

# THE VACCINE DAMAGE PAYMENT SCHEME: A PROPOSAL FOR RADICAL REFORM

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*In this article, Stephanie Pywell outlines the intended and actual operation of the Vaccine Damage Payments Act 1979, and proposes an alternative statutory scheme based on the United States' Vaccine Injury Compensation Program.*

## Background

Vaccination and vaccine damage are topics ignored by most academic lawyers. Medical lawyers thrive on fascinating but rare events such as conjoined twins and the compulsory sterilisation of incompetents, yet rarely consider the biological agents which are injected into virtually all the babies and young children in this country. Social security lawyers are apparently almost oblivious to the State's response when vaccines cause damage: two major articles were published in the U.K. when pertussis (whooping cough) vaccine was causing concern<sup>1</sup>, and *J.S.S.L.*'s last article on this topic appeared five years ago<sup>2</sup>. This article seeks to bring readers up-to-date with the nature and operation of the Vaccine Damage Payment Scheme (V.D.P. Scheme), and offers a critical view of some aspects of its operation.

In theory, there are two routes to financial recompense for the victims of vaccine damage: they can claim under the V.D.P. Scheme, and/or bring claims before the civil courts. The common law route has never led to a successful claim in England or Wales, principally because of the outcome in *Loveday v Renton*<sup>3</sup>, when Stuart-Smith L.J. declared that the claimant had failed to establish, on the balance of probabilities, that pertussis vaccine could cause brain damage in young children<sup>4</sup>. Litigation has begun on behalf of several hundred children who claim to have been damaged by measles-mumps-rubella (MMR) vaccine. Their action is founded on the Consumer Protection Act 1987, under which a

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<sup>1</sup> Dworkin, G. Compensation and Payments for Vaccine Damage. (1978/9) *Journal of Social Welfare Law*, 330 – 336. Lee, R G. Vaccine damage: adjudicating scientific dispute. In Howells, G G (Ed). *Product Liability: Insurance and the Pharmaceutical Industry: An Anglo-American Comparison*. 1991, Barry Rose.

<sup>2</sup> Goldberg, R. Vaccine Damage and Causation – Social and Legal Implications. (1996) 3 *J.S.S.L.*, 100 – 120.

<sup>3</sup> [1990] 1 Med.L.R. 117. The case is discussed further below.

<sup>4</sup> At present a multi-party action is being prepared on behalf of over one thousand children whose parents believe they have been injured by measles-mumps-rubella (MMR) vaccine. Three administrative hearings have been held in the last two years, but the case is not yet close to a full hearing.

“defect”<sup>5</sup> has been generously interpreted by the High Court<sup>6</sup>. To date, several case management hearings have been held, but no date has been set for a full hearing. The only proven route to redress for people damaged by vaccines is therefore the V.D.P. Scheme.

This article outlines the criteria for awards under the V.D.P. Scheme, and examines how each criterion applies in practice. An outline of the appeals procedure is included, and there is research-based analysis of trends in the numbers of awards made. There is a brief critique of some of the medical literature pertaining to vaccine damage. The conclusion is that the V.D.P. Scheme is failing to fulfil the purpose for which it was designed, and a proposal is made to replace it with a system modelled on the USA’s Vaccine Injury Compensation Program.

## The Vaccine Damage Payments Scheme

The V.D.P. Scheme was introduced by the Vaccine Damage Payments Act 1979 (the 1979 Act)<sup>7</sup> as part of the Government’s response to *The Pearson Report*<sup>8</sup>. Section 1 of the 1979 Act provides for a single payment, currently £100,000<sup>9</sup>, to anyone who can prove that she was at least 80 per cent<sup>10</sup> disabled by any prescribed vaccine<sup>11</sup>. The time limit for

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<sup>5</sup> S2 of the Consumer Protection Act provides strict liability in respect of damage, personal injury or death caused by defective products, and s3 defines a “defect” as existing when “the safety of the product is not such as persons generally are entitled to expect...”.

<sup>6</sup> See, eg:

Worsley v Tambrands Ltd (1999), QBD, judgment obtained from Lawtel Document No C9500498.  
Abouzaid v Mothercare (UK) Ltd (2000), CA, judgment obtained from Lawtel Document No C0100475.  
Richardson v LRC Products Ltd (2000), QBD, transcript obtained from Smith Bernal Reporting Limited via Lawtel.

A and Others v The National Blood Authority and Others [2001] 3 All ER 289.

<sup>7</sup> 1979 c. 17.

<sup>8</sup> Great Britain: Royal Commission on Civil Liability and Compensation for Personal Injury 1978. *Report of the Royal Commission on Civil Liability and Compensation for Personal Injury. Chairman Lord Pearson*. London: H.M.S.O. (Cmnd 7054).

<sup>9</sup> The original statutory sum was £10,000. It rose by £10,000 increments to keep pace with inflation, and was increased to £40,000 in 1998. Its increase to £100,000 was announced in the House of Commons on 27 June 2000, and was effected on 22 July 2000 by S.I. 2000/1983. Top-up awards, to bring total awards up to the contemporaneous equivalent of £100,000, have been made to 864 recipients of awards, including over 100 payments to the next-of-kin in cases where the vaccine-damaged person has died.

<sup>10</sup> S1(4) of the 1979 Act. It was announced in the House of Commons on 27 June 2000 that the threshold is to be lowered to 60%. This will be enacted via a Regulatory Reform Order, which is provided for in the Regulatory Reform act which received the Royal Assent on 10 April 2001. A consultation paper about the changes, *Amending the Vaccine Damage Payments Act 1979*, was issued by the Department for Work and Pensions in July 2001; responses were sought by 15 October 2001.

<sup>11</sup> The prescribed vaccines are those recommended by the Department of Health for routine administration to all babies and children.

bringing a claim is six years from the later of the date of administration of the vaccine and the claimant's second birthday<sup>12</sup>.

The V.D.P. Scheme is administered on behalf of the Secretary of State for Work and Pensions by the Vaccine Damage Payments Unit (V.D.P. Unit), which advises claimants whether an award is to be made. Such decisions are based solely upon assessments of claims by SEMA Group, a medical agency sub-contracted to the Department of Work and Pensions, which determines the cause and extent of claimants' disabilities<sup>13</sup>.

S4 of the 1979 Act provides that appeals against these decisions may be made to a Vaccine Damage Appeal Tribunal (V.D.A.T.) on questions of both fact and law<sup>14</sup>. Each V.D.A.T. is chaired by a legally-qualified employee of the Tribunals Service, assisted by a medically qualified person<sup>15</sup>. The selection process is careful because V.D.A.T.s deal with complex, sensitive and often emotive matters. The medical member is therefore in practice a consultant paediatrician or neurologist; until 18 October 1999 there was usually one paediatrician and one neurologist<sup>16</sup>. There is no time limit within which an appeal to a V.D.A.T. must be lodged<sup>17</sup>. This contrasts favourably with the one-month time limit for appeals for other benefit decisions.

There is currently no appeal from the decision of a V.D.A.T., although s45 of the Social Security Act 1998 provides that the Secretary of State may reverse decisions made by a V.D.A.T. or by himself<sup>18</sup>. Applications for such reversals must be made in writing, and must explain why the claimant believes the decision to be wrong. The time limits for applications to the Secretary of State are six years for V.D.A.T. decisions, and two years for previous decisions made by the Secretary of State. The Secretary of State must inform

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<sup>12</sup> S3(1) of the 1979 Act. It was announced in the House of Commons on 27 June 2000 that the limitation period is to be extended to include any time until the claimant's 21st birthday. This will be enacted via a Regulatory Reform Order, which is provided for in the Regulatory Reform act which received the Royal Assent on 10 April 2001. A consultation paper about the changes, *Amending the Vaccine Damage Payments Act 1979*, was issued by the Department for Work and Pensions in July 2001; responses were sought by 15 October 2001.

<sup>13</sup> Personal communication with V.D.P. Unit, 13 January 2000.

<sup>14</sup> This procedure was introduced by the Social Security and Child Support (Decisions and Appeals) Regulations, SI 1999/991, made under ss 46 – 47 of the Social Security Act 1998 (1998 c 14). These took effect from 18 October 1999. Until that date, Vaccine Damage Tribunals heard applications on points of law only under s4(2) of the Vaccine Damage Payments Act 1979. These Regulations brought questions of fact within the jurisdiction of the Tribunals, thus giving them the same range of powers as all other Social Security and Child Benefit Tribunals.

<sup>15</sup> SI Reg 1999/991, Reg 36(2).

<sup>16</sup> Personal communication with Appeals Service on 13 January 2000.

<sup>17</sup> SI 1999/991, Reg 31.

<sup>18</sup> S45 *Social Security Act 1998*.

claimants in writing of his decisions and the reasons for them, and may also reverse a decision on his own initiative<sup>19</sup>. There is no appeal to a court except via judicial review.

Awards made under the V.D.P. Scheme are not clawed back via income-related benefits provided that the money is held in a trust fund. Awards may, however, be taken into account if compensation for vaccine damage is awarded by a court<sup>20</sup>.

### **Decision-Making Under the V.D.P. Scheme**

Each claimant's disability is quantified, to determine whether it meets or exceeds the 80 per cent threshold, in accordance with s103 of the Social Security Contributions and Benefits Act 1992<sup>21</sup>. It proved extremely difficult to ascertain how this is applied to children, as staff at both the Department of Health and the Department of Social Security, as it then was, were unaware of any published guidance. Staff at the D.S.S. Policy Unit responsible for the administration of the V.D.P. Scheme were unaware of the method of assessing the extent of injuries, but stated that assessments were rarely carried out because "most cases fail on causation"<sup>22</sup>. There are no Government-issued guidelines on assessing vaccine damage. The document currently used by SEMA Group to determine the extent of disability is taken from the July 1995 *Severe Disablement Allowance: Handbook for Adjudicating Medical Authorities*<sup>23</sup>. Appendix 1 of this document<sup>24</sup> details various physical conditions such as loss of limb, giving a percentage disablement for each. Appendix 5.f, entitled *Mental impairment – 'Learning difficulties'*, describes a range of psychological conditions but expressly declines to offer guidance as to what constitutes 80 per cent disablement. This contrasts strongly with the clear guidelines offered for physical disablement. Appendices 5.g and 5.h to the same document deal respectively with cerebral palsy and epilepsy. They describe the symptoms and effects of these conditions, but do not give guidance as to what constitutes 80 per cent disablement in either case.

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<sup>19</sup> SI 1999/2677, Regs 11 and 12.

<sup>20</sup> Hansard, 2000. *Delegated Legislation Committee Debates. Fifth Standing Committee on Delegated Legislation*. 18 July 2000 (Internet: no Volume number).

<sup>21</sup> S1(4) (as amended) Vaccine Damage Payments Act 1979.

<sup>22</sup> Personal telephone communication, D.S.S. Policy Unit, 7 March 2000.

<sup>23</sup> Full reference not available; photocopies of various appendices sent with personal communication from V.D.P. Unit dated 19 January 2000. It has been stated in Parliament that the Handbook is published by SEMA Medical Services, and is approved by the Department of Social Security's Chief Medical Adviser (Source: personal communication from Department of Social Security, 8 August 2000).

<sup>24</sup> The Appendix is taken from Schedule 2 to the General Benefit Regulations 1982, SI 1982/1408.

A document<sup>25</sup> supplied by the Policy Unit of the D.S.S. responsible for the administration of the V.D.P. Scheme includes a section headed “[t]est of severity of disablement”. This involves comparing the individual with a person of the same age and sex whose physical and mental condition is normal. Examples are given of what would constitute 80 per cent physical disablement, which are “easily described by a doctor who has been given the special training required to make such assessments .... [T]he same applies to certain types of mental disablement”, of which some examples are given; “all can be reasonably assessed by a doctor specially trained in making such assessments”. Claims involving mentally disordered individuals usually include a Griffith’s Assessment for Special Educational Needs from which “can be extrapolated an assessment as to the actual performance of a person when considered with the age of the person”.

The next section is entitled “[m]ethod of assessment”. It states that the method of assessing disablement is the same as that for War Pensions and Industrial Injuries Schemes, and acknowledges the difficulty of applying schemes designed for physical disabilities in adults to developmental delays in children. The section concludes by stating that doctors “have to use clinical judgment in deciding whether the total percentage disablement is more or less than the sum of its component parts”.

The available evidence therefore suggests that the assessment of the extent of mental disabilities caused by suspected vaccine damage is based upon individual clinical judgment, rather than quantifiable criteria. If the assessing doctors are specially trained to assess psychological disorders in children, their professional judgment is likely, based upon other areas of mental health law, to be deemed as objective science. If they are not so trained, however – and the document does not actually state whether this is the case – these arrangements may be vulnerable to legal challenge under the *Human Rights Act 1998*<sup>26</sup>.

The statement that “most cases fail on causation” indicates the major difficulty facing claimants under the V.D.P. Scheme. This issue was discussed when the Vaccine Damage Payments Bill was being debated. The proposal for the test of causation was described thus:

“... the balance of probabilities .... and of course the balance must be swung in favour rather than against ... We shall look very sympathetically on all the cases”<sup>27</sup>.

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<sup>25</sup> This anonymous and undated word-processed document is entitled *Vaccine Damage Payments Act 1979*. It was received in March 2000. All the quotations in this and the next paragraph are taken from the third and fourth pages of this document [the pages are not numbered].

<sup>26</sup> 1998 c. 42. Article 6 of the E.C.H.R., which is incorporated into English law by the *Human Rights Act* provides for the right to a fair trial. It might be invoked here, as it expressly includes the “determination of ... civil rights”.

<sup>27</sup> Hansard, 1979. *Parliamentary Debates (House of Commons)*. Vol. 949, Col. 981.

“... the balance of probability ...this will entail looking at each case as a whole, taking into account the medical history and the current condition of the disabled person. In some cases there is a clear record of vaccination, closely followed by febrile convulsions, and evidence of brain damage within a week or so. In such a case, unless there is some compelling evidence of another cause, the claim will clearly be accepted”<sup>28</sup>.

The statutory wording is simply “[i]f ... the Secretary of State is satisfied that ...”<sup>29</sup>.

Staff at the D.S.S. Policy Unit responsible for the administration of the V.D.P. Scheme were unaware of the medical questions used to determine causation, but knew that the standard of proof was the balance of probabilities<sup>30</sup>. The criteria currently used to determine causation are contained in a document published by SEMA Group<sup>31</sup>. The document uses standard headings for medical causation – close temporal proximity, biological plausibility, and so on, but its whole tenor is against attributing causation in all but the most clear-cut circumstances. The last section is entitled “Issues Relating to the Individual Case” which, given that all claims are assessed individually, seems likely to be determinative of whether an award will be made.

Causation requires, *inter alia*, acceptance by informed medical opinion of a possible link. The main reference work used is *Adverse Events Associated with Childhood Vaccines*<sup>32</sup>, whose authors were not required to report on pertussis, diphtheria-tetanus-pertussis or measles-mumps-rubella vaccines<sup>33</sup>, those which have caused most public concern. It is stated that SEMA doctors “also carry out regular electronic searches of published medical research papers. The majority of such research in the past three years has been published in *Lancet*”<sup>34</sup>. The current state of research is such that the evidence for most postulated links between vaccines and injuries is insufficient to accept or reject a causal relationship, so it is inevitable that claims based on such injuries will fail.

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<sup>28</sup> Hansard, 1979. *Parliamentary Debates (House of Commons)*. Vol. 962, Col. 35.

<sup>29</sup> S1(1) Vaccine Damage Payments Act 1979.

<sup>30</sup> Personal telephone communication, D.S.S. Policy Unit, 7 March 2000.

<sup>31</sup> SEMA Group, 1999. *Procedural Guidance on Processing Referrals for Advice on Vaccine Damage Claims: Causation*. This title is taken from a word-processed front sheet deposited in the House of Commons Derby Gate Library on 18 July 2000 following a Parliamentary Question tabled at my request by the Rt. Hon. Peter Lilley M.P. Previous information from the Vaccine Damage Payments Unit suggests that the title of the whole document is *Vaccine Damage Payments Scheme – Protocol for Medical Guidance*. Both sources supplied the same photocopied extract – Section 4 – of the document, which appears to be an internal document published only by SEMA Group.

<sup>32</sup> Stratton, K, Howe, C and Johnston, R (Eds), 1994. *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. Washington DC: National Academy Press.

<sup>33</sup> *Ibid*, Preface.

<sup>34</sup> Personal communication from Department of Social Security, 8 August 2000. The same communication provided the information about the main source of information used by SEMA.

## Awards Under the V.D.P. Scheme

This section reports the outcomes of claims under the V.D.P. Scheme using both data from the V.D.P. Unit and information from parents who believe their children to be vaccine-damaged<sup>35</sup>.

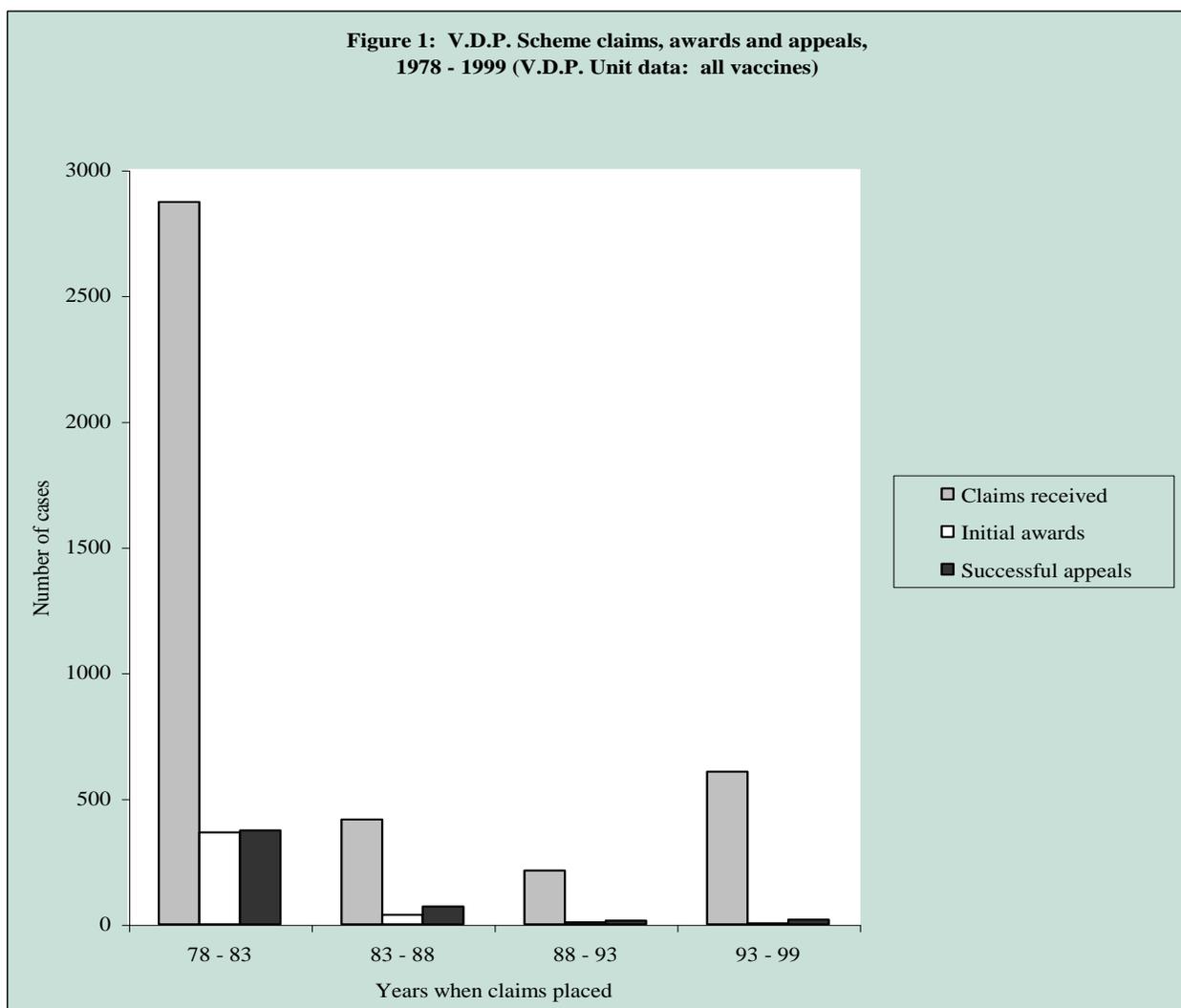
Figure 1 depicts data from the V.D.P. Unit. The V.D.P. Unit stated that there are no records of which vaccines are suspected of causing the damage which leads to claims and awards<sup>36</sup>. In 1981, however, such data appeared to be available: Sir George Young MP reported in Parliament that 2,081 of the 2,705 claims then received by the V.D.P. Unit involved pertussis vaccine<sup>37</sup>. The data given here relate to all vaccines.

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<sup>35</sup> As part of the research for a PhD I sent questionnaires to over 1,000 members of Justice Awareness Basic Support, (JABS), a vaccine support and information group. 360 usable responses were received. Those used here were from parents who had placed claims under the V.D.P. Scheme. They have been analysed using other data from the same questionnaires in order to indicate possible patterns in success rates.

<sup>36</sup> Personal communication from V.D.P. Unit, 7 December 1999.

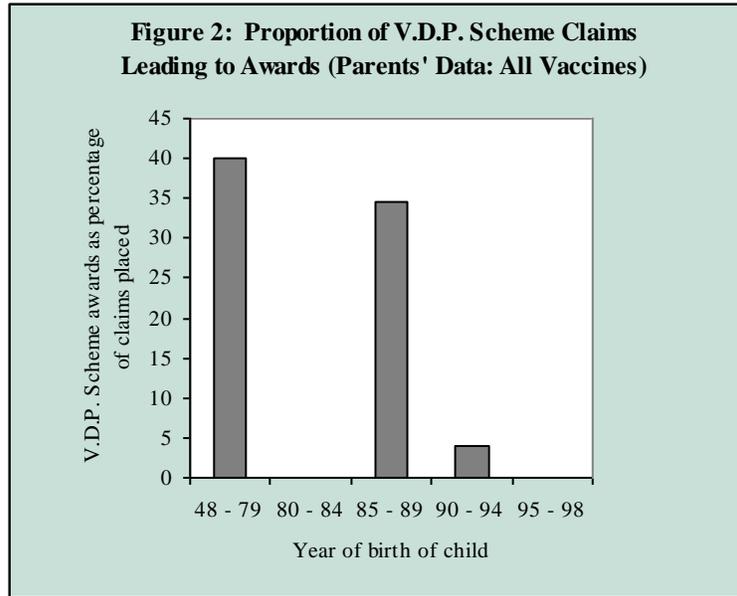
<sup>37</sup> Hansard, 1981. *Parliamentary Debates (House of Commons)*. Vol. 5, Cols 255 – 257.



As would be expected, the great majority of claims were received in the first five years of the Scheme's operation, when there would have been a backlog of cases. It is apparent from Figure 1 that very few awards have been made since 1988. Detailed data from the V.D.P. Unit show that for the 10-year period from April 1989 to March 1999 there were only 44 awards, of which 32 were made after appeals. 895 awards were made from 1979 to 1999, 95% of them in the first 52% of time.

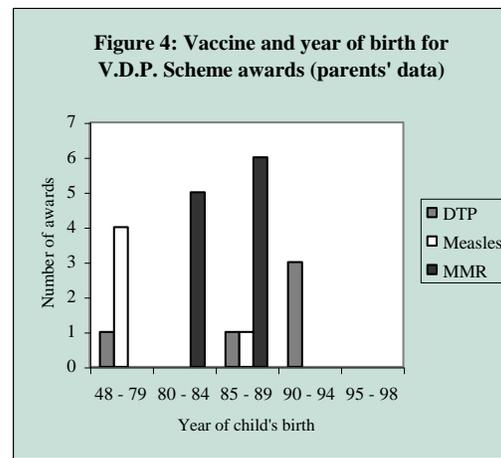
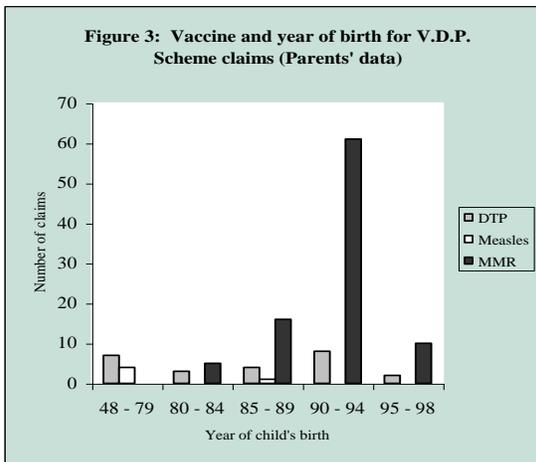
The V.D.P. Unit data is classified by the financial year when claims were received and awards made, with no reference to when the claimants were born. This data was, however, available from parents, and the success rates of claims for children born before 1979 and in each subsequent five-year period are plotted in Figure 2.

The most striking feature in Figure 2 is the almost total lack of awards made in respect of



children born since 1990. There is no obvious reason for the failure to make any awards in respect of the 15 children born between in 1980 – 84, or the 14 born in 1995 – 98, on whose behalf claims were submitted.

Parents' data also revealed differences in patterns of claims and awards for different vaccines. These are depicted in Figures 3 and 4 respectively.



The scales on the vertical axes of these figures – the one for claims (Fig 3) is calibrated in units ten times the size of that for awards (Fig 4) – confirm that very small percentages of

claims are met. The success rate does, however, vary for different vaccines. The precise percentages for each vaccine, for all years, are as follows:

Diphtheria-tetanus-pertussis (DTP)	21 per cent	(five awards from 24 claims)
Measles	100 per cent	(five awards from five claims)
MMR	6 per cent	(six awards from 93 claims).

There are notable time trends, too:

There has been no award for any child born in or since 1995.  
There is a total of three awards (from 69 claims) for children born in 1990 – 94.  
No MMR claim for any child born in or since 1989 has led to an award; the vaccine came into general use in 1988.

Another finding from parents' responses was that no award had ever been made to a child in respect of a vaccine administered only in the 1990s – the compound diphtheria-tetanus-pertussis-Hib, Hib itself or measles-rubella, although 20 claims were placed.

If justice is being done, therefore, vaccines are now much safer than they previously were, and the most recently-introduced vaccines are so safe that it is not necessary to have any means of offering financial recompense in respect of their unintended adverse effects. An extensive, though not exhaustive, search of medical literature revealed no studies which support this suggestion: the scientific evidence about vaccine safety is at best inconclusive, and at worst non-existent, depending upon the vaccine. This assertion is supported by the two most comprehensive meta-analytical studies of vaccine safety ever carried out<sup>38</sup>. Both studies were carried out for the US Institute of Medicine, both lament the absence of systematic investigations and both note that further research is urgently required. The decade since the publication of the first study has not yielded a single study, either purportedly confirming or denying vaccine safety, which has not been subject to serious and apparently justified criticism. Most papers in the current debate concern MMR vaccine, about which scientists remain bitterly divided; their vituperative comments on others' studies indicate a factional dispute, rather than a mutual quest for truth.

## **Vaccine Safety Data**

The spatial constraints of a journal make it impossible here to report and evaluate the conflicting scientific studies about vaccine safety. What follows is a brief overview;

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<sup>38</sup> Howson, C, Howe, C and Fineberg, H (Eds), 1991. *Adverse Effects of Pertussis and Rubella Vaccines*. Washington DC: National Academy Press. Stratton, K, Howe, C and Johnston, R (Eds), 1994. *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. Washington DC: National Academy Press.

much more detailed information is contained in the PhD thesis for which my research was conducted<sup>39</sup>.

Most concern about the safety of DTP vaccine centres on its pertussis component. The best matched-pairs vaccine safety study ever carried out, the National Childhood Encephalopathy Study<sup>40</sup>, examined the case histories of children satisfying certain criteria who were admitted to hospital with acute neurological illness between July 1976 and June 1979. The Study found that encephalopathy which occasionally resulted in permanent brain damage or death occurred more often than would happen by chance in children who had suffered the onset of neurological symptoms within seven days of pertussis vaccination. In an unusually proactive judicial intervention, however, Stuart-Smith L.J. ordered discovery of some of the individual medical records and subsequently adjusted the tables to eliminate the effect of certain cases which appeared to have caused errors. His Lordship concluded that the published results were erroneous, and that the study did not reveal any meaningful additional risk attributable to pertussis vaccine<sup>41</sup>. The scientists' interpretation of the study therefore cast doubts upon the absolute safety of DTP vaccine, although Stuart-Smith L.J. held that the claimant had failed to prove on the balance of probability that the vaccine could cause brain damage in young children. Although the common law claim failed, official acknowledgement of the subsisting doubts about the safety of pertussis vaccine are reflected in the making of some awards to children claiming to have been damaged by it.

It has always been accepted, too, that monovalent measles vaccine can cause some unintended adverse effects, principally febrile convulsions that sometimes cause permanent brain damage. This is implicit in the paper reporting the MMR safety studies conducted in North Hertfordshire, Fife and Somerset in 1987<sup>42</sup>. This official acceptance of the vaccine's potential dangers is reflected by the finding that all the five respondents who placed V.D.P. Scheme claims placed in respect of it received awards.

The MMR safety study mentioned in the preceding paragraph is the only comparative safety investigation reported in a considerable volume of medical literature. The study compared parental reports of reactions following the administration of either monovalent

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<sup>39</sup> Pywell, S, 2001. *Compensation for Vaccine Damage*. Unpublished PhD thesis. University of Hertfordshire.

<sup>40</sup> Alderslade, R *et al*, 1981. *The National Childhood Encephalopathy Study. Whooping Cough; Reports from the Committee on Safety of Medicines and the Joint Committee on Vaccination and Immunisation*. London: HMSO.

<sup>41</sup> Loveday v Renton [1988] *The Times*, 31 March. LEXIS transcript, 106 – 107. It has been argued that His Lordship's conclusion is "debatable" because the outcome of the amended figures – a relative risk of 2.5 with a confidence interval of 0.67 – 10.94 – is greater than two, which is statistically significant evidence of a causal link. See Goldberg, R, 1999. *Causation and Risk in the Law of Torts: Scientific Evidence and Medicinal Product Liability*. Oxford: Hart Publishing, 139.

<sup>42</sup> Miller, C *et al*, 1989. Surveillance of symptoms following MMR vaccine in children. *The Practitioner*, 233, 69 – 73. This article is the source of all the information in this paragraph.

measles vaccine or MMR to children under five years of age. Reactions to MMR vaccine were similar in nature to, but usually greater in frequency than, reactions following monovalent measles vaccine, with the exception of a similar rate of convulsions between the sixth and 11th days after vaccination. This last finding is the only one reported in the Department of Health's widely-circulated "Memorandum" to healthcare professionals about vaccination<sup>43</sup>; the other findings, where MMR appears to be associated with a greater incidence of damage than monovalent measles vaccine, have been, in current parlance, "buried".

Widespread public alarm about the safety of MMR vaccine followed extensive press coverage of a self-identified "Early Report" by Dr Andrew Wakefield and others which reported an apparent association between the vaccine, a new paediatric bowel syndrome and autistic symptoms in children<sup>44</sup>. The official response to this study, issued one month after its publication, followed a specially-convened meeting of 37 experts. The conclusion was that "[b]ased on the views of the experts at the M.R.C. [Medical Research Council] meeting, and on previous material ... there is no link between measles, measles vaccine or MMR immunisation and either Crohn's disease or autism ...no evidence was presented to suggest that MMR vaccination gives rise to autism"<sup>45</sup>. It has been pointed out that one outcome of the meeting was that the Medicines Control Agency set up a working party to investigate links between autism and MMR vaccine, suggesting official doubts beneath the public confidence<sup>46</sup>. One of the 37 experts at the meeting, Dr Ken Aitken, publicly announced in September 1999 that he had "changed [his] view somewhat". Dr Aitken accepted US studies linking MMR vaccine with Heller's syndrome, an autistic spectrum disorder, and therefore believed that a small number of children may have been adversely affected by the vaccine. He nonetheless urged parents to continue to accept MMR for their children, as did the Department of Health<sup>47</sup>.

More recently, Dr Aitken has publicly voiced doubts about the validity of a Finnish study whose results have been widely used by public health physicians affirming the safety of MMR vaccine<sup>48</sup>. The study lasted for 14 years, and involved three million doses of vaccine. There was no evidence of either lasting bowel disorders or autistic spectrum disorders in any of 31 patients who had exhibited severe gastrointestinal symptoms

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<sup>43</sup> Great Britain: Department of Health, Welsh Office, Scottish Office Department of Health and DHSS Northern Ireland, 1996. Salisbury, D M and Begg, N T (Eds). *1996 Immunisation Against Infectious Disease*. London: HMSO.

<sup>44</sup> Wakefield, A J *et al*, 1998. Ileal-lymphoid nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *Lancet*, 351, 637 – 641.

<sup>45</sup> Department of Health, 1998. *MMR vaccine is not linked to Crohn's disease or autism*. Press Release 98/109. Obtained from <http://www.doh.gov.uk>, 2 April 1998.

<sup>46</sup> Hansard, 1999. *Parliamentary Debates (House of Lords)*. 11 January 1999, Col 56.

<sup>47</sup> Hall, C, 1999. New fear over autism link to triple vaccine. *The Daily Telegraph*, 8 September.

<sup>48</sup> Steele, L, 2001. 'It is not about the science. It's about belief.' *The Guardian*, 5 December.

within three weeks of receiving the vaccine<sup>49</sup>. The study has been criticised for investigating the wrong hypothesis, on the grounds that the appropriate patients to study would have been those who initially presented with behavioural changes, not acute gastrointestinal symptoms<sup>50</sup>. Another problem is that the onset of symptoms of diseases such as autism and bowel disorders is “typically insidious and usually first observed outside the time frame of these safety studies”<sup>51</sup>. Dr Aitken’s concern is that the study does not acknowledge the fourfold rise in autism in Finland identified in other studies<sup>52</sup>.

The paper published by Patja *et al* (2000) makes assertions in its “Results” and “Discussion” sections which are not clearly justified by its reported methods. The detail is beyond the scope of this paper, but they include the fact that the study design was based upon a voluntary “passive” reporting system. Such systems are known to lead to gross under-estimates of incidences of adverse reactions to pharmaceuticals. The level of reporting may be as low as 5 – 6.3% of all suspected adverse reactions to vaccines<sup>53</sup>. Another major flaw in the project is that the first symptoms of regressive autism are minor, so would not have fallen within the reporting criteria of the study. There is an average of 4.42 years between a parent’s initial concern about a child’s condition and a diagnosis of autism<sup>54</sup>. Although no temporal limit was imposed in the study, reporting occurred via two-part forms, the second part of which was submitted three weeks after the first. This makes it most unlikely that diseases with insidious onset would have been identified. Despite these shortcomings, Dr Elizabeth Miller<sup>55</sup> has been quoted as saying “cases of autism in association with bowel disease would certainly have been detected” by this study<sup>56</sup>.

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<sup>49</sup> Peltola, H *et al*, 1998. No evidence for measles, mumps and rubella vaccine-associated inflammatory bowel disease or autism in a 14-year prospective study. *Lancet*, 351, 1327 – 1328. Patja, A *et al*, 2000. Serious adverse events after measles–mumps–rubella vaccination during a fourteen-year prospective follow-up. *The Pediatric Infectious Disease Journal*, 19 (12), 1127 – 1134.

<sup>50</sup> Wakefield, A J, 2000. *Testimony before Congressional Oversight Committee on Autism and Immunisation*. April 2000. Allergy-Induced Autism, 1999. Summary of Study. In JABS, 2000. *Newsletter*, 13, 5.

<sup>51</sup> Wakefield, A J and Montgomery, S M, 2000. Measles, mumps, rubella vaccine: Through a glass, darkly. *Adverse Drug Reactions and Toxicological Reviews*, 19(4), 265 – 283 at 278.

<sup>52</sup> Kielinen, M, Linna, S-I and Moilanen, I, 2000. Autism in Northern Finland. *European Child and Adolescent Psychiatry*, 9, 162 – 167 at 165 – 166.

<sup>52</sup> See, eg,

Hansard, 1999. *Parliamentary Debates (House of Lords)*. 11 January 1999, Col 58.

Not certain, not severe, not noteworthy? Under-reporting of adverse drug reactions. Study published in *Brit J Clin Pharmacol*, 1996,42, 423, abstracted in West Midlands Centre for Adverse Drug Reactions Reporting 1996. *re:ACTION*, No. 11. Obtained from [www.chtpharm.demon.co.uk](http://www.chtpharm.demon.co.uk), 31 July 2000.

<sup>54</sup> Howlin, P and Moore, A, 1997. Diagnosis in Autism. *Autism*, 1 (2), 135 – 162 at 147.

<sup>55</sup> Head of the Immunisation Division at the Public Health Laboratory Service.

<sup>56</sup> Boseley, S, 2001. Stop stifling debate, critics warn government. *The Guardian*, 24 January.

It has not been widely reported that the study was funded by Merck and Co, USA, which distributed all except 2,570 of the doses of vaccine given during the project. It is unclear whether the funding source influenced the research design, which has been criticised above, but independently funded research would have greater credibility. Experience in the tobacco industry suggests that research funded by interested parties should be treated with caution<sup>57</sup>.

The most public example of the political controversy underlying the current scientific debate is Dr Wakefield's agreement to leave his post at the Royal Free Hospital because his research was "no longer in line with the Department of Medicine's research strategy"<sup>58</sup>. Dr Wakefield was quoted as expressing the hope that his departure would "take the political pressure off [his] colleagues"<sup>59</sup>, indicating in the clearest terms that the doubts his work has cast upon the safety of MMR vaccine are deeply unpopular in official circles.

It is impossible at present to determine from published papers whether MMR vaccine causes autistic spectrum or bowel disorders, and if so, how frequently. What is certain is that the vaccine will sometimes cause some adverse effects in some recipients, purely because it is a pharmaceutical product. What is also certain is that there is an unprecedented level of stated official belief in the absolute safety of the vaccine despite obvious scientific doubt. This belief is reflected in the outcome of V.D.P. Scheme claims in respect of MMR vaccine which compares unfavourably with those for DTP and monovalent measles vaccine. There is some evidence, as discussed above, that MMR is liable to cause more damage than measles vaccine; there is no published work which suggests that it is safer. The dearth of awards in respect of MMR vaccine, which is now given to almost all toddlers, is therefore inexplicable.

### **Reasons for the Rejection of V.D.P. Scheme Claims**

Against this background of scientific uncertainty, it is unsurprising that the principal reason why V.D.P. Scheme claims fail is the claimant's inability to establish causation – in my research this was a stated reason for rejection in 52 per cent (57 out of 130) of cases. The next most common reason was failure to meet the 80 per cent disability threshold, which accounted for 30 per cent (39 out of 130) of cases<sup>60</sup>. These empirical

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<sup>57</sup> Ong, E K and Glantz, S A, 2000. Tobacco Industry efforts subverting International Agency for Research on Cancer's second-hand smoke study. *Lancet*, 355, 1253 – 59. This article revealed that the tobacco company Philip Morris had allocated \$6 million to ostensibly neutral scientific studies refuting earlier findings that passive smoking was dangerous.

<sup>58</sup> Meikle, J, 2001. Doctor who linked jab to autism quits. *The Guardian*. 3 December.

<sup>59</sup> *Ibid.*

<sup>60</sup> Pywell, S, 2001. *Compensation for Vaccine Damage*, unpublished PhD thesis, University of Hertfordshire. The number of stated reasons for the rejection of claims is greater than the number of rejected claims because survey respondents were invited to select as many reasons as applied in respect of each rejection.

findings suggest that the above concerns about the operation of the V.D.P. Scheme relate to issues which are problematic for claimants.

Ostensibly, therefore, most V.D.P. Scheme claims fail because there is insufficient evidence that vaccines have caused the threshold level of harm. As indicated above, the supporting science is seriously flawed, but scrutiny of *Hansard* suggests that there might be other reasons for the battening of fiscal hatches which has now taken place.

In 1978, when the V.D.P. Scheme was being debated, 700 was suggested as the likely number of awards which would be made<sup>61</sup>. At that time, pre-school children were routinely vaccinated only against DTP, polio and measles. For the whole period 1948 – 1999 there were 895 awards, despite the introduction of MMR in 1988, Hib in 1992 and the measles-rubella campaign in 1994.

The closeness of the estimated figure and the total number of awards is remarkable. It is most unlikely that Parliamentarians in 1978 were aware of how many new vaccines would be introduced over the ensuing 20 years, yet 700 seems to have been a total estimate for “this and succeeding financial years”. Even if this was a future projection based upon cases believed to exist at the time of the debate, it is difficult to imagine that it included possible future damage caused by undiscovered antigens.

£60M has been allocated to fund the recent legislative changes<sup>62</sup>. A mid-range top-up payment of £63,000 for each of the 895 recipients of previous awards would have cost £56,385,000. Additional incapacity benefits for these people are also being made available: assuming none of them had received it previously, this would cost £1,242,618 per year. This would leave finance available for 24 new awards, which seems likely to last for several years at the current rate of awards. It was, however, recently confirmed in Parliament that payments to V.D.P. Scheme claimants meeting the revised criteria will be made, regardless of the number of future awards<sup>63</sup>. This indicates that there is no overall financial limit applicable to the revised V.D.P. Scheme.

Whatever the explanation, it is reasonable to conclude that the V.D.P. Scheme is currently failing to make an appreciable number of awards, despite the increased number of vaccines in routine use and heightened public concern about vaccine safety. It therefore seems that a fundamental reform of the system is required, and a possible basis for a new statutory system is the USA’s Vaccine Injury Compensation Program (V.I.C.P.).

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<sup>61</sup> Hansard, 1978. *Parliamentary Debates (House of Commons)*. Vol. 949, Col. 975.

<sup>62</sup> Hansard, 2000. *Parliamentary Debates (House of Commons)*. 27 June 2000, Cols 719 – 727 (Internet: no Volume number). The changes are described above in Notes 6, 7 and 9.

<sup>63</sup> Hansard, 2000. *House of Commons Written Answers*. 18 July 2000, Col. 115W (Internet: no Volume number). The answer was given by the Minister of State for Social Security in response to a question tabled at my request by The Rt. Hon. Peter Lilley M.P.

## The Vaccine Injury Compensation Program

In the United States some childhood vaccines are compulsory, and unvaccinated children may be refused state-funded education. This is not the case in Britain, where vaccines are merely encouraged. The vaccine schedules differ in the two jurisdictions: the US aims for immunological perfection, whereas the UK minimises the number of visits to vaccination clinics. Hib, diphtheria, tetanus and MMR are routinely given in both regimes.

Inactivated polio and acellular pertussis vaccine are generally administered in the US, whereas their live counterparts are given in the UK. Meningococcal C is now routinely given in the UK but not US; the reverse is true of Hepatitis B and chicken pox<sup>64</sup>. Overall, therefore, children receive similar quantities of similar vaccines, with the United States eschewing two live vaccines because they are believed to cause harm to some recipients.

The V.I.C.P. was introduced in October 1988 to offer a mechanism for compensating vaccine victims. Its official policy goals are to provide an accessible forum for vaccine damage claims, to ensure vaccine supply and to stabilise vaccine costs. An important constraint of the Program is that no-one is allowed to file a civil lawsuit in respect of damage due to any vaccine covered by the V.I.C.P. unless she has first claimed under the Program and either the petition has been judged non-compensable or the petitioner has rejected the award offered. The V.I.C.P. has almost eliminated civil lawsuits for vaccine damage: there have been fewer than 20 such claims across the whole of the U.S.A. in each year since 1990, compared with 255 in 1986.

The V.I.C.P. is funded by a trust comprising tax levies on vaccine manufacturers<sup>65</sup>. The rate is \$0.75 per antigen, so divalent vaccines are now taxed at \$1.50, and trivalent vaccines, such as MMR, at \$2.25.

Because it is funded by levy, the V.I.C.P. has a permanent source of income from which to pay awards. This avoids any of the possible financial problems, speculated on in the previous section, which may arise because the V.D.P. Scheme is funded from the general Social Security budget. Levy funding also fosters the morally satisfying feeling that the burden of vaccine damage lies with its benefit – vaccines are hugely profitable for pharmaceutical manufacturers. One potential problem with introducing such funding in the U.K., however, is that pharmaceutical companies would be tempted to increase vaccine charges to cover the cost of the levies. If this happened, the cost would be borne by the N.H.S., so the ultimate loser would be the tax-payer. The preferred option would

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<sup>64</sup> Full details of vaccine schedules in the two jurisdictions are given in Pywell, S, 2001. Vaccination. In Martin, R and Johnson, L (Eds), 2001. *Law and the Public Dimension of Health*. London: Cavendish Publishing Limited.

<sup>65</sup> USA, 1996. *Background Information on VICP*. Health Resources and Services Administration. Last updated 17 July 1996, 2. Obtained from <http://bhpr.hrsa.gov/vicp>. This website is the source of all the information in this V.I.C.P. information in this section.

therefore be for levies to be introduced accompanied by price regulation so that the financial liability was actually paid from pharmaceutical manufacturers' profits.

The V.I.C.P. causative criteria are that the petitioner suffered either an injury listed in the Vaccine Injury Table, or injuries which she "can demonstrate" were caused or aggravated by the vaccine. The latter categories of injury are harder to prove. The Table is regularly reviewed by the U.S. Institute of Medicine to reflect the latest validated research into vaccine safety, and it specifies which injuries occurring within which time intervals after each vaccine will be presumed to have been caused by the vaccine. This statutory "presumption of causation" is close to what was intended to happen under the V.D.P. Scheme, as the above extracts from Hansard show<sup>66</sup>. Such generosity is morally appropriate, given the consensus among public health officials and writers that the primary purpose of vaccination is to eliminate infectious diseases from society, rather than to protect individuals vaccinees against them<sup>67</sup>. Overall the percentage of claims adjudicated as compensable under the Program is 31 per cent, which is fifty per cent higher than the comparable rate under the V.D.P. Scheme. Altogether, 62 per cent of adjudicated claims have resulted in awards, although about half of these have been for attorneys' fees only<sup>68</sup>. It is likely that the V.I.C.P.'s more generous causative criteria account for the higher success rates amongst American victims of vaccine damage, since the only Table injuries attributable to vaccines not used in the UK are anaphylaxis or anaphylactic shock and any sequelae following hepatitis B or inactivated polio vaccine<sup>69</sup>.

Awards for deaths under the V.I.C.P. are limited to \$250,000, plus attorney's fees and costs. Awards for injuries range from \$120 to \$9.1 million, with averages of over \$1 million for awards made in 2000 and 2001. Awards are usually used to purchase an annuity which will pay out considerably more than this amount over the claimant's lifetime. Awards such as these are realistic for serious injuries, so they remove the need for successful claimants to go to court. By contrast, the V.D.P. Scheme's award of £100,000 is a fraction of what a claimant would expect to receive from a civil court<sup>70</sup>.

The Canadian judge Osler J remarked in *Rothwell v Raes*<sup>71</sup> that the courts constitute an inappropriate forum for resolving claims of vaccine damage because the basic issue which fell to be determined was a matter of scientific fact. His Honour remarked that "the

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<sup>66</sup> See Notes 25 and 26.

<sup>67</sup> See, eg, Nokes, D J and Anderson, R M, 1991. Vaccine safety versus vaccine efficacy in mass immunisation programmes. *Lancet*, 338, 1309 – 1312.

<sup>68</sup> Data obtained from <http://bhpr.hrsa.gov/vicp/monthly.htm>, 16 July 2001.

<sup>69</sup> Vaccine Injury Table obtained from <http://bhpr.hrsa.gov/vicp/table.htm>, 10 July 2001.

<sup>70</sup> The amount awarded by a court in cases of serious brain damage with symptoms comparable to those believed to have been caused by vaccines is approximately £2,000,000. See further Pywell, S, 2000. A Critical Review of the Recent and Impending Changes to the Law of Statutory Compensation for Vaccine Damage. *JPLI*, 4/00, 246 – 256, especially pp 254 – 5.

<sup>71</sup> (1989) 54 DLR (4th) 193 at 354.

strain of a long trial, the disappointment of a long waiting period, the disappointment of an unsuccessful outcome” added to the burden already borne by the claimants, and that the expense and time of the litigation constituted a “staggering cost”. If the U.K.’s statutory system were reformed so as to offer compensation rather than a token fixed payment, the costs and stress of civil litigation for vaccine damage could be avoided.

The procedure for processing a claim under the V.I.C.P. is relatively quick and straightforward. Claims are filed at the U.S. Court of Federal Claims, and are reviewed by a physician from the Division of Vaccine Injury Compensation at the Department of Health and Human Services. The physician’s non-binding report is provided to the Department of Justice, which forwards it to the Court. A special “master” appointed by the judges of the Court then makes an initial ruling, usually after a hearing lasting only one or two days. Appeals lie to the Court of Federal Claims, then to the Federal Circuit Court of Appeals and then to the Supreme Court. This contrasts with the V.D.P. Scheme procedure described above, whereby claims are received by a clerical agency of the Government, reviewed by a medical agency whose report determines whether an initial award is made, appealed to a Tribunal and ultimately determined by the Secretary of State for Work and Pensions. Given that the Secretary of State is ultimately responsible to the Treasury for the budget from which awards are made, this procedure seems unlikely to meet the natural justice requirement that no-one should be a judge in his own cause. It may therefore infringe Article 6 of the European Convention on Human Rights, which enshrines the right to a fair trial; it certainly exposes the Secretary of State to a potentially powerful fiscal influence over his decision-making. The fact that the whole appeals procedure is within the jurisdiction of the Secretary of State also gives greater scope for officially-denied practices such as tightening of causative criteria within a system which lies entirely outside the scrutiny of the court system.

## **Conclusion**

Although in theory there are two routes to financial recompense for people who appear to have been injured by vaccines in the U.K., neither system is working satisfactorily. Civil compensation for damage apparently caused by whooping cough vaccine has been effectively denied by the decision in *Loveday v Renton*, and the claim for damage attributed by parents to measles-mumps-rubella vaccine has yet to reach court.

The statutory Vaccine Damage Payment Scheme no longer achieves the objectives for which it was set up, for reasons which are not clear. The U.S. statutory Vaccine Injury Compensation Program is demonstrably more successful, and provides realistic levels of compensation to people injured, or apparently injured, by vaccines.

Since vaccines are administered principally for the good of society as a whole, it is morally important that those injured by their adverse effects should have an accessible means of obtaining adequate compensation. A system modelled on the V.I.C.P. and funded by vaccine levies would be workable, relatively simple to introduce and cheap to administer. The public money saved from the Legal Services Commission’s budget – the

current 1,000-plus claimants are being publicly funded, and there is a generic certificate to fund the necessary medical research – would be much better spent on large-scale, prospective, epidemiological investigations into alleged links between vaccines and damage, and on compensating those whose health has been damaged in the public interest.