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Contestation and the Council of Europe

As this book demonstrates, the construction of a scientific ‘fact’, such as an H1N1 pandemic, is a product of multiple social forces and relations. In the context of scientific uncertainty, institutional decisions regarding risk management must occur despite a scarcity of evidence. This need to act upon the perceived threat, combined with the presence of a multiplicity of perspectives surrounding contemporary global risks, served to render the WHO’s risk management actor network fragile and open to interpretation and critique. This chapter presents a case study of one prominent institutional challenge to the actions of the WHO in managing H1N1 – the critique mounted by the Council of Europe. Politically, the Council of Europe challenged the WHO’s use of vaccines as a risk-management strategy. However, as this I argue, such a critique was only made possible through the contestation of fundamental aspects of the ‘science’ of H1N1. Sociologically, I demonstrate the fragility of the H1N1 actor network through an illustration of the Council of Europe’s contestation. I furthermore demonstrate the democratized nature of contemporary science, where an outside actor – the Council of Europe – was able to impinge upon the WHO’s internal institutional processes.

All aspects of the WHO’s representation of the H1N1 pandemic threat were contested by the Council of Europe. In fact the WHO’s management of H1N1 was (and at this time continues to be) a site of intense controversy. This is explained sociologically as the result of competing conceptualizations surrounding H1N1, which were a consequence of the WHO’s failure to effectively bring about ‘closure’ and establish the H1N1 pandemic as a scientific fact. The Council of Europe mounted the most prominent and first organizational and political voice of criticism against the WHO. Aided by the benefit of hindsight, it emphasized the mildness of H1N1 in criticizing the WHO’s management. The way

in which the Council of Europe represented H1N1 therefore provides a telling contrast with the WHO's narrative of its management of the H1N1. This chapter, which explores the Council of Europe's account, will be structured following the themes of the previous substantive chapters of this book: the construction of the influenza and the H1N1 virus; the construction of 'pandemic'; the construction of risk; the declaration and definition of Pandemic Alert Phases; the use of vaccines as a risk-management strategy; and, finally, the Council of Europe's construction of the WHO's role in global public health. The juxtaposition between the accounts of the two organizations demonstrates both that the H1N1 threat could be differentially conceptualized, and that the WHO's construction of events was weak and ineffectual.

The Council of Europe's interest in the WHO's handling of H1N1 began at the end of 2009. One of the loudest voices of criticism came from the German epidemiologist/physician and Council of Europe parliamentarian Wolfgang Wodarg. He was the first institutional critic of the WHO's handling of H1N1, and he emphasized what he described as the undue influence of pharmaceutical manufacturers upon the WHO's actions. He presented a recommendation, endorsed by 13 other members, to the Council of Europe on 18 December 2009 entitled 'Faked Pandemics: A Threat to Public Health'. The motion suggested that

In order to promote their patented drugs and vaccines against flu, pharmaceutical companies have influenced scientists and official agencies, responsible for public health standards, to alarm governments worldwide. They have made them squander tight health care resources for inefficient vaccine strategies and needlessly exposed millions of people's health to the risk of unknown side-effects of insufficiently tested vaccines.

The 'bird flu'-campaign (2005/2006) combined with the 'swine-flu' campaign seem to have caused a great deal of damage not only to some vaccinated patients and to public health budgets but also to the credibility and accountability of important international health agencies.

The definition of an alarming pandemic must not be under the influence of drug-sellers. The member states of the Council of Europe should ask for immediate investigations in the consequences at national as well as European levels.

(Wodarg, 18/12/09)

This motion foreshadowed what would become key themes in the debate surrounding the actions of the WHO, namely assertions of the undue alarm caused by the declaration of a pandemic and the inappropriate influence of the vaccine-manufacturing industry upon the organization's actions. This was all associated with the primary claim that a 'true' H1N1 pandemic did not exist; the issue of definition is again prominent. The claims were investigated through several key discussions and committees of the Council of Europe, which form the basis of the analyses made in this chapter.

The assertions of Wodarg and his associates revolved around four main themes. These included the claims that

- H1N1 could not be considered a pandemic;
- the WHO caused undue panic in its handling of the case;
- this was due to the influence held by pharmaceutical corporations;
- the products of these manufacturers were not merely unnecessary and ineffective but also dangerous.

The Council of Europe's enquiries concentrated on an analysis of the role of the WHO in what it characterized as the costly and wasteful reactions to H1N1. At times the speakers and parliamentarians were highly critical of, and polemical against, the WHO, asserting conscious manipulation of the situation. For example, it was suggested that 'Everyone had been a victim of a chain of massive deceptions' (Diaz Tejera (representative for Spain) in Council of Europe Parliamentary Assembly, 24/06/10). On the whole, the mood of the proceedings is highlighted by the following:

Our message is a powerful, thunderous and intelligent one of anger against a foolish act by the World Health Organization. We are the first body in the world to look at this problem and to denounce what happened. This is not going to go away.

(Flynn (rapporteur) in Council of Europe
Parliamentary Assembly, 24/06/10)

However, while these overtly political aspects of the proceedings are interesting in themselves, for the purpose of this book the focus will be maintained on using the Council of Europe's narratives as a case study to indicate the lack of conceptual closure surrounding H1N1 and the difficulty of managing risk where scientific evidence is indeterminate. This failure to reach closure thereby rendered the H1N1 actor network unstable at the most fundamental level.

Co-productionist analyses provide some indications of ways in which the contemporary structure of science means that scientific policy can become contested. For example, the democratization of science (the opening up of scientific institutions to public debate) provides a greater avenue for the criticism of science policy than in the past when scientific fact appeared to be more certain (Nowotny, 2003a). Under previous conditions there was a clearer distinction between insiders (scientists and scientific institutions) and outsiders (the rest of society). However, in the contemporary era, while some boundaries are maintained (and while continuous boundary work seeks to strengthen authority), 'outsiders' have far greater input and ability to critique scientific endeavours. This is because (due to the conditions of risk and expertise) scientific institutions are incapable of producing conclusive answers. This means that 'outsiders' have a greater ability to force themselves into the scientific dialogue. Where the debate about science is conducted before the public, such 'outsiders' may be able to criticize the scientific institutions and even set the agenda (Funtowicz & Ravetz, 1993). This can be seen in the incursion of the Council of Europe upon the knowledge-producing authority of the WHO. It is clear here that the WHO had lost full authority over the management of global public health, and the greater movement towards institutional transparency and 'democratization' forms part of the reason why criticism of the organization became possible.

The maintenance of boundaries of authority is pivotal to the acceptance of science and scientific policy, and the cost of failure to an institution is high. If boundaries between science/non-science, science/politics and experts/policy-makers are not maintained then knowledge and policy will be subject to contestation. In this case an allegation of a conflict of interest, and declarations that the science of H1N1 reflected the flawed processes of the WHO, reinforced the critique of the WHO's policy. The critique was made more possible in a climate which Wehling and Boschen (2004) refer to as the rise of a 'reflexive governance of knowledge' in the management of risks (Braun & Kropp, 2010). This suggests that there is a greater chance of debate and contestation of the production, regulation and application of the science that surrounds risks and (importantly in the present case) the ideas and institutions which conduct this management. The legitimacy of any policy decision rests upon the ability to reconstruct a plausible scientific rationale for the action (Jasanoff, 1987). However, the reflexive governance of knowledge means that these rationales are more likely to be publically scrutinized, and the tenuousness of scientific evidence that surrounds

risks suggests that policy-making institutions are more easily subject to criticism. This chapter illustrates these arguments by directly comparing the Council of Europe's account with the themes drawn from the WHO's account.

The nature of the virus/the nature of influenza

When an actor network fails, multiple associated concepts (i.e. linked actor networks) can come under observation as black boxes are opened or destroyed. Within the actor networks of scientific institutions, this can then lead to contestation of what constitutes scientific 'fact'. As demonstrated earlier, within the WHO narrative, the understanding that H1N1 causes the disease of influenza was a taken-for-granted reality. However, this primary assumption was questioned by the Council of Europe's investigations. In fact, this fundamental divergence provides a good example of the way in which an apparently unquestionable scientific 'reality' (that H1N1 causes the disease influenza, and that influenza is a harmful disease) can become contested at points of scientific dispute, where closure had not been definitively established.

Contrary to the WHO, the Council of Europe depicted the concept of 'influenza' itself as problematic. This was first suggested by one of the key scientific experts who was called upon by the Council of Europe in the March meeting, Dr Tom Jefferson. Following this meeting, the ideas proposed by Jefferson were integrated into the official documents produced by the Council of Europe's committee. Pivotal to the argument was the suggestion that it is impossible to differentiate between influenza-like illness (ILI) and 'true' influenza. Thus it was argued that

Influenza surveillance programmes in different places appear to report on the presence and degree of threat of influenza but what they are really looking at are influenza-like illness/flu.

And therefore

we cannot say for certain how much influenza is circulating as influenza is an unknown proportion of an unknown whole (influenza-like illness/flu).

(Jefferson, 29/03/10)

It was therefore suggested by the Council of Europe that the WHO, through its global influenza surveillance programme, made no distinction (or did not measure the distinction) between ILIs and

influenza. Extending from this, it was maintained that much of what the WHO proposed to be H1N1 was actually not influenza at all.

According to Jefferson's account, the failure to distinguish between ILIs and influenza resulted in the WHO's misplaced reaction. Specifically, like most of the Council of Europe's narrative, this suggestion asserted the misuse of vaccinations. Thus

vaccination programmes are directed against what surveillance systems worldwide call 'influenza' but in reality are influenza-like illness/flu. Surveillance systems cannot distinguish the two and provide reliable estimates of impact. This point is the key to understanding what comes next. The false equation 'influence-like illness/flu = influenza' has misled some of the research on the effects of influenza vaccines and (most of all) the interpretation of such evidence.

(Jefferson, 29/03/10)

And again,

Another consequence is the idea that influenza-like illness ('flu') and its ravages can be prevented or minimised with influenza vaccines... vaccines could only affect at the most (i.e. if they had 100% efficacy) some 7–15% of the annual flu burden, since this is the proportion of people with the flu who truly have influenza. This 'specificity' of approach (go for influenza, disregard all other cases of flu) is probably based on what I call availability creep... But, if you think about it, it is a wonderful utopian policy against a syndrome as unspecific as this (just think of the role that other viruses play). In my opinion, the lack of logic in this thinking is stunning.

(Jefferson, 29/03/10)

The Council of Europe's critics' accounts thus suggested that the WHO mistargeted, such that

the currently available evidence does not allow us to know in a reliable way how many cases of influenza there are, nor its impact in terms of death and disability with any degree of certainty. However, the confusion between influenza and influenza-like illness ('the flu') has led to an obsession with a single agent (the influenza virus) which is not based on any sound evidence and, as I hope you now realize, is potentially dangerous and misleading (because even a perfect vaccine can not work against influenza-like illness/flu as a whole).

(Jefferson, 29/03/10)

In this way the problematization of the nature of H1N1 supported the Council of Europe's main point of contention elaborated below regarding the (mis)use of mass vaccination campaigns. Important here is that basic scientific assumptions can become questioned in the event of scientific dispute. Here, the notion of 'influenza' and its surveillance were deconstructed.

This depiction of the conflation between influenza and ILIs was taken up in the official documentation produced by the rapporteur Paul Flynn. For example, it was stated that mortality rates had been inflated due to this

With regard to such a possible overstatement [of risk], the rapporteur would notably like to point out that, in many countries, no clear distinction had been made between patients dying *with* swine flu (i.e. showing symptoms of swine flu whilst having died of other pathologies) and patients dying *of* swine flu (i.e. swine flu being the main lethal cause).

(Flynn, 23/03/10: 3)

From this perspective the threat of H1N1 had been magnified because the WHO had failed to take into account differences between illness that merely presented like influenza – ILIs – and 'true' influenza. What the WHO had stated to be 'swine flu' H1N1 was therefore, according to the Council of Europe, not necessarily influenza at all because surveillance systems were unable to effectively distinguish between different forms of respiratory illness.

In addition to the Council of Europe questioning the 'fact' of influenza, the veracity of the claim that H1N1 had pandemic potential was questioned. As has been shown, one of the main features that are characteristic of a potentially pandemic influenza strain was, according to WHO guidelines, the novelty of the viral agent. However, the Council of Europe's narrative contradicted the WHO's assertion that the 2009 H1N1 was a novel strain. Here,

the WHO declared ... that this was an entirely new virus. Now what here we see [sic] on the 22nd of May in 2009, we see that 10% of the under-60s and 30% of the over-60 age bracket already have an immunity against this virus. So we say, 'well, why stage things in this way, why manipulate things in this way?' when the virus is used in this way.

(Rivasi, 29/03/10)

In this quote the presence of immunity in certain populations underpinned the assertion that H1N1 was not a novel strain of influenza, thereby asserting the argument that H1N1 was highly unlikely to cause a pandemic. In fact the events were said to be 'staged'. The viral threat was thereby deconstructed from an objective reality (in the WHO version) to an object that was manipulated ('used') in order to achieve political ends.

Wodarg and Keil suggested that influenza is typically a mild illness of little concern, and that the 2009 H1N1 strain in particular was indistinguishable from seasonal flu. Thus Wodarg claimed that H1N1 is a 'mild flu. People fall ill as they usually do in winter season' (Wodarg, 26/01/10), and furthermore that the extent of illness and especially severe respiratory symptoms associated with ILIs 'is considerably less than in previous years. Thus, not only is H1N1 not an unusual and novel threat but it is furthermore claimed that the incidence of illness is actually lesser than the typical influenza season' (Wodarg, 26/01/10; emphasis added). Keil's address reinforced the statement that H1N1 did not represent a novel threat, suggesting that 'the H1N1 virus is not a new virus, but has been known to us for decades' (Keil, 26/01/10).

The Council of Europe therefore put forward a fundamentally different account of the nature of influenza and H1N1 from that proposed by the WHO. Through its narrative it suggested that H1N1 wasn't novel, threatening or even distinguishable from seasonal influenza and ILIs. Thus the concept was contested at the most basic level of the nature of both H1N1 specifically and influenza generally, demonstrating the malleability of scientific 'fact' under conditions of dispute and uncertainty.

What/when is a pandemic?

Another major point of conceptual contestation is found in the definition of 'pandemic'. Within the Council of Europe's narrative, suspicion surrounding the WHO's declaration of the pandemic was prominent. It was maintained that the WHO's decision to declare H1N1 as a pandemic was erroneous. This assertion was reiterated through several key points of argument, many of which utilized the WHO's own 'evidence' to make the case. The question of what constitutes a pandemic was heavily disputed.

Epidemiological statistics, and the way in which the accounts of the WHO and the Council of Europe each employed them, were a recurring theme in the debate surrounding the validity of labelling H1N1

as a 'pandemic'. Wodarg and Keil pointed to epidemiological aspects of the H1N1 virus to suggest that in fact this particular virus should never have been recognized by the WHO as pandemic-causing. The morbidity and mortality statistics of the disease were cited as evidence of this proposition. For example, Wodarg said:

Given the fact that the influenza is always a very contagious disease which spreads very rapidly and leads to a greater number of cases, it is surprising to see the extent to which attention was focused on that flu [H1N1] after the reporting of only hundreds of cases.

(Wodarg, 26/01/10)

Furthermore, the epidemiology of the virus was suggested by Wodarg to be indicative of its non-threatening nature. He argued:

Those who are over 60 years of age hardly contracted the [H1N1] flu. There is a relatively higher number of young people who contracted this flu which is not surprising at all. Usually, when we observe a flu coming, one of the factors, which helps us determine if it is already known or not is the occurrence amongst the elderly. If they do not fall ill they seem to already have immunity...

(Wodarg, 26/01/10)

As with Keil's statement in the previous section, Wodarg implied here that the 2009 H1N1 strain did not actually constitute a new virus at all. Employing analogies to seasonal influenza which mirrored (though contradicted) the WHO's, the Council of Europe argued that the low mortality rate of H1N1 demonstrated that the event could not be labelled as a pandemic. Thus, 'According to the epidemiology, this swine flu was likely to be mild' (Flynn, 29/03/10). In this way it was common for critics to compare mortality rates of H1N1 and seasonal influenza, arguing that higher death rates due to seasonal influenza had been unjustifiably used as evidence by the WHO to declare a pandemic based upon spurious evidence.

The Council of Europe contested the presence of the pandemic, and the WHO's use of epidemiological statistics to justify the designation. A central claim made by Wodarg, Keil and others was that the WHO's (2009) amendments to the definition of 'pandemic' amounted to the only reason why H1N1 could constitute a pandemic. Wodarg stated: 'the current "pandemic" could only be launched by changing the definition of a pandemic and by lowering the threshold for its criteria'

(Wodarg, 26/01/10), and added that ‘It is only this change that made it possible to transform a relatively mild flu into a worldwide pandemic’ (Wodarg, 26/01/10). Keil stated that this occurred ‘In spite of contradictory data from Mexico [the primary site of transmission] and weak and unconvincing evidence...’ (Keil, 26/01/10). This aspect of the Council of Europe’s account was key because it set the basis for the central claim that the WHO’s alteration of the definition of a pandemic coincided with the interests of vaccine manufacturers (see below). It is important to note that this contestation represents another fundamental breakdown in the WHO’s attempt to bring about scientific closure.

A second claim made by the Council of Europe’s critics in relation to the definition of ‘pandemic’ was that, even though H1N1 could legitimately have been interpreted as a potential threat in its early stages, the WHO’s announcement of a pandemic was premature. It was suggested that the WHO announced a pandemic before a true state of pandemic was in existence. Thus

Premature announcement of a pandemic, elimination of the criteria of the level of threat of the virus by WHO and using mainly the geographic criteria without taking into consideration the number of cases actually occurring within a given region has resulted in this excessive reaction by most countries in the world...

(Kopacz, 29/03/10)

It was argued by the Council of Europe that the WHO’s actions were misplaced in declaring a pandemic. The claimed misdiagnosis by the organization regarding the state of the pandemic threat was highlighted by the Council of Europe:

In statements made at the very beginning of 2010, WHO insisted that the world was facing a real pandemic, the future course of the pandemic was uncertain, the situation was neither overplayed nor underplayed, and the objective had always been to adopt a precautionary approach. In the same statements, WHO claimed that it was too early to say whether the pandemic was over and that another significant wave could still be expected across Europe this winter or spring.

(Flynn, 23/03/10: 6)

This quote captures the Council of Europe’s characterization of the WHO’s uncertainty (as has been described in Chapter 3) regarding the future course of the pandemic. However, the Council of Europe

suggested that this was not a result of the embedded risk and uncertainty of the situation but rather a result of the WHO's mismanagement. The Council of Europe questioned the judgement of the organization in declaring a pandemic and alluded to dishonest motivations behind the declaration. The pandemic potential of H1N1 was, according to the Council of Europe, not objectively evaluated by the WHO. Here it was suggested that

When looking at the still very moderate expression of the pandemic almost one year after its outbreak (May 2010), the interpretation of scientific and empirical evidence can be seriously questioned. For some experts, it seemed obvious from a relatively early stage that the new sub-type of influenza virus was doing less harm to persons infected than other forms of the virus in previous years.

(Flynn, 07/06/10: 8)

More strongly, the infectious disease specialist Rivasi said:

I think that there are several types of responses we can have. First we have 'what is the justification of the pandemic?'. First of all, I looked at data, and in particular I looked at all the WHO alerts and reports before the pandemic was declared on the 11th of June 2009. And I think that what we find ourselves confronted with here is manipulation ... It started on the 10th of April 2009 when the WHO signalled that there were flu cases in Veracruz in Mexico ... Very early on Mexico, at the request of the WHO, signified that there were more flu cases ...

(Rivasi, 29/03/10)

Rivasi made the explicit suggestion that the WHO had engaged in manipulation by declaring the pandemic when it did – as in the quote above, where Mexico's high reporting was alleged to be a result of WHO prompting. In another example, he asserted that

On the eve of the declaration of the pandemic, the WHO declared that the majority of cases were benign. So the cases were benign, the virus was benign, and nevertheless on the 11th of June the pandemic was declared, alert level 6. What I wondered about when looking at these facts, is the unfolding of this all. Even when we look at the WHO notifications we have the feeling that the WHO deliberately staged the events.

(Rivasi, 29/03/10)

According to the Council of Europe's narrative, the H1N1 virus did not represent a pandemic threat; the pandemic declaration was unjustified. The WHO's characterization of H1N1 as a pandemic was therefore fundamentally contested in this account.

There was a fundamental institutional failure with respect to H1N1 – the WHO did not present either itself or its actions in a robust and convincing manner, leaving the 'facts' of the pandemic liable to contestation. For the Council of Europe, the WHO's actions appeared not to have been supported by scientific/'objective' evidence. The suggestedly 'unscientific' actions of the organization were presented as a key failure. For example, it was stated that

Exactly a year ago, a very bad decision was taken by the World Health Organization that now seems unscientific and irrational. The result of that decision was that the whole world became scared that a major plague was on the way – a new pandemic that would have been as bad, according to reports, as the flu pandemic of 1918. There seems to have been no scientific basis for that decision.

(Flynn in Council of Europe Parliamentary Assembly, 24/06/10)

Again, this suggests that the WHO defied scientific evidence in its decision-making process. However, as we have seen, the climate of scientific uncertainty under which the organization made initial decisions rendered it susceptible to such critique after the events.

The Council of Europe's depiction of the WHO's designation of H1N1 as a pandemic demonstrates that the event had been rendered liable to deconstruction. It furthermore provides evidence for the primary social constructionist claim that scientific evidence can be socially mobilized as support for primarily divergent claims. As this chapter will continue to demonstrate, both the Council of Europe and the WHO employed the same evidence basis as support for diametrically opposing viewpoints regarding H1N1.

Risk

As demonstrated earlier, the WHO emphasized the risk surrounding H1N1 and the threatening nature of the pandemic, thereby justifying the responses made. The Council of Europe presented a contradictory narrative of risk. It suggested that the WHO presented an inflated account of risk, which resulted in a disproportionate response to the

threat. This followed from the Council of Europe's dispute of the concepts of 'the H1N1 virus' and 'influenza pandemic'.

In portraying the WHO's risk narrative, the Council of Europe suggested that the organization was duplicitous, or at the least inept, in its communication of risk to national governments and the general public. Thus its concern was posed:

When looking at the still very moderate expression of the pandemic almost one year after its outbreak, the way in which scientific and empirical evidence has been interpreted can be seriously questioned. The main question is whether WHO overstated the threat posed by the virus, ignoring the practical evidence that the pandemic seemed to be of 'moderate severity' from its very start.

(Flynn, 23/03/10: 3)

In this regard, it was suggested that that threat of H1N1 had been unduly exaggerated by the WHO. The WHO's reference to previous pandemics when narrating risk came under scrutiny in the Council of Europe's account. For example:

Professor Keil... criticised the link and references made to previously deadly influenza pandemics. In his view the comparison with the 'Spanish flu' of 1918 was generally inappropriate given the empirical figures were far from comparable. The 'Spanish flu' took place in the historical context of World War One where infections were easily transmitted by soldiers, many of whom were undernourished and without medication... Such comparisons tended to heighten fear amongst Europeans.

(Flynn, 23/03/10: 5)

However, it was acknowledged to some extent by the Council of Europe's members that the WHO was not solely responsible for this linking of H1N1 to Spanish flu and the magnification of risk. The June 2010 report asserted the weakness of such comparisons but in part absolved the WHO's responsibility for them:

[The] WHO itself continues to assert that it has consistently evaluated the impact of the current influenza pandemic as moderate, reminding the medical community, public and media that the overwhelming majority of patients experience mild influenza-like illness and recover fully within a week, even without any form of

medical treatment. Most people, however, expected more dramatic consequences, not least because in spring 2009, the approaching swine flu was repeatedly compared to previous infectious diseases, notably the avian flu and SARS in more recent years, but also the Spanish flu of 1918.

(Flynn, 07/06/10: 12)

Here it was not directly suggested that the WHO itself fostered this image of high severity but that nonetheless the expectation of dramatic consequences had been prompted. On the whole the Council of Europe's account suggested that the WHO had constructed a discourse of high risk surrounding H1N1.

The Council of Europe was unequivocal in its assessment of the WHO's management of the risk – it argued strongly that the WHO had reacted to the threat in an inappropriate manner. Specifically, the Council of Europe emphasized the role of the precautionary principle as a determinant in the WHO's actions. The characterization of the WHO as acting primarily in this context is itself an interesting one. Though the WHO mentioned the term on a few occasions in its texts, it was by no means a reiterated concept in the organization's own account of the management of H1N1. Nonetheless, the Council of Europe continually linked the concept with the WHO's motives. Though the precautionary principle is widely considered to be a valid risk-management technique (perhaps particularly where the risk is scientifically 'uncertain', such as in the case of a pandemic) (Gollier & Treich, 2003; Liess & Hrudey, 2003), it is rendered problematic here by the Council of Europe.

The Council of Europe questioned the use of the precautionary principle in the context of H1N1. Thus it stated that

all public health authorities concerned should critically review their way of dealing with the precautionary principle, including the communication about its use, given that the question of what society should do in the face of uncertainty is necessarily a question of public policy and not only a question of science. In future situations posing a serious risk to public health, decision-makers should bear in mind that the precautionary principle can contribute to a general feeling of anxiety and unease in the population...

(Flynn, 07/06/10: 9)

This understanding of a society-wide reaction mirrors the co-productionist claim regarding the participatory nature of contemporary

science. Both scientific justification and concern for public perception are central to the Council of Europe's narrative. The concept that the application of the precautionary principle caused public anxiety was fundamental to the Council of Europe's objection to its use. Here again

The rapporteur notes that, in some member states, the 'precautionary' approaches followed created a high degree of uncertainty and fear amongst the population, which were not necessarily justified by the evolution of the disease.

(Flynn, 23/03/10: 5)

The precautionary approach, and the WHO's arguably conservative stance towards risk management in general, was thereby cast as problematic in the Council of Europe's account.

However, one interesting facet of the Council of Europe's claims was recognition that, despite the WHO's strong risk narrative, its recommendations can be (and had been) differently applied across nations. This somewhat weakens the Council of Europe's central argument that the WHO was responsible for the actions taken. It also strengthens the WHO's suggestion that responsibility was far more diffused. Thus, for example,

on the 'precautionary principle' followed by WHO and recommended for national action, responses varied: some wished to take strong precautions, whilst others expected a lower level of outbreak of the disease, and took minimal steps. This can be seen from some of the various reactions by member states of the Council of Europe.

(Flynn, 23/03/10: 2)

While most of the Council of Europe's narrative focused upon blaming the WHO, at some points it accepted that the European states were responsible for making decisions and implementing WHO recommendations.

However, generally in the Council of Europe's account the WHO had applied the precautionary principle in its management of the proposed risk in a way that led to mismanagement of H1N1. One explanation of the organization's action was that it applied the precautionary principle as a means by which to protect itself from criticism if the pandemic later proved to be severe. Thus the Council of Europe suggested strongly that 'The precautionary principle is not designed to protect decision-makers'

(Gentilini, 29/03/10). However, economic (pharmaceutical) interests were also (arguably more heavily) implicated by the Council of Europe in that

In a situation where uncertainty is coupled with risks for human health and lives, there is also a danger that public opinion can be manipulated in favour of particular commercial interests.

(Flynn, 07/06/10: 8)

As evident a little further below, the Council of Europe argued that the profit interests of pharmaceutical corporations were the motivation for the WHO's action. On the whole the organization's representation of risk was completely negated by the Council of Europe.

Risk and trust

The Council of Europe asserted that the WHO's mischaracterization of risk resulted in diminished trust in the management of public health. The Council of Europe's claims highlighted the centrality of trust in the institutional management of risk (see Alaszewski, 2003; Giddens, 1991; Luhmann, 2002 and others for sociological accounts). It argued that the WHO manufactured a situation which resulted in widespread panic, including, as Keil stated, 'hysterical announcements and reactions of ministries, scientific bodies and not least the media ...' (Keil, 26/01/10). This panic and the associated lack of an actual threat (in terms of the Council of Europe's narrative of incidence and severity) resulted in diminished public confidence in the WHO and other public health institutions. In this way, as Wodarg claimed, 'WHO "gambled away" public confidence' (Wodarg, 26/01/10) through its handling of the incident.

As evidence that the WHO created undue public panic, the critics drew an analogy with past incidences of disease. Here, allusions were made to H5N1 (avian influenza), suggesting that this was also a case of WHO mismanagement which produced public panic and mistrust. Wodarg stated that 'there were doubts already about WHO's alarm in the avian flu in 2005/05 ...' (Wodarg, 26/01/10) and that 'It was then officially stated by the WHO, in panic-stricken terms, that this flu could threaten mankind and that a great number of humans could fall ill and die' (Wodarg, 26/01/10). Keil also suggested that H5N1 and other recently notable diseases such as SARS served as testament to the inappropriate way in which the WHO handled the spread of respiratory

illnesses, leading to widespread concern and efforts of containment and vaccination when 'none of these pandemic predications have become true' (Keil, 26/01/10). In the Council of Europe's account, the WHO's construction of risk produced widespread panic and ultimately distrust in the organization.

Keil also made extended reference to the history of H1N1 itself, with the implication that the H1N1 subtype was an innocuous infectious agent. Here he suggested that, after the spread of H1N1 to the USA in the 1970s,

a vaccination campaign was started in the US and about 40 million US-citizens were vaccinated because the infectious disease specialists at the CDC were convinced that H1N1 was similar to the virus that had caused that Spanish influenza... However, the H1N1 vaccination campaign was stopped abruptly when it was realized that the virus produced only a mild disease... while the vaccine produced a number of severe neurological side effects...

(Keil, 26/01/10)

The critical claim was that the WHO recommended vaccination for a mild illness with no evidentiary support for its efficacy. The Council of Europe's allusions to epidemiological history also directly echoed the WHO's own references, though leading to divergent conclusions. This demonstrates both the importance of historical analogy in the social construction of disease and the potential for a fundamentally different construction using the same source 'evidence'.

The Council of Europe's documents constantly reiterated the suggestion that the WHO's actions had undermined goodwill in public health institutions. This was considered by the Council of Europe to be one of the pivotal long-term effects of the WHO's decisions with regard to H1N1. Thus it was asked:

who will speak for the 800 million people who suffered badly as a result of this decision? And, given that we have cried wolf four times, who will suffer in the future if a very nasty disease comes along but no one believes the WHO because they no longer trust it?... We need a World Health Organization in which we can have absolute confidence...

(Flynn in Council of Europe Parliamentary
Assembly, 24/06/10)

The suggestion of 'crying wolf', and its detrimental effect on trust in the WHO, was prominent:

the next time somebody cries wolf, the overwhelming majority of people will not be listening. And who do we have to thank for that? We have to thank either the inept bureaucratic dumbness of the World Health Organization or the spiteful evil manipulation of the World Health Organization by the drug companies around the world. One or other of them have to accept responsibility. If there is a pandemic in the future and people don't listen, then they [the WHO] have only themselves to blame.

(Hancock in Council of Europe PACE Meeting, 29/03/10)

And:

if the trust in the World Health Organization is undermined, and there have been a whole series of scares around the world, um SARS, CJD, AIDS up to a point, the millennium bug, avian flu and then swine flu. Where there have been great warnings of terrible calamities, I think, and they haven't occurred. I think the danger is, that having cried wolf so often, the public – next time there might be a real scare – there might be a virus that mutates and very few people will take notice of it. And we don't want to see the trust in the World Health Organization undermined.

(Flynn, 29/03/10)

Employing a variety of techniques, including historical analogizing, the Council of Europe strongly argued that the WHO's actions eroded public trust. Having declared the pandemic in a time of scientific uncertainty, the organization opened itself up to the critique of 'crying wolf' when a severe threat did not eventuate.

The Council of Europe also suggested that the WHO could not be trusted to effectively assess public health priorities. Wodarg and Keil asserted that the WHO's actions resulted in the neglect of other diseases and risk factors. In this way, Keil suggested that

Governments and public health services are only playing lip service to the prevention of these great killers [i.e. hypertension, smoking and other risk factors] and are instead wasting huge amounts of money by investing in pandemic scenarios whose evidence base is weak.

(Keil, 26/01/10)

Wodarg too asserted that the H1N1 scare deflected efforts away from other, more important health issues. Thus the WHO's construction of H1N1 as a relevant and immediate public health threat became contested in the Council of Europe's account. In this way it was suggested that the perspective of the organization was misplaced since

We also know that the result of the warning was that the whole priorities of health services, in any countries including my own, were distorted. Money was being spent defending against a form of flu that was very mild. Now we're simply looking after the truth, we want to find out what happened, why it happened.

(Flynn, 23/03/10)

The WHO was presented as an ineffective public health institution (compare with the WHO's assertions in Chapter 7) because it was unable to manage health priorities successfully and because it did not take responsibility for its actions.

Another fundamental facet of the Council of Europe's depiction of the WHO was that the organization's actions could not be trusted because they lacked transparency. Thus

Without transparency, suspicion remains. We are not accusing anyone of any wrongdoing, but we are entitled to know what went on. We have cried wolf four times in recent years – on sudden acute respiratory syndrome, on Creutzfeldt-Jakob disease, on avian flu and now on swine flu – and the world has been greatly alarmed, yet in all four cases, there were very few deaths around the world... There was no reason for the alarm.

(Flynn in Council of Europe Parliamentary
Assembly, 24/06/10)

The WHO's apparent lack of transparency was a reiterated point of the Council of Europe's narrative:

The rapporteur is convinced that the way in which the H1N1 crisis has been handled is lacking in transparency. Certain facts have never been communicated to the European public; others have not been presented clearly enough. Even in this advanced stage of debate, and notwithstanding the lack of transparency [that] has been pointed out on various occasions, some stakeholders are still not ready to react fully to allegations made and make all possible information available.

(Flynn, 2010)

Where the WHO had attempted to render itself more transparent or explain its actions, this was cast as insufficient by the Council of Europe. For example, it was argued that

unfortunately, the testimony that we had from the World Health Organization in Strasburg [January 2010 council meeting] was not convincing. They still want to rely on secrecy and the privacy of the people involved. We don't know who took the decisions, who decided that this was going to be defined as a Phase 6 pandemic, which resulted in great alarm throughout the world.

(Flynn, 23/03/10)

The WHO's announcement that it was conducting an internal review of the matter was met with similar scepticism. Almost all of the actions and responses of the WHO have come under attack by the Council of Europe in its discussions and investigations.

The Council of Europe and the WHO presented fundamentally divergent narratives of the risk posed by H1N1. Citing many of the same sources of evidence and examples as the WHO, the Council of Europe argued that the organization's mischaracterization of risk led to an erosion of trust in the institution. With regard to controlling contemporary risks, the management of public perception is crucial, due to the heavily integrated nature of the modern scientific enterprise. The Council of Europe's emphasis upon trust foreshadows the potential effect of the WHO's management of H1N1 upon its role in global public health (as discussed in depth in Chapter 8).

Pandemic phase declarations and definitions

Given the ill-defined nature of the boundary concepts 'pandemic' and 'pandemic phases', it is unsurprising that one of the strongest points of the Council of Europe's critique surrounded the WHO's pandemic phase declarations and (re)definitions. According to the Council of Europe's account, the WHO was able to portray H1N1 as a pandemic due to the fact that the organization changed its definitions of pandemic phases immediately prior to the emergence of the new H1N1 subtype. The Council of Europe argued that the premature declaration occurred because

This declaration at a very early stage of the event... was, according to some experts, only possible because the description of pandemic alert

phases was modified by WHO in May 2009, and notably the criteria relating to the severity of the disease removed as a pre-condition for passing on to the highest alert level.

(Flynn, 07/06/10: 5)

The claim that 'scientific experts' reinforced the Council of Europe's interpretation was reiterated throughout their documents and debates. For example, it was asserted that

A number of members of the scientific community became concerned when WHO rapidly moved towards pandemic level 6 at a time when the influenza presented relatively mild symptoms. This combined with the change in the definition of pandemic levels just before the declaration of the H1N1 pandemic heightened concerns.

(Flynn, 07/06/10: 9)

The WHO's definitions of the phases was represented by the Council of Europe to have been conducted in an unscientific and unjustified manner:

Predictions of the seriousness of the outbreak and its designation as a Phase 6 pandemic were based on a limited range of scientific opinion. Billions of dollars had been spent on the vaccine and it was necessary to clarify what had happened to avoid future repetition of the problems. The WHO had changed the criteria for a Phase 6 pandemic, basing it on this outbreak. There had been no clear answer from the WHO as to why that had happened.

(Huss (representative for Luxembourg) in Council of Europe Parliamentary Assembly, 24/06/10)

Thus central to the Council of Europe's argument was the claim that the WHO (unscientifically) changed its definition of phases in order to declare an H1N1 pandemic. While the WHO referred to scientific evidence in constructing H1N1, the Council of Europe similarly enrolled scientific expertise in dismantling the organization's account.

The Council of Europe argued that H1N1 was not a 'true' pandemic and was only labelled one due to the WHO's definitional changes. The Council of Europe's position regarded the organization's statements to the contrary as further evidence of WHO manipulation and the influence of pharmaceutical interests upon the events. The Council of Europe

argued that the WHO had been misinforming national governments, as demonstrated in the Council of Europe's claim that

Although WHO continues to assert that the basic definition of a pandemic has never changed, there is watertight evidence that the former criteria... was not considered anymore in the definition used for entering pandemic level 6... the current pandemic could only have been launched by changing the definition of a pandemic and by lowering the threshold for its declaration.

(Flynn, 23/03/10: 3)

And again even more emphatically in stating complicity of the WHO in constructing a 'fake' pandemic that

It changed its criteria – when you consider it in the cold light of day and in the context of all the facts that have come out, you have to ask what the reason behind the change in the definition might have been. You cannot find anything on its website to suggest why that might have happened, who wanted it changed and on what the criteria to which it was being changed were based. There is no evidence to support that. That alone would make even the most supportive person begin to smell a rat, as they would realise that there was something seriously wrong with why such a change was being made.

(Hancock (representative for the UK) in Council of Europe Parliamentary Assembly, 24/06/10)

This quote was the strongest assertion that the WHO changed the phase definitions as a deliberate ploy to manipulate the situation. Thus the 'pandemic' was described in the Council of Europe's account not as an objective entity but as a politically and institutionally constructed event, deconstructing its validity as a scientific 'fact'.

However, among the Council of Europe's statements the assessment of blame or overt manipulation lies on a spectrum. While the quote above suggests an extreme view of the WHO's liability, on the other end of the continuum it is suggested more sympathetically that

even if WHO did not intend to modify the pandemic definition in a way that would allow for an accelerated announcement of such an event in June 2009, the changes of relevant disease descriptions and indicators at a time when a major influenza infection was already

approaching was highly inappropriate and carried out in a way which could be considered as being non-transparent.

(Flynn, 07/06/10: 10)

The fundamental claim, though, was that the WHO had changed its definition of 'pandemic' in a way that led to the mishandling of H1N1 by the organization and that H1N1 was not a 'true' pandemic.

Even more telling in terms of the WHO's lack of a stable construction was the Council of Europe's somewhat ambiguous position on the nature of pandemics and phase definitions. As noted above in the description of the nature of the virus, in parts the Council of Europe strongly asserted that the fundamental concept of 'influenza' itself is highly debateable. In the context of such a conceptualization, the definition of an 'influenza pandemic' is therefore impossible. Here it was suggested that '...if we cannot describe the ordinary (i.e. the seasonal) in any satisfactory way, we certainly cannot describe the extraordinary (i.e. pandemic)' (Jefferson, 29/03/10). Furthermore, 'This may be one of the reasons why WHO has changed the pandemic definition so many times since early May 2009' (Jefferson, 29/03/10). Within the framework of such statements it was argued by the Council of Europe that 'we can safely conclude that no one has any firm idea of how to define an influenza pandemic' (Jefferson, 29/03/10). Following from the logic of this argument, since the concept of influenza itself had been rendered contentious by the Council of Europe, the definition of a pandemic is objectively impossible. Nevertheless, in summary, it was suggested (somewhat paradoxically) that the Council of Europe

strongly recommends that further in-depth work be done by all stakeholders concerned with a view to agreeing on a common definition and description of what an influenza pandemic is.

(Flynn, 07/06/10: 10)

This again highlights the fact that definitions of pandemics (and ambiguity in the construction of these) represent one of the main points of contention within the H1N1 controversy and is symptomatic of the lack of scientific closure surrounding these phenomena. The Council of Europe's critique of the pandemic phase categories acts as further demonstration of the fragility of the construction of these definitional frames. While the phases were important in helping the WHO to define the 'thing' of pandemic, their indistinct and tenuous nature has rendered them liable to significant reconstruction and critique.

Vaccinations and other preparatory actions

The Council of Europe was interested in the issue of definitions in the context of its central concern – the WHO's management strategy, particularly the recommendation to use vaccines. H1N1 came under investigation by the Council of Europe because it was a 'pandemic whose announcement cost the world's tax payers hundreds of millions of Euros and at the same time ensured enormous additional profit for producers of vaccines for the pandemic' (Kopacz, 29/03/10). As previously argued, institutional forces within the WHO, particularly a historical dependence on vaccination, resulted in a focus on such strategies. The Council of Europe, however, suggested that the WHO's collusion with pharmaceutical corporations was the cause of this preoccupation with vaccination. Through the deconstruction of the organization's scientific fact-making, and with the added benefit of hindsight, the Council of Europe thereby questioned the motives underlying the WHO's management.

In illustrating its critique of vaccine use the Council of Europe emphasized that

one of the central issues of the ongoing debate concerns the possibility for representatives of the pharmaceutical industry to directly influence public decisions taken with regard to the H1N1 influenza, and the question of whether some of their statements have been adopted as public health recommendations without being based in sufficient scientific evidence...

(Flynn, 23/03/10: 4)

The question of the appropriate use of vaccination and suggestions of the profit-motivated influence of the pharmaceutical industry in framing the WHO's response represented the major focus of the Council of Europe's concern.

As suggested in the initial 18 December 2009 motion, the crux of Wodarg's argument revolved around the suggestion that that the H1N1 pandemic was (inaccurately) declared due to the economic interests of vaccine manufacturers. He implied that the WHO's actions had been heavily influenced by the motives of these corporations. The Council of Europe asserted that the actions of the WHO following the H5N1 (avian) pandemic, and subsequent modification of the definition of 'pandemic', were underpinned by the prospect of large financial gains by vaccine manufacturers.

Thus the Council of Europe suggested that 'As a consequence of [the] avian flu hype many contracts between national states and pharmaceutical manufacturers were signed so as to ensure the availability of relevant vaccines in case of a real future pandemic' (Wodarg, 26/01/10). These contracts were to be enacted upon the implementation of the WHO and national pandemic preparedness plans, which occurs after the WHO declares a (Phase 6) pandemic. Thus Wodarg suggested that in the case of H1N1

The pharmaceutical companies must have been waiting for this announcement, which was made even though the flu was relatively mild. This was made possible because a new definition of pandemic levels had been adopted just beforehand.

(Wodarg, 26/01/10)

It was argued that the alteration of the Pandemic Alert Phases was a result of the influence of pharmaceutical companies upon WHO actions. This argument was strongly developed in the Council of Europe's accounts. For example, it asserted that

the credibility of an organization has been so undermined by an inability to see the wood from the trees. Or in their case being unable to differentiate between somebody paying them and worrying about where the next pandemic was coming from so to speak.

(Hancock, Council of Europe PACE Meeting, 29/03/10)

And:

We have an expression in the English language about 'who pays the piper calls the tune'. Now if there ever were to be a slogan hung over the door of the WHO, it ought to be that. With a very big question mark, the rest of you better watch out. Because it would appear that they have no scruples, do they? The evidence is apparent.

(Hancock, Council of Europe PACE Meeting, 29/03/10)

These quotes demonstrate the keen interest in and the blame that the Council of Europe's members placed upon the actions of pharmaceutical corporations, and upon the WHO in yielding to their influence.

The vested interest of corporations in maximizing profit was emphasized in a number of instances. The obvious profit made by corporations was provided as evidence. Thus it was stated by the Council of Europe that

The commercial interests in the pandemic and vaccination campaigns can be illustrated by the high levels of benefit to pharmaceutical companies. According to estimations by the international investment bank JP Morgan, the sales of H1N1 vaccines in 2009 were expected to result in overall profits of between 7 and 10 billion dollars to pharmaceutical laboratories producing vaccines. According to figures presented by Sanofi-Aventis at the beginning of 2010, the group registered net profits of 7.8 billion Euros (+11%) due to a 'record year' of anti-flu vaccines sales.

(Flynn, 23/03/10: 4)

In his speech made at the March meeting, Flynn stated, slightly more charitably, that

We did know, we do know, that there was great commercial pressure because huge (4 billion pounds) of investment had been made beforehand. So there were people who had a vested interest in making sure that huge numbers of vaccines were bought and we're not reaching any conclusion on that but I think we have to see that billions of pounds of profit were made by the pharmaceutical companies, and we're entitled to ask 'what were the interests of the people involved and who were the people involved'.

(Flynn, 23/03/10)

In this way it was almost taken for granted in the Council of Europe's account that the pharmaceutical industry strongly influenced the actions of the WHO. This contrasts with the organization's narrative which suggested that vaccine manufacturers are a responsible and necessary global partner in the management of disease threats, and that vaccines presented an efficacious and essential solution to pandemic events.

However, although the industry was often strongly portrayed by the Council of Europe as the principle antagonist in the events, its narrative also at times mirrored the WHO's characterization of the pharmaceutical industry as responsible actors. For example,

The rapporteur also takes note of some of the reactions coming from the pharmaceutical industry. Realising that the H1N1 influenza was much milder than originally expected or feared, the pharmaceutical groups allowed many states to opt out of previous contractual arrangements and cancel orders for large quantities of non-delivered vaccines.

(Flynn, 23/03/10: 7)

Nevertheless, overall this defence was not sustained. Vaccine manufacturers were far more dominantly portrayed in terms of their financial interests:

this test was failed also and perhaps first and foremost by companies who produce vaccines because for them, corporate profit was more important than social responsibility.

(Kopacz, 29/03/10)

Furthermore, the companies' explanations of events were disbelieved because

during the first exchange at the January hearing, the representative of the pharmaceutical industry did not provide any new evidence to dispel doubts about the possible influence that some of their members might have had on public health decisions.

(Flynn, 23/03/10: 7)

On the whole the Council of Europe argued that the industry can and should act 'responsibly' but that it had been motivated heavily by the pursuit of profit. Primarily the blame was not placed on the industry as such but on the WHO because it allowed itself to be heavily influenced by the corporations whose nature it is to pursue profit.

Specifically, the Council of Europe argued that the advice to implement mass vaccination campaigns was a major error made by the WHO in the handling of H1N1 due to both the inefficacy and the cost associated with these actions. It was suggested that

[The pandemic] declaration kicked off an immediate international agenda setting in process [including] extensive vaccination campaigns in many countries notwithstanding evidence that the influenza overall presented relatively mild clinical symptoms. In autumn 2009, several independent medical experts raised warnings regarding excessive vaccination activities for which, according to them, there was no clinical scientific evidence to justify this.

(Flynn, 23/03/10: 2)

And again:

In June 2009, the WHO declared a level 6 pandemic and vaccines were purchased in massive quantities. Without sufficient justification, 100,000 children were vaccinated. The way the pandemic has

been handled – not only by the WHO, but by the competent health authorities at European Union level – gives cause for alarm.

(Circene (representative for Latvia) in Council of Europe Parliamentary Assembly, 24/06/10)

Such statements made it clear that the Council of Europe regarded the use of vaccination as unnecessary. These contrast of course with the WHO's account which characterizes the use of vaccinations as an inevitable and essential reaction to the pandemic threat (see Chapter 5).

The suggestion that vaccination is actually effective against influenza was contested by the Council of Europe. To emphasize this, a comparison between different national vaccination strategies was made:

Preliminary results show that there is no correlation between the amounts spent on taking precautions and the results. The country that spent the least was Poland, which rejected the idea that this disease was dangerous and which had suspicions about the safety of the vaccine . . . Britain spent £570 million on medicines that will never be used. The outcome, however, was that the number of deaths per million from swine flu in Britain was about twice the number in Poland.

(Flynn in Council of Europe Parliamentary Assembly, 24/06/10)

More importantly, and central to the contestation of the conceptualization of 'influenza' and 'pandemic', the efficacy of vaccination was questioned through the use of the expert testimony of Tom Jefferson. He suggested that,

In fact, vaccine and antivirals have a weak or non-existent evidence base against influenza. The quality of influenza vaccine studies is so bad that our systematic review of 274 vaccines studies which had [been] published between 1948 and 2007 found major discrepancies between data presented, the conclusion and the recommendation made by the authors of these studies.

(Jefferson, 29/03/10)

The Council of Europe's account of vaccines thereby again highlighted the scientific uncertainty surrounding influenza and its management. This claimed lack of data indicating efficacy is highlighted again in the quote below:

After reviewing more than 40 clinical trials, it is clear that the performance of the vaccines in healthy adults is nothing to get excited about. On average, perhaps 1 adult out of a 100 vaccinated

will get influenza symptoms compared to 2 out of 100 in the unvaccinated group. To put it another way we need to vaccinate 100 healthy adults to prevent one set of symptoms. However, our Cochrane review found no credible evidence that there is an effect against complications such as pneumonia or death.

(Jefferson, 29/03/10)

In addition to these allegations of a lack of efficacy, the WHO's path-dependent preoccupation with vaccination as a strategy was criticized by the Council of Europe with reference to alternatives. The Council of Europe presented the argument that broader public health measures would be more efficacious:

Public health interventions such as hygiene measures and barriers have a much better evidence base than vaccines. They are also cheaper and socially acceptable, as well as being life savers in poor countries, yet they are almost ignored.

(Jefferson, 29/03/10)

It was clear that the vaccination measures advised by the WHO presented a fundamental point of contention for the Council of Europe. The lack of a solid scientific construction of both influenza and H1N1, and vaccine efficacy, resulted in the potential for contestation of the WHO's account. The Council of Europe seized upon these fragilities in criticizing the organization's actions.

Nonetheless, simultaneously, with regard to management strategies the Council of Europe acknowledged that the advice of the WHO was to be taken as a recommendation rather than an edict. As will be developed further in Chapter 7, the WHO characterized itself as an institution which provides evidence and advice to nations but does not make decisions for governments. In the WHO's account the governments are themselves responsible. In fact, the Council of Europe's debates showed that national governments (within the European Union and elsewhere) took a variety of different actions in response to H1N1. For example, the Polish government decided not to purchase large quantities of the vaccines. These actions were explained by the Polish health minister stating that

the conditions of purchase for vaccines proposed by producers were dubious for us, vaccines were to be purchased only by governments and not available directly to individuals, and to units of health care system, the producers of the vaccine expected that [the] Polish

government would take full responsibility for any undesirable side effects offering sale at the risk and on the responsibility of the purchaser.

(Kopacz, 29/03/10)

Thus the Polish example (and the discrepancies across European Union nations in the implementation of the WHO's advice more generally) highlighted the fact that national governments made the final decision in reacting to the WHO's declarations. Nevertheless, the WHO's role was always emphasized as the responsible and accountable agent in the Council of Europe discussions, and it was suggested that the organization 'thereby forced countries to spend billions on unnecessary supplies of medicine, as well as scaring the public all over Europe and the rest of the world' (Frahm (representative for Denmark) in Council of Europe Parliamentary Assembly, 24/06/10). Despite the potential diffusion of decision-making, the WHO was held responsible as the initiator of the situation.

The nature of the particular vaccines used against H1N1 was also a cause for criticism in Wodarg's account. As previously noted, a proportion of the vaccines (those which Wodarg critiques) used during the H1N1 pandemic had been manufactured using a new method which allows for quicker production. Wodarg suggested: 'It seems, that the indication for the new, patented vaccines primarily follow economic strategies and was not necessarily to optimise public health needs' (Wodarg, 26/01/10). Here again, he argued that economic motives were fundamental to the choice of the vaccine used. This, he asserted, was to the detriment of those who were vaccinated. Additionally, one of Wodarg's key claims was that the H1N1 vaccines were not merely unnecessary but also dangerous, arguing that the WHO acted irresponsibly in advising member states to purchase them. Due to the relatively novel method of manufacture, he suggested that the vaccines

involved higher risks than usual vaccines against seasonal flu in [that] some adjuvants were added and injected of which we know, that they stimulate the immune system manifold, which means that they could possibly lead to autoimmune diseases (such as multiple sclerosis) and immunological complications.

(Wodarg, 26/01/10)

Along with the possibility of an autoimmune response, Wodarg suggested that the vaccines might even induce cancers, asserting that

New procedures [for manufacturing the H1N1 vaccines] were allowed onto the markets to produce vaccine products including bioreactors using fast growing cancer-like cells. The possibility that their proteins could induce cancer when injected involuntarily as impurities to the patient has never been excluded from clinical testing, that needs a much longer observation period...

(Wodarg, 26/01/10)

The allusion to the possible carcinogenic nature of the vaccines is particularly interesting, and (while not strongly emphasized in Wodarg's statement at the Council of Europe hearings) it has been widely taken up by the media and other commentators (e.g. the anti-vaccination movement) (Ncayiyana, 2010; Odent, 2010; Wodarg & Villesen, 2009). Wodarg himself has been cited as having made more forceful claims of this nature to the media (see, e.g., Bancroft-Hinchey, 2010; Odent, 2010; Wodarg & Villesen, 2009). Thus, in addition to claiming that the pandemic was 'false', Wodarg suggested that the vaccines subsequently utilized in reaction to the declaration were potentially seriously harmful to those citizens who were vaccinated.

The WHO's management of H1N1 through vaccination represented an overtly political concern of the Council of Europe. The Council of Europe emphasized the role of pharmaceutical corporations and the WHO's misrepresentation of the threat. However, these claims were only made possible through the basic fallibility of the organization's construction of H1N1, the risk of pandemics, and the phase definitions. This institutional failure in establishing a solid construction led to the disintegration of the entire H1N1 actor network, rendering the management strategies open to critique.

Contested experts

As we have seen, both the Council of Europe and the WHO made reference to scientific experts in explaining H1N1. The use of scientific experts in the public management of risk has now become institutionalized. Here, 'experts' possess a key relationship to the problem at hand due to the democratized structuring of science. Experts inhabit a special status since membership of the category of 'expert' confers considerable authority and credibility (Nowotny, 2003a; Nowotny, 2003b; Nowotny et al., 2001). Furthermore, expertise is upheld not through the actions of individuals but through perceptions of the collective merit of experts as a group (Lynch, 2004; Shackley & Wynne, 1996).

Risks pose challenges to expert systems because experts must act outside their disciplinary sphere of 'expertise' in order to answer the questions that risk presents (Lynch, 2004; Shackley & Wynne, 1996; von Schomberg, 1993a). Also, importantly, the study of risk often makes use of fields in which the 'expert' may not be accomplished. For example, in the case of influenza pandemics, expert committees may consist of virologists and immunologists, as well as epidemiologists. As has been evident throughout this book, epidemiology is central to explaining H1N1. However, this field is seen as being the source of information that is not strictly objectifiable or, ultimately, authoritative. These types of 'softer' science (e.g. epidemiology, risk analysis and ecology) are less prestigious or authoritative, in many cases are less developed/'newer' disciplines, and produce results which are far more open to interpretation (Funtowicz & Ravetz, 1993). This 'objectively' indistinct nature of evidence surrounding pandemics lends to the fragility of the constructions.

The question of scientific expertise was central to both the WHO's construction and the Council of Europe's contestation of events. One of the ways in which the WHO was said to have made itself susceptible to the influence of pharmaceutical corporations was through the selection of expert committees. As illustrated in Chapter 4, the WHO phase (and pandemic) declarations and action plans were formulated in part through the use of expert committees. The Council of Europe criticized these committees, citing their lack of transparency.

The Council of Europe argued that this lack of transparency fostered situations whereby the WHO's experts might be simultaneously involved with pharmaceutical companies, leading to conflicts of interest which then resulted in the misactions. In this way it was suggested that

Some members of these advisory bodies evidently have professional links to certain pharmaceutical groups – notably through receiving extensive research grants from big pharmaceutical groups – so that the neutrality of their advice could be contested. To date, WHO has failed to provide convincing evidence to counter these allegations and the organisation has not published the relevant declarations of interest...

And furthermore, in arguing collusion,

It seems that the exaggeration of the pandemic was perhaps neither a mistake nor a coincidence. The pharmaceutical industries that earned

a fortune from the pandemic had their people in the WHO, which had the power to declare the pandemic and thereby oblige a number of countries to buy large supplies of products from those industries.

(Flynn, 23/03/10: 4)

As such the lack of transparency of the WHO's actions presented a reiterated point of criticism made by the Council of Europe. The institutional procedure through which scientific facts were established thereby themselves became contested.

The WHO's experts were heavily criticized in these accounts. It was suggested that 'The advisory bodies of WHO are particularly exposed to the risk of conflicts of interest regarding scientific experts' (Flynn, 23/03/10: 4). One of the main points of antagonism between the two bodies was the WHO's reluctance to release the details of the make-up of the expert committees. Thus the Council of Europe report suggested that

The rapporteur continues to be very concerned by the lack of transparency regarding the identity of experts whose recommendations have had a major impact on public health budgets and people's health. He considers that the right of 800 million Europeans in Council of Europe member states to be fully informed should prevail over the right of a relatively small number of experts to privacy.

(Flynn, 07/06/10: 17)

And:

The Organization continues to hold back on releasing further information on the interests of experts, justifying this position by the need to protect experts' privacy and to prevent them from coming under extreme pressure from certain private companies or interest groups. The rapporteur is very concerned by this attitude...

(Flynn, 07/06/10: 11)

The issue of experts had therefore become one of the most obvious points of conflict between the WHO and the Council of Europe, and it was also central to the process of institutional fact-making of both parties.

One of the reasons why the Council of Europe's members were so critical of the role of the WHO's experts may lie in their perception that such experts have undermined the politicians' own functions. This is evident in the texts analysed. For example, it was suggested that

The lack of transparency raised wider issues, such as the increasingly technical nature of issues on which politicians were required to make decisions. Experts should help decision makers, but not replace them. There was a need for the ethical questions to be considered and probably for a code of conduct.

(Huss (representative for Luxembourg) in Council of Europe Parliamentary Assembly, 24/06/10)

The insecure and contestable function of experts was thus highlighted in this debate, demonstrating the nature of 'expertise' under conditions of contemporary risk science. The public nature of expert decisions came to the fore in this case.

The Council of Europe's narrative suggested that the individuals on these committees have been deliberately misleading in their influence. For example,

Much has been said about the role of experts in advising policy makers on both seasonal and pandemic influenza. We know that some of them have been parsimonious with declaring their interests and their role as members of lobbying organizations which are financed by industry and some did not think it important to disclose pretty hefty industry funding of their institutions. We know that transparency is probably not taken very seriously by WHO.

(Jefferson, 29/03/10)

In this way the experts were presented as inherently subjective. Experts are liable to such critique due to the necessity of their inhabiting a broad multiplicity of roles within contemporary scientific knowledge production. However, for the Council of Europe, the experts are described as definitively acting in the interests of pharmaceuticals:

We have the so-called 'advisers', who offer advice to the WHO. Nearly every one of the people concerned either was or had been in the pay of one or another of the drug companies. In what other business or institution would it be possible for somebody in the pay of a body that would be the significant beneficiary of any change be able to give such unfettered advice? When the WHO received the advice, it did not even bother to challenge it.

(Hancock (representative for the UK) in Council of Europe Parliamentary Assembly, 24/06/10)

This suggested that the experts on the WHO's committees were consciously manipulating the situation in favour of pharmaceutical manufacturers, reflecting the heavily integrated nature of contemporary science which, in part, makes interaction with corporate bodies necessary.

Tellingly, the very notion of expertise was questioned by the Council of Europe, which argued that the individuals who are presented as experts are in fact manufactured entities (and thus are not 'true' experts on the subject) (for critical social scientific accounts of this nature, see, e.g., Brown, 2000; Rose & Rose, 1976). Thus

Few realize that most experts (or KOLs – key opinion leaders – as they are known by communication agencies) do not appear like daisies in a field, they are 'made' over decades after having been recruited by specific image or communications agencies ...

(Jefferson, 29/03/10)

And:

even experts with no ties to industry or government civil servants have career motivations, especially if they make policy and evaluate its effects.

(Jefferson, 29/03/10)

Thus it was suggested that the use of expert opinion was fundamental to (what the Council of Europe described as) the inappropriate actions taken by the WHO. Here it was suggested

that the result of the expert system (in which selection is on the basis of fame or sponsorship, with transparency being the exception) are plain for all to see: catastrophic predictions that have failed to materialize, poor science, a thriving pandemic industry and the reputation of public health structures in tatters.

(Jefferson, 29/03/10)

The Council of Europe's position on experts therefore represented a clear departure from the WHO's use and characterization of such individuals, where the organization often cited expert committees in validating its claims. Nevertheless, despite this criticism of the WHO's experts, competing 'experts' were also frequently cited when providing

evidence for the Council of Europe's participants' own claims (e.g. referring to the WHO acting even where expert opinion found the virus to be mild). However, though the general notion of 'expertise' was mobilized, particular experts as such are rarely mentioned, apart from the political experts who underpinned the Council of Europe's contestation.

Experts are seen as the source of objective information. However, due to the nature of risks, information surrounding a risk is necessarily tentative. This is seen in the case of H1N1, where the WHO made only heavily qualified scientific proclamations through most stages of the events. This means that in situations of risk there is likely to be disagreement among experts as to the scientific facts. In most instances of knowledge production, research occurs against a backdrop where stakeholders implicitly agree upon and 'know' (in pragmatist terms) what counts as valid knowledge (Jasanoff, 2004b). However, under circumstances of risk there tends to be greater contestations of the 'facts' of the case (Miller, 2004; Nowotny et al., 2001; Shrader-Frechette, 1993). This is because the study of uncertainty is now core to the practice of science. Thus 'Expertise is at once contested, problematical, central, and indispensable' (Nowotny et al., 2001: 215). Expert advice is sought and cited for policy-making, despite the fact that the nature of risks makes them in many ways immeasurable.

The Council of Europe's accounts strongly problematized the WHO's handling of the H1N1 threat, especially with regard to the organization's reliance upon vaccinations as a pre-emptive measure against the virus. The use of expert committees in justifying these claims was regarded by the Council of Europe as a mechanism through which the pharmaceutical corporations' influence could be fostered. This signifies one important way in which the WHO's construction of H1N1 was challenged, again indicating the instability of the construction as a whole.

Portraying the WHO's management of H1N1

Due to the fragility of the institution's constructions of H1N1, the WHO rendered itself liable to critique by the Council of Europe on basic assumptions and concepts. Overall it was argued by the Council of Europe that

There is a great deal of evidence that the decisions were taken on an unscientific basis. We are not making accusations, but we are

entitled to transparency. There is no transparency... The only ones to benefit from the decision were the pharmaceutical companies and the vaccine manufacturers.

(Flynn in Council of Europe Parliamentary
Assembly, 24/06/10)

According to the Council of Europe, the WHO's actions did not represent objective and scientifically based decisions but rather were made by a non-transparent institution which was heavily influenced by monetary interests. The weakness of the WHO's construction of H1N1, as presented in the earlier chapters of this book, meant that the Council of Europe could question its actions.

On the whole, however, the WHO was presented by the Council of Europe as an indispensable international body, but one that has made incorrect decisions in the case of H1N1. As

the World Health Organi[z]ation is the essential body in the world, it should be the health beacon for human-kind and it must assume its responsibilities and make the right choices, and there at least twice it made the wrong choices, on avian flu as well...

(Gentilini, 29/03/10)

Here the Council of Europe mirrored the WHO's accounts (Chapter 8) with regard to its role in global health:

Potential pandemics such as swine flu demonstrated the importance of having a body such as the World Health Organization, able to respond to major health threats. It was important that countries were prepared for pandemics and primed to act should there be an outbreak. It was important that countries should take preventive measures but it was wrong to force people to take such measures under the pretence of a pandemic.

(Ünal (representative for Turkey) in Council of Europe
Parliamentary Assembly, 24/06/10)

In this way the work of the WHO was presented by the Council of Europe as essential. Nevertheless, the actions taken by the organization (and its lack of transparency) were heavily criticized. This placement of responsibility and blame on the WHO was the overwhelming response within the Council of Europe's discussions and documentation. There were very few examples of clear defence of the WHO's action within the

Council of Europe's documents. For instance, one French representative suggested that

It could be true that wanting to know everything before acting meant not acting at all. It was not right to condemn the WHO, which had had to rely on expert opinions.

(Rouquet (representative for France) in Council of Europe Parliamentary Assembly, 24/06/10)

However, such attempts to deflect blame from the WHO were rare in the Council of Europe's proceedings.

In some cases, wider-ranging institutional overhauls of the WHO were proposed by the Council of Europe. For example, one representative asserted that

The WHO was an excellent organisation but it was notable that its long-term work was very good while its efforts to deal with emergencies were poor. It was a very closed organisation and there was not sufficient information about it... Transparency was the best way forward.

(Huss (representative for Luxembourg) in Council of Europe Parliamentary Assembly, 24/06/10)

And another suggested that

we believed the World Health Organization. I agree that we still have to believe them, but we must believe that the WHO will find the strength to face its own deficiencies. That is why we are sending this resolution out to the world; we do so in good faith and as an appeal. We have to face and handle all future epidemics responsibly; we must gather and act on transparent information and facts that are available to all in order to accept and estimate the degree of danger to ourselves. We should not allow ourselves to be treated as guinea pigs by anyone ever again.

(Ivanji (representative for Serbia) in Council of Europe Parliamentary Assembly, 24/06/10)

Overall, the Council of Europe placed blame on the WHO for its decisions with regard to the specific problem of H1N1, and at times in its fundamental institutional aspects and alleged collusions with industry. As I have argued, all aspects of the WHO's construction

and management were contested at fundamental levels. This serves to demonstrate the fragility of the WHO's construction of the H1N1 actor network. The disease was so ineffectively constructed and managed that all associated actor networks, including the WHO, were rendered liable to criticism.

Taken in the whole, the Council of Europe's descriptions of H1N1 and the influenza pandemic demonstrates that the virus failed to reach closure as a scientific fact. This is evidenced by the analysis that the Council of Europe's discussions, which show a fundamentally different description of the nature of the virus, the nature of its threat and the justified reaction to the threat. This would not have occurred if the scientific fact had been definitively established. Additionally, the manner in which the 'fact' of H1N1 was constructed (within the WHO through expert committees) came under attack by the Council of Europe, showing the fragile nature of the institutional process. Thus the Council of Europe's accounts demonstrate both that the WHO's construction of H1N1 was unstable and open to contestation, and that the WHO as an institution had become vulnerable to attack through its management of this case.