to £13.2 million in scenarios where there are successful claims from one round of vaccination and £63.2m in the scenario with future rounds of vaccination.[185] Given that VDPS is managing about 76 claims a year, claims are likely to increase to an estimated 230–670 per year, ie a three- to nine-fold increase in claims, even if ultimately none is successful.[186] As of 26 August 2021, 260 claims had been been received by the Vaccine Damage Payments Unit in respect of vaccination against Covid-19.[187] This will result in an increasing workload for the Vaccine Damage Payments Unit and will probably lead to large increases in administrative costs. In addition, increasing number of claims is likely to result in a corresponding increase in the number of appeals.[188]

Whilst it has been argued that a bespoke Covid-19 vaccines compensation system should be introduced in the UK,[189] it is submitted that there are no justifiable reasons for treating Covid-19 vaccines differently from any others. First, while there has been use of a rapid approval process resulting in temporary authorisations for the Covid-19 vaccines as opposed to the usual granting of a product licence for a vaccine, that has not compromised the safety of any of the vaccines to merit a distinction in treatment. As a result of a 'rolling review' of data, the Medicines and Health Products Regulatory Agency (MHRA) concluded, on the advice of the Commission on Human Medicines, that all three Covid-19 vaccines in use in the UK had sufficiently strong evidence of safety, quality and effectiveness from clinical trials to authorise their supply. Notwithstanding these approvals being rapid, the MHRA Chief Executive has confirmed that 'no corners have been cut':[190] temporary authorisations were only granted in the light of a 'rigorous scientific assessment of all the available evidence of quality, safety and effectiveness'.[191] Data now published from the MHRA have confirmed that the approved vaccines meet strict regulatory standards for safety.[192]

Secondly, the provision of an ad hoc preferential bespoke compensation scheme for Covid-19 vaccines, while other vaccines remain within the ambit of the VDPS, would create a hierarchy in the

[184]See A Heppinstall 'Covid-19, vaccines, Brexit and vaccine damage claims' (2020) 2 European Pharmaceutical Law Review 104, at 105. An attraction of the VDPS is that an appeal to the Tribunal is affordable; there is no cost risk and legal aid is preserved for such appeals, although the statutory charge applies in the event of success. Often the preferred method of funding is through a conditional fee arrangement, as costs tend to be less than when dealing with the Legal Aid Agency. However, pursuing a claim under the Consumer Protection Act against the manufacturer has costs of between £7–15 m to get to trial. Given these difficulties, it is unsurprising that there have been no vaccine cases under the CPA: personal communication, Peter Todd, Hodge Jones & Allen Solicitors, 25 January 2021.

[185]See IA No 9564, above n 181, pp 2, 12.

[186]Ibid, pp 13–14.

[187]FO12021/61679. This figure has been calculated from 1 February 2021: ibid.

[188]See IA No 9564, above n 181, p 14. This could range from 66 in the scenario where there are no successful VDPS claims to 628 in the scenario with future rounds of vaccination: ibid.

[189]D Fairgrieve et al 'In favour of a bespoke Covid-19 vaccines compensation scheme' (2021) The Lancet, 3 February, available at https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00065-7/fulltext; and further, Briefing paper on bespoke compensatory scheme for possible adverse effects caused by a Covid-19 vaccine, https://www.biicl.org/documents/10510_briefing_note_for_cv-19_vaccine_acceptability_-_11_nov_20_-_final.pdf. Cf the argument that countries with existing no-fault schemes could incorporate Covid-19 into their programmes, small countries can utilise the WHO insurance mechanism for vaccines deployed under emergency use authorisations and that the COVAX Facility, an international partnership ensuring access to vaccines for lower income countries, should have a procedure for compensating people in these countries who suffer a severe adverse event after immunisation.

[190]See https://www.gov.uk/government/news/june-raine-how-we-backed-a-covid-19-vaccine-before-rest-of-the-west (accessed 16 February 2022).

[191]See https://www.gov.uk/government/news/uk-medicines-regulator-gives-approval-for-first-uk-covid-19-vaccine (accessed 16 February 2022).

[192]See https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions (accessed 16 February 2022).

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importance of vaccines, which would undermine the effectiveness of the UK vaccination programme and, in so doing, generate vaccine hesitancy. Whilst the global size of the pandemic is unprecedented in modern times, Covid-19 will become a vaccine-preventable disease in the same way as the other 28 diseases for which vaccines are available.[193] From a fairness perspective, compensation for Covid-19 vaccines should be no different from compensation for measles or any other disease prescribed by the Secretary of State. The previously discussed US experience of the Swine Flu Act of 1976, which led to increasing governmental reluctance to assume financial risks with vaccination programs in the absence of scientific evidence of causation, is a salutary reminder of the dangers of an ad hoc overly preferential system directed to one set of vaccines. A much fairer proposal is for countries like the UK with existing no-fault schemes to incorporate Covid-19 into their programmes,[194] with any legislative improvements in these schemes applying to all covered vaccines. However, with its consistently low success rates, and the impact of the extension of the 1979 Act to those vaccinated against the Covid-19 virus still to emerge, especially in the case of children and young people aged 12–15,[195] the UK VDPS is clearly not fit for purpose and needs radical reform.

3. Reform: towards a revised national vaccine policy in the light of Covid-19

This paper favours the re-examination of the distribution of liability for vaccine-related injuries in both the US and UK within the context of a revised national vaccine policy in both countries.[196] The revised national vaccine policies must take into consideration their respective current and long-term national vaccine strategies to prepare for future pandemics. Improvements to both the US and UK schemes must be consistent with the following principles.[197] First, they must promote public health by incentivising innovation into the design of new vaccines. Secondly, a fair scheme of protection must be provided for those who suffer vaccine-related injuries, whilst also encouraging public confidence in vaccines through transparent decision-making, which is soundly based on scientific evidence.

(a) Reforms to VICP

In the US, as far as reforms to the VICP are concerned, it is submitted that any changes must be viewed in the light of the Biden Administration's Covid-19 vaccination strategy of January 2021. This strategy aims to ensure the availability of safe and effective coronavirus vaccines for the American public, as well to build public trust through a vaccination public health education

[193]See https://www.who.int/immunization/monitoring_surveillance/ (accessed 16 February 2022).

[194]WHO and COVAX are developing a no-fault compensation system for 92 low-income countries to individuals that suffer severe adverse events associated with Covid vaccines: see S Halabi et al 'No fault compensation for vaccine injury – the other side of equitable access to Covid-19 vaccines' (2020) 383 New England Journal of Medicine 23; F Guarascio 'Under pressure, WHO plans Covid-19 vaccine insurance scheme for poor nations' https://www.reuters.com/article/us-health-coronavirus-who-vaccines-idUKKBN27E2CM (accessed 16 February 2022).

[195]The UK Chief Medical Officers have recommended universal vaccination of children and young people aged 12–15 with the Pfizer-BioNTech Covid-19 vaccine on the grounds that the likely benefits of reducing educational disruption and a consequent reduction in public health harm from educational disruption on balance provide sufficient extra advantage, in addition to a marginal advantage at an individual level in this age group: see https://www.gov.uk/government/publications/universal-vaccination-of-children-and-young-people-aged-12-to-15-years-against-covid-19/universal-vaccination-of-children-and-young-people-aged-12-to-15-years-against-covid-19 (accessed 16 February 2022).

[196]See especially the arguments in favour of reform of vaccine liability within a holistic framework involving vaccination policy, espoused in Apolinsky and Van Detta, above n 25, at 537–538, 544, 620–622.

[197]Cf the broadly consistent guiding principles of reform to the US Vaccine Act suggested in E Parasidis 'Recalibrating vaccination laws' (2017) 97 Boston University Law Review 2153 at 2221. However, this paper departs from his proposals on restructuring the burden of proof for claims alleging off-Table Vaccine Related Injuries (cf ibid, at 2236–2239) in favour of defining rigorous criteria used to determine causation on a balance of probabilities.

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campaign.[198] Reforms must also take into consideration the long-term national vaccine strategy of the US to prepare for future pandemics. A national vaccine policy that adopts the overriding recommendation of Van Tassel et al that Congress should amend the PREP Act by requiring all vaccines recommended by the CDC to ameliorate a public health emergency to be immediately added to the VICP, regardless of whether they are recommended for pregnant women or children, is prima facie compelling.[199] However, this is likely to run up against powerful Congressional opposition, given the arguments of manufacturers in favour of the broad protection given by the PREP Act. As Kirkland has observed, the difficulty of getting anything though Congress, 'let alone small a relatively set of reforms'[200] to the vaccine court, remains a considerable obstacle. Inclusion of all such vaccines into the VICP might only be accepted by Congress with a further *quid pro quo* in favour of scientific rigour in determining causation. A concession that the programme should now define fair but rigorous criteria used to determine causation on a balance of probabilities to ensure public confidence in the science behind vaccination seems a necessary counterweight to the expansion of the VICP to cover pandemic vaccines.

(b) Reforms to VDPS

Any reforms to the UK scheme should be included in a revised national vaccine policy as a part of the Department of Health and Social Care's ongoing 10-year vaccination strategy,[201] including the long-term vaccine strategy to prepare the UK for future pandemics, established by the UK Government's Vaccine Task Force (VTF).[202] A UK-wide national vaccine programme, similar to that in the US, should be administered by the Secretary of State for Health and Social Care with the aim of optimal prevention of human infectious diseases through vaccination and immunisation and to achieve optimal prevention against adverse reactions to vaccines.[203] The director of the programme would be required to coordinate vaccine research and development, and coordinate direction for safety and efficacy testing of vaccines carried out through the MHRA.[204]

The programme should introduce a statutory requirement for the Secretary of State for Health and Social Care to review periodically, but least every three years, the current medical and scientific evidence on vaccines and vaccine adverse events by an expert advisory group of the Commission on Human Medicines (CHM).[205] The current VDPS should be reformulated as a Vaccine Damage Compensation Programme. A rigorous review of the current medical and scientific evidence on vaccines and vaccine adverse events by the CHM expert advisory group[206] will be needed, in order to generate a vaccine damage claims Table akin to that in the US under NVIA. All claims must be assessed in accordance with this evidence. Claims should continue to be brought in the Vaccine Damage Tribunal, but with specialist docketed tribunal judges appointed to deal with vaccine cases.

Learning from previous controversies, the programme must define stringent criteria to determine causation on a balance of probabilities.[207] This will reflect the need to give sufficient weight to

[198]National Strategy for the Covid-19 Response and Pandemic Preparedness (White House, January 2021) pp 8–11, 36–53 https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-Covid-19-Response-and-Pandemic-Preparedness.pdf (accessed 16 February 2022).

[199]Van Tassel et al, above n 126, e34(3).

[200]Kirkland, above n 38, p 207.

[201]E Rough House of Commons Briefing Paper, *UK Vaccination Policy*, Number CBP 9076, 21 January 2021 https://researchbriefings.files.parliament.uk/documents/CBP-9076/CBP-9076.pdf (accessed 16 February 2022).

[202]*UK Vaccine Taskforce 2020 Achievements and Future Strategy: End of Year Report* (Department of Business, Energy & Industrial Strategy, December 2020).

[203]Cf the existing US programme: 42 USCA §300aa-1.

[204]Cf 42 USCA §300aa-2.

[205]Cf Pub L 99–660, Title III, §312, Nov 14, 1986, 100 Stat, 3779 and §313, Nov 14, 1986, 100 Stat 3781.

[206]See Human Medicines Regulations 2012, SI 2012/1916, regs 9, 10.

[207]Offit 'Vaccines and autism revisited – the Hannah Poling case' (2008), above n 58, 2091. It is submitted that while policy choices statutorily adopted by vaccine damage schemes will influence how demanding causation rules should be, and

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scientific evidence, utilising hierarchies of evidence for vaccine injury. The presence of specialist tribunal judges will reflect the need for increased judicial expertise and training used in scientific evidence with the assistance of tribunal appointed experts (if necessary). It is submitted that greater clarity in the use of scientific evidence in determining causation should help to restore the public's confidence in the uptake of vaccines.

To balance the need for rigorous criteria to determine causation with a fair scheme, the programme should adopt the US practice of allowing negotiated settlements between the parties, where the Secretary of State for Health and Social Care's review of the evidence has not concluded that the vaccine(s) caused the alleged injury but where there are close calls concerning causation.[208] Secondly, more generous levels of compensation awards should be available. In the light of the range of severity of disablement, the current single lump sum approach should be abandoned, and damages should be awarded in accordance with the Judicial College Guidelines for the Assessment of General Damages in Personal Injury Cases to reflect the severity of disablement in each case.[209] Loss of future earnings as well as the costs of future medical care should also be available to claimants. While a right to claim compensation in the civil courts should be permitted, every claim must commence in the tribunal and any payment made by the tribunal should continue to be treated as a payment on account and deducted from any future award.[210] To generate increased confidence and transparency, all decisions on whether to award compensation or not should be published with any necessary redactions, including the reasons for the award and demonstrate clear communication on any issues of scientific evidence.

Conclusion

This paper has attempted to reappraise the vaccine compensation schemes currently available in the US and UK in the light of the Covid-19 pandemic.

Despite controversies concerning the perception of an adversarial environment, due to the heavy onus on petitioners to show that a covered vaccine caused the injury when there are no associated injuries on the Table, there is much to be said for the success of the US VICP. In particular, the vaccine court has helped to uphold the 'immunization social order' through its gatekeeping mission of keeping lawsuits out of the tort system, its role as both an audience and an engine for scientific evidence, and its expression of society's ethical obligations to injured vaccinees.[211]

This paper supports the view that giving epidemiological evidence appropriate weight, along with the other evidence of the record, has reduced the dangers of elevating lower ranking hierarchical evidence of biologically plausible mechanisms to connect vaccines to adverse events over published contrary epidemiological studies. For the continued effectiveness of the VICP, it must be seen to be part of a national vaccine policy that encourages public confidence in vaccines through transparent decision-making, while being soundly based on scientific evidence.

specifically how they address the scenario where aetiology is merely *plausible*, the need for 'defined boundaries and proof on the balance of probabilities' should remain at the heart of any scheme: S Todd 'Treatment injury in New Zealand' (2011) 86 Chicago-Kent Law Review 1169, at 1196 (discussing modifications to the ordinary principles of causation in the context of treatment injury claims under the New Zealand Accident Compensation Act 2001, s 32(1)(b); claims for injuries resulting from vaccines are classified as treatment claims). Cf the criticism that the threshold for causation under the Accident Compensation Act 2001 is contingent on changes in the policy choices or practices adopted by the New Zealand Accident Compensation Corporation in its assessment and application of the causation test: W Foster et al *Solving the Problem: Causation, Transparency and Access to Justice in New Zealand's Personal Injury System* (NZ Law Foundation, 2017) ch 3, https://www.lawfoundation.org.nz/wp-content/uploads/2017/05/Solving-the-Problem-Public-Report-22.May_.2017.pdf (accessed 16 February 2022) (advocating a statutory definition of the causation test in line with lay understanding).

[208]Cf the US Vaccine Court decision in *Althen v Secretary of Health & Human Services* 418 F 3d 1274, 1280 (Fed Cir 2005).

[209]*Judicial College Guidelines for the Assessment of General Damages in Personal Injury Cases* (Oxford University Press, 15th edn, 2019).

[210]Cf Vaccine Damage Payments Act 1979, s 6(4).

[211]Kirkland, above n 38, pp 202–207.

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The controversial role of the PREP Act, offering 'targeted liability protection'[212] to the manufacturers of drugs, vaccines and medical devices used in declared public health emergencies, was examined. The decision to place Covid-19 vaccine claims for compensation within the CICP has been highly criticised, given the broad immunity and limitations on compensation established by the PREP Act. Despite the legitimate argument of manufacturers in favour of broad protection, given the expectation of government and the public that manufacturers develop and manufacture such vaccines as quickly as possible, the arguments in favour of inclusion of coronavirus vaccines in the VICP (especially the societal benefits through individual vaccination) are strong.

The enacting of the Vaccine Damage Payments Act 1979 in the UK to restore the public's confidence in its vaccination programme has revealed a contrasting claims experience under the VDPS to that of the US VICP. Success rates are extremely low. By far the majority of claims to the VDPS have been disallowed on the basis that the vaccination did not cause the disability and determination of causation continues to be a major source of difficulty in Tribunal appeals. The decision to extend the 1979 Act to those vaccinated against the Covid-19 virus is clearly correct on vaccine confidence grounds. However, this has come at the expense of any attempt to address the need for changes to the scheme, particularly in the way the VDPS determines causation, which appears by no means clear or consistent.

It has been argued that any improvements to the UK VDPS should be included in a revised national vaccine policy as a part of the Department of Health and Social Care's ongoing 10-year vaccination strategy. Again, as with the US scheme, this policy must promote public health by incentivising innovation into the design of new vaccines, whilst encouraging public confidence in vaccines through transparent decision-making based soundly on scientific evidence. A UK-wide National Vaccine Injury Compensation Programme, similar to that which exists in the US, should be administered by the Secretary of State for Health and Social Care. Learning from previous vaccine controversies over causation, the programme must define rigorous criteria to determine causation on a balance of probabilities. To balance the need for these rigorous criteria with the need for fairness, the programme should adopt the US practice of allowing negotiated settlements between the parties, where the Secretary of State for Health and Social Care's review of the evidence has not concluded that the vaccine(s) caused the alleged injury but where there are nonetheless close calls concerning causation.

Including these improvements to both the UK and US schemes within their revised national vaccine policies will help to create long-term vaccine strategies to prepare for future pandemics and other illnesses, from the research, development, manufacture and distribution of vaccines through to liability and compensation for those injured by them. In so doing, such changes should help to restore public confidence in the uptake of vaccines, which has been seen as a crucial tool in reducing the threat of vaccine hesitancy.

[212]Public Readiness and Emergency Preparedness Act, 42 USC §247d-6d.

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