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RATIONALIZING VACCINE INJURY COMPENSATION

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ABSTRACT

Legislation recently adopted by the United States Congress provides producers of pandemic vaccines with near-total immunity from civil lawsuits without making individuals injured by those vaccines eligible for compensation through the Vaccine Injury Compensation Program. The unusual decision not to provide an alternative mechanism for compensation is indicative of a broader problem of inconsistency in the American approach to vaccine-injury compensation policy. Compensation policies have tended to reflect political pressures and economic considerations more than any cognizable set of principles. This article identifies a set of ethical principles bearing on the circumstances in which vaccine injuries should be compensated, both inside and outside public health emergencies. A series of possible bases for compensation rules, some grounded in utilitarianism and some nonconsequentialist, are discussed and evaluated. Principles of fairness and reasonableness are found to constitute the strongest bases. An ethically defensible compensation policy grounded in these principles would make a compensation fund available to all individuals with severe injuries and to individuals with less-severe injuries whenever the vaccination was required by law or professional duty.

In November 2005, President Bush outlined a national preparedness strategy for a pandemic influenza outbreak.[1] The plan called on Congress to pass liability protection for vaccine manufacturers, in order to 'remove one of the greatest obstacles to domestic vaccine production.'[2] Subsequently adopted legislation has given producers of pandemic vaccines near-total immunity from civil lawsuits for vaccine-related injuries.[3] Providing such immunity has ample historical precedent, but an extraordinary feature of the recent legislation is that it contains no alternative provision for compensating individuals injured by covered vaccines.

This omission – which sets pandemic countermeasure vaccinees apart from all other persons with

[1] United States Homeland Security Council. 2005. *National Strategy for Pandemic Influenza*. Available at: http://www.whitehouse.gov/homeland/pandemic-influenza.html. [accessed 16 February 2006]

[2] White House. 2005. *Fact Sheet: Safeguarding America Against Pandemic Influenza*. Available at: http://www.whitehouse.gov/news/releases/2005/11/20051101.html. [accessed 10 November 2005]

[3] Public Readiness and Emergency Preparedness Act, P.L. 109–148, 119 Stat. 2680. 109th Congress, 1st Session, 2005.

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vaccine-related injuries – has ignited objections in the US[4] and highlighted broader questions about the rationality and consistency of the American approach to vaccine-injury compensation. Policies in this area reflect political pressures and economic considerations more than any cognizable set of principles. Because the issue is likely to recur as new disease threats emerge, it is timely to consider what a less *ad hoc* policy for vaccine injury compensation grounded in principles of public health ethics might look like.

This article identifies a set of morally relevant principles that could guide decisions about the circumstances in which vaccine injuries should be compensated, both inside and outside public health emergencies. The concept of what constitutes adequate compensation for a given injury is not straightforward,[5] but that issue is distinct from the question of the circumstances under which compensation ought to be offered, and is beyond the scope of the article. For the purposes of this discussion, 'compensation' can be defined as restitution in the amount of past and expected future economic losses (such as lost income and medical expenses), perhaps supplemented by an amount given in consideration of the injured person's pain and suffering.

CURRENT PROVISIONS FOR VACCINE INJURY COMPENSATION

For many vaccines, persons who believe they have a vaccine-related injury may file a tort lawsuit against the manufacturer. Such claims are usually heard by state courts and based on state-law doctrines of product liability. Plaintiffs may allege that the vaccine was defectively manufactured or defectively designed (unreasonably unsafe), or that the manufacturer failed adequately to warn of the risks. Claims that reach trial are generally decided by a jury.

This process is problematic for both claimants and vaccine makers. From the claimant's perspective, litigation is adversarial, protracted, uncertain, and requires that an attorney agree to take the case, which may pose a considerable obstacle for claimants with low earnings or fairly minor injuries. Tort doctrine in most states sets the liability standard for vaccines and other drugs relatively high, making it difficult for plaintiffs to prevail on design-defect claims. Vaccine manufacturers dislike tort because of the uncertainty involved in allowing juries to determine injury causation and damages awards. Even if catastrophically large awards rarely occur, the threat of them weighs heavily on manufacturers and their insurers.[6]

Historically, when vaccine makers have objected that tort liability makes vaccines too risky to manufacture, the government has responded by creating an alternative legal remedy.[7] In 1976, the federal government banned lawsuits against swine flu vaccine manufacturers and assumed liability for vaccine-related injuries, and in 1986, Congress created the Vaccine Injury Compensation Program (VICP). The VICP provides no-fault, administrative compensation for adverse effects that have been scientifically established as linked to covered vaccines. Vaccinees can file a lawsuit only after going through the VICP, and special rules make those suits difficult to win. Originally limited to vaccines recommended by the Centers for Disease Control and Prevention for routine administration to children, the VICP has recently been expanded to cover smallpox vaccine and trivalent influenza vaccine, including injuries to adults.

While the addition of influenza reflected concerns that manufacturers might be unwilling to make the vaccine, the addition of smallpox stemmed from the need to encourage vaccination. In December 2002, the Bush Administration announced a plan for voluntary smallpox vaccination of 500,000 health care workers as part of bioterrorism preparedness. Physicians and nurses, who were aware of the vaccine's

[4] N. Pelosi, S. Hoyer, R. Menendez R, et al. 2005. *Letter from Nancy Pelosi and House Democrats to President George W. Bush*. 7 October 2005. Available at: http://www.housedemocrats.gov/news/librarydetail.cfm?library_content_id=553. [accessed 16 February 2006]; D. Henderson. Bush Flu Plan Eases Firms' Liability. *Boston Globe*. 8 November 2005: D1.

[5] B.R. Boxhill. 1982. Consent and Compensation. In: *Compensating for Research Injuries, Volume Two*. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research. Washington: President's Commission: 41–55.

[6] M.M. Mello & T.A. Brennan. Legal concerns and the influenza vaccine shortage. *JAMA* 2005; 294(14): 1817–1820.

[7] Ibid.

risks,[8] balked; after six months, only 7 per cent of the targeted group had volunteered.[9] Among their concerns was that the plan made inadequate provision for compensating vaccinees who experienced adverse effects.

The Homeland Security Act had, in fact, created a legal remedy: although vaccinees could not sue a smallpox vaccine manufacturer, they could sue the federal government.[10] In some states, workers' compensation programs would also provide limited compensation. This 'incomplete and confusing patchwork' of remedies failed to lead to widespread uptake of vaccination,[11] however, so the government added smallpox vaccine to the VICP in 2003.[12]

The history of vaccine injury compensation has been that when the government closes a door, it opens a window. Legal protection for vaccine manufacturers is coupled with an administrative remedy for vaccinees. The alternative remedy is not always provided in a timely fashion, however. For smallpox vaccine, it was not created until it became clear that the voluntary vaccination strategy was failing without it.

The smallpox story raises the question whether an approach to pandemic preparedness that begins with the presumption of no compensation could risk delay in achieving needed rates of vaccination. Because this presumption was present in the recent legislation, it is timely to consider its defensibility. To be sure, smallpox and pandemic flu present different challenges because of differences in the perceived imminence of the threat and the known risks of vaccination. But both should lead us to ask: On what basis, and in what circumstances, ought compensation be available for vaccine-related injuries? In particular, when is the government ethically obliged to assume responsibility for providing compensation?

RATIONALES FOR GOVERNMENT COMPENSATION

At first, pandemics and other public health emergencies may seem to present a weaker case for government compensation of injuries than routine vaccinations. It might be argued that emergencies are special; ordinary presuppositions about fairness and compensation find little applicability in a context in which urgency and necessity govern the choice of policy interventions. Moreover, providing compensation for all of the inevitable adverse effects of emergencies could severely encumber public budgets at a time when they are already straining under the burden of responding to vast social needs.

This is not, however, a view the US has consistently taken towards the victims of emergencies. Families affected by September 11, Hurricane Katrina, and other disasters have had access to large government compensation funds. A pandemic infectious disease could present disaster on a much larger and more costly scale, but the point stands that our approach to emergencies is not generally to ask those who are injured to bear the full costs.

If it is justifiable to think about vaccinations inside and outside the context of emergencies similarly, then there are a number of arguments in favour of providing government compensation for vaccine-related injuries under various other conditions. Some arguments are utilitarian, pointing to social benefits that outweigh the costs of compensation. Others are nonconsequentialist, grounded in notions of fairness and other deontological principles.

VACCINATION AS A COLLECTIVE-ACTION PROBLEM

Underpinning many of the arguments for compensation is the concept that under some circumstances, vaccination presents a collective-action problem. Collective-action problems arise where there is an

[8] C.G. Casey, et al. Adverse Events Associated With Smallpox Vaccination in the United States, January-October 2003. *JAMA* 2005; 294(21): 2734–2743.

[9] W.K. Yih et al. Attitudes of Healthcare Workers in US Hospitals Regarding Smallpox Vaccination. *BMC Pub Health* 2003; 3: 20.

[10] Centers for Disease Control and Prevention. 2006. *Smallpox Program Implementation: Liability Issues*. Available at: http://www.bt.cdc.gov/agent/smallpox/vaccination/vaccination-program-qa.asp?type=cat&cat=Smallpox+Program+Implementation&subCat1=Liability+Issues. [accessed 16 February 2006]

[11] A. Baciu et al. eds. 2005. *The Smallpox Vaccination Program: Public Health in an Age of Terrorism*. Washington: National Academies Press.

[12] *Smallpox Emergency Personnel Protection Act of 2003*, P.L. 108–20, 117 Stat. 638 (April 30, 2003), codified at 42 USC 239.

outcome that makes all members of a group better off, but which they cannot achieve because they cannot agree on how to share the costs or cannot enforce that all members share the cost. The canonical collective-action problem is the 'free-rider problem' wherein the group would be better off if all cooperated toward production of a social good, but many members do not cooperate because they believe they can get away with enjoying the benefits of the good without contributing toward its cost. In the context of vaccination programs, the relevant public good is herd immunity against the disease.

Individuals benefit from vaccination both by gaining disease immunity themselves and through herd immunity. The optimal situation for an individual is generally that enough people participate in a vaccination scheme to achieve a sufficient level of herd immunity that the individual's risk of catching the disease will be very low, but the individual himself opts out of vaccination, avoiding the risk of a vaccine injury. If enough people decline vaccination, however, herd immunity will be insufficient. In this 'volunteer dilemma,' the individually rational decision, if chosen by enough individuals, leads to the worst outcome for all. The volunteer dilemma is a special kind of free-rider problem in which free-riding is encouraged only when most people are not free-riding.

The payoff matrix associated with getting preemptively vaccinated for a potentially pandemic disease varies with the risk of contracting the disease, as well as the risk associated with vaccination.[13] When the risk of disease is high, either because there is a high risk of an outbreak or because the disease is highly transmissible, the collective-action problem dissipates. When the risk is low (especially relative to the risk of vaccine injury), there will be little incentive for people to volunteer for vaccination if they believe most other people will volunteer. This insight has implications for vaccine injury compensation. It should also be noted that pandemic vaccines present special difficulties in calculating a payoff matrix because the risks of new vaccines are not initially clear.

[13] C.T. Bauch, A.P. Galvani & D.J. Earn. Group Interest Versus Self-Interest in Smallpox Vaccination Policy. *Proc Natl Acad Sci U S A* 2003; 100(18): 10564–10567.

UTILITARIAN ARGUMENTS FOR VACCINE INJURY COMPENSATION

Encouraging voluntary vaccination

The primary motivation for offering compensation for smallpox-vaccine-related injuries was to encourage first responders to submit to voluntary vaccination. Encouraging parents to seek early childhood vaccinations was also one of the motivations for creating the VICP (vaccinations are not required until children enter school). The operating assumption here is that some individuals will be willing to undergo vaccination if they know that compensation for resulting injuries is easily obtainable through an administrative program, but not if the only remedy is to file a lawsuit, or if there is no remedy at all.

If compensation programs really are effective in boosting vaccination rates, they could conceivably preclude the need for mandatory vaccination laws. They would constitute a less restrictive alternative to coercive laws, which is desirable according to principles of public health ethics and law. This will only be the case, however, if voluntary programs with compensation are as effective as coercion (or nearly so).

At present, there is little evidence to support the assumption that easy availability of compensation increases willingness to undergo vaccination. News reports[14] and commentaries[15] have emphasized the possible role that compensation concerns played in decisions regarding smallpox vaccination, and the advocacy of several health care worker unions and professional organizations was influential in putting such concerns on the policy agenda.[16] The issue, however, has never been comprehensively studied. Small survey studies[17] have concluded that compensation concerns were not a significant predictor of physicians' willingness to receive smallpox vaccination. Rather, unwillingness to receive the vaccine

[14] V. Kemper. Smallpox Vaccinations Falter Over Compensation. *Chicago Tribune*. 6 February 2003: N16.

[15] D.J. Kuhles and D.M. Ackman. The Federal Smallpox Vaccination Program: Where Do We Go From Here? *Health Aff* 2003; Suppl. Web Exclusives: W3-503-10.

[16] Baciu et al., *op. cit.* note 11.

[17] A.L. Benin et al. Reasons Physicians Accepted or Declined Smallpox Vaccine, February Through April, 2003. *J Gen Intern Med* 2004; 19(1): 85–89; Yih et al., *op. cit.* note 9.

appears to hinge largely on the perception that the risk of disease outbreak was extremely low.[18]

If these findings are generalizable, then an offer of compensation alone is unlikely to be effective in substantially boosting voluntary vaccination rates. It is possible, though, that these findings may not generalize to a scenario in which the risk of an outbreak is perceived to be appreciable. It may be that a perception of near-zero risk is sufficient to turn people against vaccination but when the perceived risk is higher, people may weigh a range of factors in making their decision. On the other hand, it is also possible that public mention of the availability of compensation could discourage vaccination by highlighting the safety risks associated with it.

Encouraging vaccine production

An alternative rationale for vaccine injury compensation programs – the one that most strongly drove the creation of the VICP – is to respond to vaccine manufacturers' objections that tort liability costs make vaccines too expensive to produce. There is a strong social need to maintain an adequate number of vaccine suppliers. Companies may be especially reluctant to produce new vaccines against a threatening pandemic because time pressure may mean less opportunity to test the vaccine fully and, therefore, greater risk of injury.[19] Alternatively, companies may produce vaccines but price them very high to cover their expected liability costs (a socially undesirable outcome).

Such concerns may argue for eliminating manufacturer liability but they do not squarely address the question of whether injured vaccinees should have access to compensation. Manufacturers could be relieved of liability with or without the creation of an alternative compensation mechanism. As long as they are not subject to liability, there is no reason to think that their willingness to make vaccines is increased by the presence of a government compensation fund. In fact, manufacturers might prefer it if the VICP did not exist, since the scheme is funded through a vaccine tax, which raises the price of their products.

Overall, utilitarian arguments provide a weaker foundation for government compensation of vaccine injuries than is frequently assumed. More persuasive are several nonconsequentialist principles.

NONCONSEQUENTIALIST ARGUMENTS FOR COMPENSATION

Fairness to persons subject to coercion

It is a well-accepted principle of public health law and ethics that the government may exercise its coercive powers to restrict individual liberty in ways that are reasonably calculated to achieve public health goals. Accompanying the exercise of coercive power, however, should be measures to promote fairness to individuals who are burdened by it. One such measure is to provide due process before a person is deprived of liberty or property; another is to require that the government select the least restrictive intervention that will achieve its public health objective.

Arguably, a third measure should be to require that individuals who are harmed by the exercise of coercive power (such as through mandatory vaccination) be offered restitution, to the extent that the government can reasonably provide it. Such a policy would follow from the same impulse that leads us to prefer the least restrictive alternative: the notion that we should take whatever steps are practically available to minimize the intrusion on the individual. If it is not possible to lighten the burden of the intervention itself (for example, by making vaccination voluntary rather than mandatory or developing a vaccine that presents little or no risk of injury), we can at least mitigate the collateral harm that results from the intervention for an unlucky few. This harm consists of the physical suffering of a vaccine-related adverse event and the economic loss (lost income, medical expenses, and other costs) that result from it. The physical suffering cannot be prevented but the secondary losses that flow from it can be recompensed.

[18] Benin et al., *op. cit.* note 17; N. Kwon. et al. Emergency Physicians' Perspectives on Smallpox Vaccination. *Acad Emerg Med* 2003; 10(6): 599–605; R.J. Blendon at al. The Public and the Smallpox Threat. *N Engl J Med* 2003; 348(5): 426–432; P.M. Wortley et al. Healthcare Workers Who Elected Not to Receive Smallpox Vaccination. *Am J Prev Med* 2006; 30(3): 258–265.

[19] Testimony of Michael O. Leavitt before the Energy and Commerce Committee of the US House of Representatives, Hearing on Pandemic Flu Preparedness, 8 Nov 2005.

Although fairness to persons subject to mandatory vaccination did not drive the creation of the VICP, it is frequently cited as an *ex post* justification for the program. Commentators describe the VICP as a means of caring for children who are injured as a result of mandatory school entry vaccinations.[20] The coercion argument also has considerable moral force and resonates strongly with American political ideology, with its emphasis on individual autonomy.

Nevertheless, it might be pointed out that the government generally does not, in fact, offer compensation to individuals who have been deprived of liberty due to an exercise of public health powers; it usually offers only procedural protections against wrongful deprivations. But arguably, the burdens associated with vaccination requirements are special: they go beyond dignitary harms and economic losses to actual physical injury; severe consequences will occur with statistical certainty; and the victims are often children, the elderly, or other vulnerable persons. Consequently, this form of coercion should be viewed as particularly ethically problematic, triggering fairness concerns. This would suggest that vaccine injuries – at least severe injuries – ought to be compensated whenever the vaccination was mandatory.

Fairness to persons with professional obligations

Another strand of fairness argument for vaccine injury compensation relates to the professional obligations of health workers. Longstanding principles of medical ethics emphasize physicians' and nurses' duty to treat patients in need, even if it endangers their own health. While some ethicists have argued that the duty to treat diminishes as risk increases,[21] others argue that in the context of a threatening epidemic, a sliding scale of professional obligation cannot be entertained; the risk is a biological given and excusing some providers from it would mean unfairly shifting the risk to others.[22] Physicians appear sympathetic to this view: in one survey, 80 per cent reported that they would be willing to care for patients in the event of an outbreak of an unknown but potentially deadly disease.[23]

If doctors and other emergency responders have a professional ethical obligation to care for patients during infectious-disease outbreaks, arguably this entails an obligation to take the necessary measures to minimize the likelihood that they themselves fall ill and cannot work. Therefore, where vaccination is available, it becomes, by extension, obligatory. When individuals encounter the risk of a vaccine injury out of professional duty, it is reasonable to argue that they should not be left to bear the financial burdens associated with that injury.

Some may argue that health and safety professionals assume these obligations out of a sense of altruism and duty, not in the expectation of a *quid pro quo*. But their motivation for service is not necessarily relevant. Regardless of their reasons for choosing their profession, we do routinely compensate those who protect public safety and suffer injury as a result. For example, injured soldiers, police officers, and firefighters and their families receive a range of benefits for injuries sustained in the line of duty. These policies arise from a sense that even if compensation is not expected by these public servants, it is still fair, virtuous, and perhaps morally obligatory to offer it, because they have entered into a 'special relationship of service' to society,[24] from which all benefit. Compensation is a way of providing some reciprocity in this relationship, or at least of showing gratitude.

The principle that those who undertake these professional obligations deserve a basic safety net arguably extends to health care workers who must be vaccinated in order to be able to care for patients in a disease outbreak. In the aforementioned survey, 88 per cent of physicians felt that society should

[20] Association of American Physicians and Surgeons. 2003. *Doctors: Vaccine Compensation Bill Only Half a Solution*. Press Release, 27 March 2003. Available at: http://www.scienceblog.com/community/older/archives/K/2/pub2826.html. [accessed 16 February 2006]; National Vaccine Information Center. *Homeland Security and Vaccine Compensation*. Available at: http://www.909shot.com/Issues/briefing_paper.htm [accessed 16 February 2006].

[21] N. Daniels. Duty to Treat or Right to Refuse? *Hastings Ctr Rep* 1991; 21: 36–36.

[22] L. Reid. Diminishing Returns? Risk and the Duty to Care in the SARS Epidemic. *Bioethics* 2005; 19(4): 348–361.

[23] G.C. Alexander & M.K. Wynia. Ready and Willing? Physicians' Sense of Preparedness for Bioterrorism. *Health Aff* 2003; 22(5): 189–197.

[24] *Report of HEW Secretary's Task Force on the Compensation of Injured Research Subjects*. 1977. Washington: US Department of Health, Education, and Welfare.

ensure that health professionals were optimally protected against health threats in the course of their work.[25] Although this line of thinking does not justify compensation of all vaccine injuries, it does support compensation of injuries sustained by health professionals and others who are on the front lines of a (potential) disease outbreak. Notably, this argument has both deontological and utilitarian strands: compensation is merited by fairness concerns, but also because it is socially important to maintain an adequate supply of emergency responders who are willing and able to care for victims of disease outbreaks.

Fairness to those who act against self-interest

Part of the appeal of the argument from professional obligation is the notion that health workers and emergency responders operate out of a sense of duty which verges on altruism. If other-regarding behaviour is a legitimate ethical reason to compensate vaccine injuries, then perhaps the compensation policy should also extend to other private citizens who get vaccinated in circumstances in which they likely have more to lose than to gain by vaccination. That is, perhaps fairness demands that vaccine injuries be compensated where vaccination was voluntary and contrary to the individual's self-interest.

The collective-action problem described earlier is helpful in analysing such a claim. For many vaccinations, the public-health benefits of herd immunity are greater than the benefit that vaccination confers on any individual vaccinee; indeed, the risk/benefit calculus for the individual may weigh against preemptive vaccination (vaccination before an actual outbreak occurs). This is likely to be the case when the individual's risk of contracting the disease without vaccination is low because the risk of a disease outbreak is low and/or the disease is not highly transmissible. Some individuals will accept preemptive vaccination in these circumstances even in the absence of a mandate, out of a sense of obligation to contribute to herd immunity. Conversely, there may be a vaccine with an injury risk so low that as long as there is any risk at all of disease outbreak, it would be individually irrational not to be vaccinated.

One possible compensation policy would be to offer compensation where the circumstances of the injured person's vaccination fit the description of a collective-action problem. That is, compensation should be available when the person accepted vaccination notwithstanding a personal risk/benefit calculation suggesting that he should refuse it, but not where vaccination was clearly in the person's self-interest. Even if we accept that it seems unlikely that the offer of compensation will encourage more individuals to get vaccinated, such a policy would be justified on the basis of fairness to those who voluntarily risk personal harm for the benefit of the community, or by a social desire to reward behaviour that is perceived as virtuous. A strong version of this argument would posit that a community which benefits from an individual's altruistic act has a moral obligation to provide restitution to the individual; a weaker version would simply assert that although compensation is not morally required, it is morally desirable as a charitable act.[26]

Such a rule has moral appeal, but might be difficult to operationalize. It is clear that some types of vaccinations are sought primarily out of self-interest and confer substantial benefit on the vaccinee. Vaccinations obtained in advance of travel to regions where infectious diseases are endemic are one example; vaccines against human papillomavirus are another (with parents acting on behalf of their children's best interests).[27] Other vaccinations maintain herd immunity against a disease that individuals are very unlikely to be exposed to in the US, such as polio. Those vaccinations are not generally sought out of self-interest; they are generally mandatory.

For a third group of vaccinations, however, the risk/benefit calculus for individuals is much less clear. Vaccines developed in anticipation of potential new pandemics or bioterrorist attacks fit this description, because the likelihood of a disease

[25] Alexander and Wynia., *op. cit.* note 23.

[26] W.K. Mariner. Compensation Programs for Vaccine-Related Injury Abroad: A Comparative Analysis. *St. Louis Univ Law J* 1987;31(3):599–654; J.P. Swazey & L. Glantz. 1982. A social perspective on compensation for injured research subjects. In: *Compensating for Research Injuries, Volume Two*. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research. Washington: President's Commission: 3–18.

[27] C. Bowe. Viral Links Spur the Search for Cancer Vaccines. *Financial Times*. 21 Oct 2005: 13.

outbreak is not known with reasonable certainty. Nor, in the case of new infectious agents such as mutated strains of influenza, is the transmissibility of the agent known with precision.[28] Also, the risk of vaccine-associated adverse effects will be murky for new vaccines. In such circumstances, the principle of fairness to those who act against self-interest does not point to a clear answer about compensating vaccine injuries. Because this group of vaccinations is likely large, such a principle does not create a workable compensation rule.

A second objection to the self-interest principle relates to the definition of a benefit to the vaccinee. Even if a disease outbreak never in fact occurs, individuals arguably receive a benefit from vaccination in the form of protection against a possible risk. The argument is best explained by analogy to purchasing insurance: even if the risk of loss is uncertain at the time of purchase and, in retrospect, extremely low, still it does not seem right to say that the insured received no benefit from having bought insurance. The benefit could be described as peace of mind or complete security from risk. Thus, an expansive concept of individual benefit would hold that there are no circumstances in which vaccination is contrary to self-interest. If this is the case, then the self-interest principle is not useful for identifying vaccine injuries that merit compensation. (A counterargument might be that although individuals may receive a security benefit, it may not outweigh the risks of vaccination in some circumstances; therefore, the self-interest principle could distinguish circumstances under which compensation is and is not warranted.)

Solidarity

Many countries around the world have implemented compensation schemes for vaccine injuries, not primarily out of a utilitarian desire to keep vaccine markets well supplied or encourage vaccination, but as an expression of solidarity.[29] In some countries, the schemes are an outgrowth of other types of social insurance schemes, reflecting a broader social judgment that medical risks should be shared. In others, vaccine injuries were viewed as special due to their severity, complexity, and propensity to befall children and others who would not qualify for extensive benefits under existing accident insurance programs.[30]

Solidarity tends to wax and wane in American ideology; it has blossomed during times of war, economic depression, and civil rights movements and tends to recede during calmer, more prosperous periods. The ethos may again shift towards an embrace of solidarity, and solidarity is an important part of thinking about vaccine injury compensation elsewhere in the world.[31] Though not explicitly identified as such, solidarity arguments have been influential in deliberations in the US over whether society has a moral obligation to compensate injured research subjects.[32]

Intrinsic to the concept of solidarity is the notion that every member of the community should share risks and the burdens associated with those risks. This is particularly important where the risks are associated with the production of a public good, such as herd immunity. Solidarity means that members of the community should not have to bear terrible risks alone, and that the community should stand by those who are harmed by the measures we take to protect ourselves.

Versions of the solidarity argument that refer to the injured person's participation in the production of a social benefit resemble general fairness arguments. Both types of argument respond to the fact that among vaccinees, the injured and the uninjured pay unequal shares of the social cost of producing the shared good of herd immunity. In other words, the uninjured are (unintentionally) free-riding on the injured.[33] It is true that all vaccinees have borne the same share of risk of injury, but the

[28] C.E. Mills et al. Pandemic Influenza: Risk of Multiple Introductions and the Need to Prepare for Them. *PloS Med* 2006; 3(6): e135.
[29] Mariner, *op. cit.* note 26.
[30] Ibid.; G. Evans. Vaccine Injury Compensation Programs Worldwide. *Vaccine* 1999; 17 Suppl 3: S25–35.
[31] Evans, *op. cit.* note 30.
[32] W.K. Mariner. 1994. Compensation for Research Injuries. In: *Women and Health Research, Volume 2*. A.C. Mastroianni, R. Faden, D. Federman, eds. Washington: National Academy Press: 113–126; President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research. 1982. *Compensating for Research Injuries, Volume One*. Washington: President's Commission: 49–64.
[33] H.M. Smith. 1982. Compensating Research-Related Injuries: Ethical Considerations. In: *Compensating for Research Injuries, Volume Two*.

burden of injury itself is unequally distributed. Fairness and solidarity both militate in favour of a safety net for those whose sacrifice is especially large. Other versions of the solidarity argument, which refer not to individual sacrifices in the course of producing a social good but to the general virtue of not allowing members of the community to bear catastrophic losses alone, apply even when fairness concerns do not.

The principle of solidarity supports a policy of compensating those vaccine injuries that, in the judgment of the community, individuals and families cannot reasonably be expected to bear alone. Compensation might be limited to rare and severe adverse reactions, for example. There would be no distinctions drawn based on the reasons for which the individual obtained the vaccination, including whether or not it was voluntary. Distinctions might be made on the basis of the individual's ability to bear the financial loss associated with his injury (e.g. compensation might not be offered to millionaires).

The notion of solidarity is out of step with strongly held American values such as self-reliance, voluntary assumption of risk, and individual decision-making about whether and how much insurance to buy. The principle seems to find greater traction during emergencies, however, and in other circumstances in which the risk in question is neither voluntarily encountered nor easily insured against. Solidarity could perhaps be used to justify compensation of severe effects of vaccines during public health emergencies, but it is a fragile buttress for a more general policy of compensation of vaccine injuries in the US.

Failure of informed consent

An alternative basis for compensation would be to compensate when the conditions for individuals to give informed consent to vaccination are not present. Ruth Faden has proposed such a policy for smallpox vaccine injuries.[34] In the smallpox vaccination effort, she argued, meaningful informed consent was not possible because the risk of a bioterrorist attack was not known or reasonably knowable; thus, individuals could not accurately weigh the risks and benefits of vaccination.

Similar circumstances apply to other preemptive pandemic vaccinations. They also inhere in the use of all new vaccines, because insufficient experience has accumulated to understand the range and risk of adverse reactions. Pandemics and bioterrorist attacks pose additional challenges for informed consent once an outbreak has occurred: during the ensuing emergency, immediate vaccination would be critical and the chaos in public health systems may make it infeasible to put vaccinees through a detailed informed consent process.[35]

Faden argues that during emergencies, justice requires a social compact in which the usual requirement of informed consent for medical interventions is suspended but, in return, the government offers compensation for serious vaccine injuries. The resonance of this proposition with important provisions of American law is clear – for example, the constitutional provision that the government may not deprive citizens of property without offering just compensation.[36] Some ethicists, however, might object that many ordinary medical treatments involve the kinds of conditions Faden cites as precluding informed consent – yet there is no suggestion that resulting adverse outcomes merit compensation (in the absence of negligence).[37] In a range of medical situations, we accept a patient's informed consent as valid although it is given under conditions of uncertainty about risk. Also, when medical needs are emergent or pressing, the patient may be ill situated to offer meaningful informed consent or indeed any affirmative consent at all. It is not clear why vaccination should be treated differently from other medical interventions (many of which are equally or more burdensome and disabling), at least when vaccination is voluntary.

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research. Washington: President's Commission: 19–39.

[34] R.R. Faden, H.A. Taylor, N.K. Seiler. Consent and Compensation: A Social Compact for Smallpox Vaccine Policy in the Event of an Attack. *Clin Infect Dis* 2003; 36(12): 1547–1551.

[35] Ibid.

[36] US Constitution, Amendment V.

[37] I am grateful to Dan Wikler and Dan Brock for this suggestion.

THE ARGUMENT FROM REASONABLENESS

A final argument for vaccine injury compensation, which mixes utilitarian and nonconsequentialist considerations, is that rational vaccinees would prefer a world in which such an insurance scheme existed, if it could be provided efficiently. Vaccination is a high-stakes scenario in which some individuals will suffer catastrophic losses and in which no one can know who will be injured. Vaccinees are, in this sense, behind a Rawlsian veil of ignorance.

A utilitarian strand of this argument, drawing on principles of rational-choice economics and Harsanyi's theory of average utilitarianism,[38] is that a rational utility maximizer who has decided (or is required) to be vaccinated would support a scheme like the VICP because it improves the expected outcome of vaccination at a very low price (the VICP is funded by a $0.75-per-dose excise tax on covered vaccines[39]). One way of thinking about this is to consider that if each individual who presented for vaccination was offered the option to purchase an insurance policy against vaccine injuries for 75 cents, it is likely that few would turn it down. Another is that it produces greater total disutility for a small number of people to face a catastrophic injury alone than for everyone to pay a small tax on vaccines in order to fund a compensation program.

The nonconsequentialist strand of the reasonableness argument springs from Rawls's theory of justice as fairness.[40] His maximin principle suggests that under the circumstances, individuals would agree to form an insurance plan to protect those who turn out to be big losers in the pursuit of a general social gain. The scheme would likely apply only to severe injuries, since the motivation is to minimize terrible outcomes. Thus, reasonableness suggests that severe vaccine injuries should routinely be compensated, regardless of the reasons vaccination was sought.

CONCLUSIONS

A number of conclusions emerge from the foregoing. First, although the primary rationales for creation and expansion of the VICP have been utilitarian ones – encouraging vaccination and vaccine production – close analysis reveals these to be relatively weak justifications for compensation. Vaccination decisions do not appear to be strongly linked to the availability of a compensation fund, and the need to maintain vaccine supplies implies a need for liability protections for vaccine makers, not necessarily a compensation fund for vaccinees. Moreover, there are probably better ways to ensure an adequate vaccine supply, such as ensuring a stable market for vaccines.[41]

Second, some nonconsequentialist considerations do form a strong foundation for vaccine injury compensation. Arguments articulating a moral obligation to provide compensation for persons subject to *de jure* or *de facto* coercion are especially strong. Where vaccinations are legally mandatory, or are effectively required in order for health workers or emergency responders to fulfill their professional duties in the event of a disease outbreak, the government should provide ready access to compensation for injuries that result.

Such circumstances raise profound fairness concerns because the individual's choice set has been limited. Clearly, unfairness does not occur whenever choices are limited; it is not meaningful to speak of unfairness arising because a mere state of the world, such as a pandemic outbreak, limits the range of available choices. In the above circumstances, however, it is not the fact of the disease outbreak that results in limited liberty but, rather, the social decisions to require vaccination and to impose duties on certain individuals to care for others during emergencies. Such decisions are entirely justifiable but justice requires that redress is made to those who are so burdened, insofar as we can

[38] J.C. Harsanyi. Cardinal Utility in Welfare Economics and in the Theory of Risk-Taking. *J Polit Econ* 1953; 61: 453–455.

[39] US Department of Health and Human Services, Health Resources and Services Administration. *National Vaccine Injury Compensation Program: funding*. Available at: http://answers.hrsa.gov/cgi-bin/hrsa.cfg/php/enduser/std_adp.php?p_sid=hkCRuM*h&p_lva=&p_faqid=353&p_created=1112906594&p_sp=cF9zcmNoPTEmcF9ncmlkc29ydD0mcF9yb3dfY250PTMwJnBfc2VhcmNoX3RleHQ9JnBfY2F0X2x2bDE9MzAmcF9jYXRfbHZsMj1_YW55fiZwX3BhZ2U9MQ**&p_li= [accessed 21 February 2006]

[40] J. Rawls. 1971. *A Theory of Justice*. Cambridge, MA: Belknap Press of Harvard University Press.

[41] Mello & Brennan, *op. cit.* note 6.

provide it. The obligation seems especially strong when these decisions are implemented in advance of an actual outbreak.

Third, the reasonableness argument is also a compelling justification for a compensation scheme. It supports the extension of compensation beyond those who are required to be vaccinated to those who sustain severe injuries from voluntary vaccinations. In summary, an ethically defensible vaccine compensation policy would make a compensation fund available to all individuals with severe injuries and to individuals with less severe injuries if the vaccination was required by law or professional duty.

Lawrence Gostin has written that 'infectious diseases tend to bring out the best and worst in societies'.[42] When it comes to vaccine injury compensation policy, the need for a rapid response to each emerging threat has sometimes led to disease exceptionalism in policy-making,[43] rather than consistency in our treatment of those who are harmed by our collective self-defence efforts. The threat of pandemic influenza – particularly now, when it is still theoretical – presents an opportunity to reconsider and rationalize these policies. Reflection suggests the desirability of reaching agreement on a set of ethical principles to govern vaccine compensation and applying them in a consistent fashion, rather than allowing policy flow from political expediency.

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[42] L.O. Gostin. 2005. Public Health Preparedness and Ethical Values in Pandemic Influenza. In *The Threat of Pandemic Influenza: Are We Ready?* S.L. Knobler et al. eds. Washington: National Academies Press: 357–372.

[43] Z. Lazzarini. What Lessons Can We Learn From the Exceptionalism Debate (Finally)? *J Law Med Ethics* 2001; 29: 149–151.