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How Did the Smallpox Vaccination Program Come About? Tracing the Emergence of Recent Smallpox Vaccination Thinking

Dale A. Rose

In December 2002 the President of the United States, in light of persistent advocacy and a gathering consensus within the public health and national security communities about imminent biological threats such as smallpox, announced the enactment of the Smallpox Vaccination Program (SVP).[1] The announcement represented both the initiation and the culmination of certain sets of processes. On the one hand, a program was about to be put into place which, in terms of its scope and the dominant logics guiding it, had no parallels in the long histories of infectious diseases, public health, and immunization. It was, in many respects, the start of a very novel program. The stated purposes of the program, articulated at various points by an assortment of usually senior officials, were varied and occasionally contradictory. Some of the discernable purposes were: 1) to enable the US to respond effectively to an outbreak of smallpox in the US, the theoretical possibility of which had become an increasing source of concern; 2) to protect the public; 3) to strengthen the public health system; 4) to contribute toward a general system of *bioterrorism preparedness*; 5) to foster material readiness related, specifically, to *smallpox preparedness*; 6) to facilitate a general push towards domestic and *public health preparedness*; and 7) to reap the benefit of the program's deterrent effect on state or non-state actors considering developing or deploying smallpox against the US.

On the other hand, the SVP was also an outcome – one that, to be sure, was by no means certain. It was the product of a long, occasionally arduous process, characterized in no small measure by attempts to articulate new relationships and rationalities for public health, national defense and an embryonic homeland security apparatus. The program was to bring together elements of the nation's vast, if only loosely coordinated, public health infrastructure with additional elements historically at some distance from the field of public health, including: the US national security and defense apparatus(es), assorted public safety communities, "first responders," the health/medical care communities, and disaster/emergency management agencies. Under the aegis of a nascent technical and political rationality known as *preparedness*, the SVP was meant ostensibly to reflect new thinking about the ways in which existing elements of the public health and national security apparatuses could and should map onto emerging strategic demands. The emergent logic of preparedness deemphasized orientations towards specific threats, for example emanating

[1] The annoucement in its entirety can be found at: http://www.whitehouse.gov/news/releases/2002/12/20021213-7.html

from specific sources or actors, which had calculable probabilities. Instead, it constituted a shift towards vague or uncertain future threats, which in some respects eluded calculability. To know these threats, for example, whether a "dirty bomb" or a virulent engineered pathogen would be released (not to mention when or where), therefore required knowledge not about likelihoods – those could not be meaningfully known, per se – but about the extent to which their possible realization would impact the critical infrastructure of the US, including the ability of various assets, populations and jurisdictions to respond and recover from a potentially catastrophic event. Thus, preparedness came to orient itself towards *vulnerabilities*, and the *capabilities* or *capacities* needed to act effectively in light of uncertain future situations.[2]

This chapter focuses on a select set of events, discussions, and key participants tasked with thinking through and articulating the principal public health response to smallpox, namely through vaccination and associated practices. It is oriented largely towards the ways in which experts, situated in an advisory capacity to the Centers for Disease Control and Protection (CDC), as well as officials at the CDC and other organizations, came both to problematize smallpox, and to put forward sets of solutions to those problems in line with a nascent and ill-defined preparedness rationale.

The chapter is organized as follows. The next section provides a brief overview of the planned structure of the SVP, as well as key points in its implementation. Following this, the chapter steps back to bring into view some of the salient contexts in which biological agents came to be problematized as *threats* (to various populations and to the state), as well as emergent modes of response to these threats. Thereafter discussion centers on activity at the CDC and the organization charged with producing vaccination recommendations in the US, the Advisory Committee on Immunization Practices (ACIP). The findings in this section were drawn from nearly twenty interviews with officials in both these organizations and from local public health departments, conducted in 2004-2006. Additional data includes ACIP meeting minutes and transcripts of CDC/ACIP "telebriefings" (press conferences). The subsequent section traces back a particular technique and logic related to risk/benefit analysis, focusing specifically on its employment in the context of vaccination recommendations and the ACIP. The chapter concludes with provisional diagnoses regarding the emergence of recent smallpox vaccination thinking and the Smallpox Vaccination Program.

[2] A growing body of work has begun to explore preparedness in some depth. See Collier et al. (2004); Collier and Lakoff (2006); and Lakoff (2006).

The planned structure of the SVP

The SVP was to consist in a number of elements, with both military and civilian components. Only the latter will be treated here. Although the CDC, which had nominal responsibility for the oversight of the program, would not officially sanction use of the terms (at least through mid- to late-2003, when the program was "paused"), most commentators understood the program to be comprised of at least two, or possibly three, *stages* or *phases*.[3] Stage 1 would consist in the voluntary vaccination of approximately 500,000 healthcare providers throughout the United States, to be accomplished – although this was later deemphasized by CDC officials, as was the target number itself – in a 30 day time period. Vaccinations were to be administered under the auspices of state and local public health departments. Specifically, individual states were tasked with requesting and receiving vaccine from the CDC, as well as distributing it to local agencies; they were further tasked with identifying which personnel were eligible to receive the vaccination. Local jurisdictions were, in turn, placed in charge of administering the vaccine to individuals. These public health departments were tasked with educating, training and vaccinating their own appropriate staff, as well as certain hospital personnel in their respective jurisdictions. They were further assigned the responsibility, as called for in earlier CDC guidance on the subject (CDC 2001a), of putting together plans for mass vaccination of the entire local population.

Ultimately, these half million individuals were to constitute one of two types of Smallpox Response Teams (SRTs). Public health department officials occupying various specialties and professions, including medical epidemiologists, infectious disease specialists, public health nurses, fieldworkers, vaccinators, etc., were to constitute discrete response units based in specific geographic locales and local jurisdictions. These were to be known as Public Health SRTs, and their purpose was to exist as a ready "force" capable of responding to any possible smallpox outbreak within their respective jurisdictions. A second type of team, Health Care SRTs, consisting of a subset of an area's, or region's, hospital personnel (principally acute care, emergency care, and other relevant specialties), was to be established throughout the United States. Health care SRTs were to provide local hospitals with a staff of personnel capable of handling possible smallpox cases in their respective locations. Both types of team were to have the capacity to vaccinate additional individuals, whether healthcare personnel or members of the community.

Stage 2 of the SVP was to consist in the wide-scale expansion of the voluntary program to include up to 10 million individuals situated throughout the public

[3] In addition to information derived from interviews with several CDC officials, this section is based on the following sources: GAO (2003); Johnson (2003); Kuhles and Ackman (2003); Pilch (2003); IOM (2005); and Poland et al. (2005).

health, medical, and public safety establishments. Specifically, vaccines were to be offered to "first responders"; that is, those working in fields such as firefighting, emergency medical services and law enforcement. The principal argument for bringing this population into the fold initially revolved around the notion – not rigorously developed – that such individuals would likely be involved in some organized response effort to a possible biological incident/attack, presumably of smallpox.

Stage 3 of the SVP was of a different mold than the stages preceding it. Stage 3 efforts were to consist in vaccinating members of the general public who specifically requested receiving smallpox vaccine. Although a small number of people from the general public did end up receiving the vaccine, this stage was never formally implemented.

The programmatic elements of the program's first two stages were designed to effect a strategy with a proven track record against smallpox on the world stage. The third stage, on the other hand, fit with no known public health strategy; its benefit from a public health standpoint was therefore considered largely dubious. According to most experts, the most effective strategy to counter a verifiable outbreak of smallpox (even if only one case), was *ring vaccination*, also known as "trace vaccination" or a surveillance and containment strategy (Henderson et al. 1999b). Such a strategy had been utilized effectively, more often than not, not only to control outbreaks of smallpox when the disease was endemic to many areas of the world (primarily before 1970), but to eradicate worldwide the disease itself (Fenner et al. 1988).

The principal features of ring vaccination include: (a) Surveillance for first signs and symptoms of smallpox-related illness, which by 1975, when smallpox was receding, meant surveillance for rashes; (b) if unknown initially, identification and isolation of "index" (first) cases, a task usually carried out by field epidemiologists, infectious disease specialists, public health personnel, or healthcare providers with similar or related credentials; (c) contact tracing of the index case (i.e., investigating who the index case came in contact with; often this would include family members, friends, and other community members); (d) pre- and post-exposure vaccination to all such individuals (whether given pre- or post-exposure is often a matter of speculation; (e) in the case of smallpox, post-exposure vaccination does provide some protective benefit if given within a specific window of time); (f) additional vaccination for individuals who may have come in contact with the previous group of presumably exposed individuals (and so on, and so on), thereby creating a "ring" of protected individuals around individuals known to be exposed to the pathogen; (g) if deemed necessary, vaccinations of yet additional rings; and (h) continued surveillance of all said individuals (and/or specific signs/symptoms within specified geographic areas, up to and including entire countries) to monitor for

additional outbreaks (with a new round of ring vaccinations should it be called for).[4]

Amongst other things, it is by virtue of smallpox's various characteristics that a strategy of ring vaccination has proven most successful historically. In the context of the SVP, stages 1 and 2 – and contemporaneous efforts to dilute extant (dry) vaccine to increase the number of available doses – were to be implemented as a way to make a strategy of ring vaccination *possible*. In previous decades, smallpox campaigns were conducted not only with already-immunized vaccinators, but with some semblance of an infrastructure either planned for or in place (trained personnel, a secure supply chain, planning activities, a funding stream, etc.), as well as a global population with a fair degree of native immunity and prior exposure to the pathogen.[5] These conditions proved necessary to allow for the development of the ring vaccination strategy, which otherwise would likely have been ineffective and rather dangerous for ostensibly unprotected vaccinators. Because the situation in 2002, when these strategies were debated once again, looked much different than thirty years earlier, public health experts found that to incorporate the proven ring vaccination approach would require a kind of preliminary step-- that is, the development of an initial "pre-" strategy so that the "actual" strategy, the desired, primary strategy of ring vaccination, could be carried out if needed. This pre-strategy was to be actualized – at least in part – with the implementation of the first stage of the SVP.

Program Implementation

The CDC began shipping vaccine to states – that is, to states that specifically requested it – in late January 2003, about one month after the president's announcement. Although the timetable for the program called for half a million doses of vaccine to be given within 30 days, official records indicate that at nearly the one month mark, only 7,000 doses had been administered. Within a few weeks of this point, that is, by early- to mid-March 2003, the Administration in conjunction with the CDC announced that the "so-called" stage 2 of the SVP would commence immediately – despite the fact that stage I had missed its target, in terms of sheer numbers of individuals vaccinated, by nearly two orders of magnitude. With the commencement of the next stage, vaccinations were to be opened up to a whole range of first responders across the health

[4] The most authoritative source regarding the effectiveness of the ring vaccination approach (for smallpox) is Fenner et al. (1988), noted above. Other sources discussing the ring vaccination strategy include: Committee on Infectious Diseases (2002); Bozzette et al. (2003); Kretzschmar et al. (2004); Porco et al. (2004); and Pourbohloul et al. (2005).

[5] Public health experts suspect that immunologically "naïve" populations – that is, populations with little or no prior exposure to smallpox – would be particularly susceptible to the disease, both in terms of acquiring it and its severity.

and public safety domains, including firefighters, EMTs, police officers, and additional hospital personnel.

In February, reports began to surface that the program was being hampered by the lack of an effective compensation plan in cases of vaccine-related injury. The initial thinking at the Department of Health and Human Services (HHS) was that compensation-related issues for (essentially inevitable) claims of injury would be handled by State Worker's Compensation programs. Such thinking solidified the program's orientation towards specific occupational groups (healthcare providers), effectively framing a hybrid national security-public health policy – or at least a substantial component of it – as an occupational health issue in practice. Yet by relegating vaccine injury compensation to a highly variable set of Worker's Compensation programs, many of which were resistant in covering smallpox vaccine injuries, federal officials essentially construed injury compensation not as integral to the smallpox vaccination enterprise, but rather as a hindrance to it – for which, it should be added, the federal government should not be responsible.[6] As no additional bioterrorism monies were initially appropriated for the program at the federal level either for compensation or implementation, the SVP also effectively took on the contentious status of an unfunded mandate.

By March 2003, reports began to surface at CDC that a range of cardiac conditions were appearing amongst some vaccinees (CDC 2003d). Despite expert pronouncements regarding the doubtfulness of a link between the vaccine and the cardiac events, the ACIP revised its recommendations. Its updated recommendations accounted for cardiac risk factors in substantially more depth. Exclusion criteria for the program continued to grow.

Already in February a few adverse events had been registered, but the numbers compounded the following month in both the civilian and military programs. Initial cardiac-related adverse events included myocardial infarction (heart attack) and acute angina, although officials would emphasize that pre-existing risk factors (for heart disease) were in evidence for the individuals in question (CDC 2003c). Such statements, articulated as a kind of "the-vaccine-had-nothing-to-do-with-it" message so often found in immunization debates, did not help their cause. Wary healthcare providers, who had through their unions and professional associations voiced some concern early on in deliberations about smallpox vaccination, were to become full-fledged skeptics – essentially vaccination opponents – within the span of a few months.[7] That such

[6] See Strongin and Salinsky (2003) for a discussion of early thoughts on issues related to compensation and liability.

[7] In California, the California Nurses Association and the Service Employees International Union actively sought to discourage their respective memberships from agreeing to vaccination, did several local public safety (police, fire, EMS) unions. Opposition quickly materialized across local, state and national organizations.

developments may not have been foreseen is an important finding, especially as a number of these groups had begun voicing concerns along these lines in preceding months.

Subsequent and largely unexpected adverse events, which would ultimately garner more scrutiny amongst medical experts, chiefly included myo/pericarditis – most simply understood as inflammation of the heart muscle (CDC 2003d). Although by this time (March-June 2003) the rate of vaccine recipients reporting adverse events appeared to be on the downswing, the announcements by the CDC, coupled with well-publicized expert articles and reports as well as a flurry of media activity, presaged at the very least a virtual, if not the official, end of the program in subsequent months. By April, a growing number of states had begun a "programmatic pause" in order to take stock of the incidence of adverse events (ASTHO 2003a); six months later almost twenty states would report this status (ASTHO 2003b). Also in April, a military reservist was reported to have died following vaccination with both smallpox and anthrax vaccines. At year's end, roughly 39,000 individuals had been vaccinated. Distributions, at least by mid-year, were heavily skewed: about half of all vaccinations occurred in eight states, and almost half of the hospitals which had begun vaccinations were located in only seven states (GAO 2003). The program has essentially remained at a standstill since that time.[8]

Depending on which accounts one reads, the SVP was either successful in achieving its goals, or it was a near-total fiasco, conjuring up uncomfortable images of the ill-fated Swine Flu Immunization Program of 1976.[9] By the CDC's reckoning, the program essentially produced a sufficient number of immunized healthcare workers to mount a credible response to a smallpox outbreak in the United States, despite the fact that the target number of immunized individuals was not reached and that, as often emphasized later in the program, numbers did not equate with preparedness. It also, according to the same officials, successfully fed into a larger, if different, orientation towards preparedness, in the sense that many of the professional skills, organizational capacities, written protocols, organized exercises and the like, particularly at state and local levels, were seen to have some crossover potential for other, non-smallpox related public health crises. The specifics of these crossovers – what had begun to be known as "dual use" within the public health community – had powerful political appeal; after all, who would not want to support programs and infrastructure for public health aimed at both naturally-occurring and intentionally-caused disease outbreaks? Still, as the Institute of Medicine (IOM 2005) would

[8] It is notable that the program technically still exists, although between mid-2003 and mid-2005, when the latest round of numbers were reported by the states, there was little if any change in the number of individuals vaccinated (data available at www.cdc.gov/od/oc/media/spvaccin.htm)

[9] Excellent references on this fascinating subject include (GAO 1977; Neustadt and Fineberg 1978; Silverstein 1981; Neustadt and Fineberg 1983).

repeatedly point out both during and after the SVP, the devil was in the details, and in instituting the program some details proved tricky to discern.

Contexts

By the early-, and no later than the mid-1990s, specific concerns about the overt and covert use of biological weapons, and related worries about the more general category of weapons of mass destruction (WMDs, of which biological weapons are usually considered a part), had been aired amongst experts and in the legislative and executive branches of the government. Similarly, the issue of terrorism, independent of the problem of WMDs, per se, had been on the radar screen for a number of years. Congressional hearings had been held, high-level meetings put together (Miller et al. 2002), and executive orders issued – all with a focus on addressing the confluence of events and trends increasingly viewed as constituting specific threats to the United States.

The histories of these early events and trends is well-documented, and has generally been tracked along four major lines (Henderson 1998; Alibek and Handelman 1999; Lederberg 1999; Tucker 1999; Henderson 1999a; Henderson et al. 1999b; Smithson and Levy 2000; Chyba 2001; O'Toole 2001; Miller et al. 2002; IOM 2002b; Guillemin 2005). These include: various international geopolitical developments and their effects (e.g., developments in Russia, including the revelation of a massive illegal bioweapons development and production program, displacement and migration of bioweapons scientists and the uncertain disposition of biological agent stockpiles; and increasing international suspicion, borne out, regarding bioweapons development in Iraq), terrorist activities (e.g., the 1993 World Trade Center bombing; the 1995 Federal Building bombing in Oklahoma City; and the 1995 Aum Shinrikyo attack on the Tokyo subway using chemical weapons – and attempted use of anthrax; and suspected Islamist fundamentalist activities aimed at acquiring biological weapons); concerns about emerging and reemerging infectious diseases, including food-borne diseases, antibiotic-resistant bacteria, and the possibility of pandemic influenza; and finally, ongoing concerns about laboratory safety and later on, the transfer of dangerous pathogens.

During the latter half of the 1990s, many of these concerns solidified, particularly as notable experts in fields such as public health and infectious diseases began to speak up publicly and forcefully not only about the risks posed by certain organisms or diseases, but in particular about how vulnerable the US was should any number of these appear in an immunologically-naïve and infrastructurally weak society (Henderson 1998; Tucker 1999; Henderson 1999a; Osterholm and Schwartz 2000). As larger-than-life figures such as D.A. Henderson and Joshua Lederberg made the rounds in Washington, government officials began to think about the problems of infectious disease and

bioterrorism as constituting two sides of the same coin. So too did legislators (and importantly, their staffers) sitting on Congressional committees with oversight in these areas.

In the years approaching the millennium, discussions in expert and policy forums about the future of infectious diseases explicitly began incorporating language covering both "natural" diseases and agents, and their intentionally-released or otherwise engineered counterparts. "Bioterrorism" thus gained substantial currency as a concept within an increasingly congruent set of (previously disparate) discourses, located principally in the infectious disease, public health, and increasingly, various security-related communities. The term also came increasingly to be seen as more insidious, and more likely, than its (nation-) state-centered analogue, biological warfare (cf. Lederberg 1999; Tucker 2000).

This increased emphasis on the multiplicity of "threats" posed by infectious diseases was accompanied by a relatively new strategy within public health circles. Under this strategy, public health would begin to concern itself with both routine, everyday public health matters *as well as* conceivable, but largely uncommon public health emergencies, utilizing the same sets of practices and techniques. The core of the "dual use" philosophy, as such a strategy came to be known, was based in an understanding that most infectious diseases, naturally-occurring or intentionally-caused, presented from a preparedness and response standpoint similar kinds of problems requiring similar kinds of solutions. So, for example, although the diseases are distinctly different, a similar kind of infrastructure, requiring similar kinds of planning, community participation, personnel training, etc., would be required for both large-scale (yearly) influenza immunization campaigns, and for smallpox (Local official #1).[10] Or: the kind of work an epidemiologist does tracking and monitoring disease, noting any unusual spikes in incidence for diseases or sequelae, would have rough parallels for a range of infectious diseases, thereby qualifying that position for dual use (or bioterrorism-related) funding.

Early articulations of *bioterrorism (BT) preparedness*, ever attuned to the political attractiveness of a dual use (i.e., cost-efficient) strategy, gained some traction at the tail end of the 1990s. In 1998, the CDC had put together a document describing the agency's overall strategic plan to address emerging infectious diseases "for the 21st century" (CDC 1998). Although the plan mentioned bioterrorism (three times in a 74 page report), it was, with the benefit of hindsight, relatively scarcely addressed.

By 1999-2000, CDC had begun organizing itself to provide some supplemental grant monies to States for planning and other BT efforts (CDC official #5). A

[10] This claimwas strongly challenged by a former senior CDC official (CDC official #8).

variety of sources document the forms of social organization, the objects, the activities, and the interventions which were to constitute early BT preparedness efforts (O'Toole 1999; Strongin 1999; Henderson 1999d; Lillibridge 2000; Osterholm and Schwartz 2000; Smithson and Levy 2000; Lane et al. 2001; O'Toole 2001; Perkins 2002; Salinsky 2002a, 2002b; Bicknell and Bloem 2003; Crupi 2003; Lister 2005). The lists generated in these documents are roughly identical, and read like a laundry list of requirements to improve the invariably characterized "fractured," "deteriorated" or "neglected" US public health system. Areas of focus have usually included some combination of: (1) detection, surveillance and epidemiological capacity; (2) laboratory capacity and diagnostics; (3) training and education for public health officials, clinicians, laboratorians and other healthcare providers; (4) a fully-staffed workforce; (5) information and communication systems; (6) vaccine and medicinal stockpiling; and (7) (preparedness) planning, exercises and evaluations. Tying bioterrorism preparedness together would be the politically necessary and intuitively rational push for a "dual use" approach, thereby making such efforts ostensibly attractive to all stakeholders. As smallpox began to make its way to the surface of political and public health discourse as a problem in need of a solution, these efforts would be severely put to the test, although not, ironically, against actual cases of disease.

Chronologies, actors, and debates in smallpox vaccination thinking and policy

Vaccination policy in the United States is messy and not easily defined. One would not be entirely inaccurate to state that a coherent national vaccination policy does not exist now, nor has it in the past. Rather, much of what constitutes vaccination policy in effect is a set of regularly issued recommendations by the ACIP, a committee convened by the CDC every three years. The ACIP consists of 15 members specializing in public health, infectious diseases and related fields, who convene about three times a year to consider revisions or new proposals for the administration of vaccines to the public. Deliberations tend to focus on both routine, childhood vaccinations and adult and other at-risk vaccinations. It is not insignificant that the ACIP issues only advisory recommendations, or that, as an independent body of experts, it is linked organizationally to the agency to which it provides its advice: the CDC.

The year 2001 marked the publication, in June, of the first revision to the official recommendations for smallpox vaccination in ten years (ACIP 2001). These new recommendations covered new strains of *vaccinia* then being studied, and incorporated updated science related to the genus Orthopox since 1991. They also kept in place the target population for smallpox vaccination: laboratorians handling viral cultures. The stated reason for taking up the issue of smallpox

vaccination, according to the ACIP, is vague, having been afforded two sentences in a 25-page recommendation. The committee noted:

> Currently, international concern is heightened regarding the potential use of smallpox (variola) virus as a bioterrorism agent. Because of these concerns, ACIP has developed recommendations for vaccinia (smallpox) vaccine regarding the potential use of smallpox virus as a biological weapon.

More notable was the recommendation's treatment of smallpox vaccine as an element of bioterrorism preparedness. The committee began by remarking that an intentional smallpox release was unlikely; other biological weapons were considered more likely to be utilized – it is not clear by whom – owing to their availability.[11] The ACIP indicated a certain sense of unease regarding this small likelihood of the appearance of smallpox. It was uneasy in part because quantifiable estimates were unavailable in the public domain, although the language used by the committee to describe this lack of needed information was open to a variety of interpretations. The committee wrote: "The risk of smallpox occurring as a result of a deliberate release by terrorists is considered low, and the population at risk for such an exposure cannot be determined" (ACIP 2001). This statement is telling: it is not clear whether the committee could not, through the scientific and technical means available to it, come up with such estimates on its own – or whether such information could not be provided to them by others with such information at their disposal.

The resulting recommendations were understandably cautious, especially in the context of a deliberate release. Having virtually no quantifiable information regarding risks of outbreak or exposure, the committee recommended a no-vaccination policy (other than laboratorians) during what it called the pre-release/pre-exposure stage. Such a "stage," of course, described the state of world at that point, as it does today. In other words, a pre-event stage obtains by default and in perpetuity, unless the disease is actually known to occur (which, in the case of smallpox as with most bioterrorism agents, it has not). Holding to the view that a positive recommendation for vaccination could only follow from identifiable increases in (quantifiable) risks or (qualitative) threats, the ACIP did indicate its willingness to reconsider its position. However, the language indicating this contingency was vague and imprecise: "If the potential for an intentional release of smallpox virus increases later, preexposure vaccination might become indicated for selected groups (e.g., medical and public health personnel or laboratorians) who would have an identified higher

[11] Such a statement was a remarkable anticipation of the dispersion of anthrax through the US Mail only four months later, although it is debatable whether, at the time, smallpox was considered by experts outside ACIP to be less likely to be employed for nefarious purposes than other agents.

risk for exposure because of work-related contact with smallpox patients or infectious materials" (ACIP 2001).

In the event of an intentional release – in other words, shifting now to a post-event/post-exposure context – the ACIP essentially laid out two recommendations. On the one hand, it provided its first indication to the public that the vaccination strategy most appropriate in such an instance would be the tried-and-true ring, or trace, approach. Taken in the context of debates then starting to swirl around appropriate vaccination strategies, it is important to note that the recommendation for this approach was unequivocal. Such a strategy had, of course, proven extremely successful on a worldwide basis some thirty-plus years earlier, when the world's smallpox eradication campaign was in full swing. On the other hand, the committee recognized that, in addition to vaccinating the contacts around infected individuals, a whole host of people in all sorts of occupational groups related to and supporting healthcare and emergency response functions would probably have to be vaccinated as well. "Probably" because the committee only equivocally indicated vaccination for certain groups, including "law enforcement, emergency response, or military personnel" (ACIP 2001). In thinking through this latter recommendation, the committee indicated that in the event of an outbreak, an immunologically-naïve population – which of course includes the very people who will be drawn upon to handle the healthcare and emergency efforts needed to fight it – would be much more susceptible, or vulnerable, to infection than a similar, but relatively more immune population in years past. Consequently, a kind of "crash" vaccination effort would likely be called for.

These early recommendations are notable for a few reasons. First, absent from them is any mention – yet – of a strategy, or the conditions necessitating a strategy, for universal vaccination. This may largely be explained by the availability of vaccine at the time (approximately 15 million doses), which precluded the possibility of physically vaccinating the entire vaccine-eligible population of the United States. In fact, the available supply of vaccine strongly constrained the options the ACIP and other government officials were initially to consider. However, because production of additional vaccine was already underway, and pressure to produce even more was reaching the higher echelons of HHS, it is still reasonable to ask how it came to be that universal vaccination received very little serious discussion – let alone an actual recommendation – in ACIP meetings between 2001 and 2002. Second, although bioterrorism preparedness efforts had gained traction and funding in the years preceding 2001, such developments had little to do with the ACIP. Consequently, this advisory body was neither directly influenced by nor beholden to such a strategy, especially in the middle of 2001. No reference was made to preparedness of any type – bioterrorism, smallpox, public health – in the June 2001 recommendations.

There is no small irony in the fact that the June 2001 recommendations seem to have been considered insufficient by the Administration, particularly as the aftershocks of 9/11 rumbled through Washington and anthrax spread through the mail. Although the recommendations explicitly referred to the need to protect various personnel "if the potential for an intentional release of smallpox virus increases," the specific details of what a vaccination program should look like in just such an instance were deferred in favor of general indications regarding populations that might need to be vaccinated. Clearly the ACIP was not itself sure of the specifics of such a plan, and there is some indication that members of the committee were hesitant to put forward any more detailed recommendations, especially for pre-event vaccination. The ACIP would get a chance to reconsider their recommendations within one year's time.

In October 2001, anthrax spores were dispersed through the US Postal Service. A number of commentators were quick to heap scorn on HHS and the CDC both for failing to respond to the threat in an appropriate manner, and for ensuring that local public health officials and the public-at-large walked away from their press conferences bewildered and confused. It was a rough time at CDC, by the Director's own admission (Gerberding 2003).

Undoubtedly, the anthrax attacks, occurring in the context of various domestic and global developments, constituted a catalyst for immediate action on the part of federal health authorities and the legislature. The vastness of the effort and the speed with which changes occurred were extraordinary by virtually any measure, and unique in modern US history.[12] Unfortunately, there is little documentary evidence describing how the White House and HHS came to the conclusion that the CDC, and ultimately ACIP, should reexamine smallpox and possible vaccination options... again. For most healthcare practitioners and public health experts, it was not obvious that, by virtue of the release of anthrax through the mail – let alone the events of 9.11 – the risk of smallpox (i.e, through an intentional release) had increased, necessitating updated recommendations. Even at the tail end of the anthrax events in November 2001, the CDC saw no pressing need to consider vaccinating local public health officials, front-line medical personnel or first-responders; the agency's senior advisor for smallpox preparedness, Dr. Harold Margolis, noted when asked by a journalist that such thinking – what would eventually constitute Stages 1 and 2 of the SVP 15 months later – was at the time "not part of the [current] strategy" (CDC 2001b).

[12] One important measure of this activity is, of course, funding. Overall spending for civilian biodefense at HHS jumped greater than one order of magnitude in the span of one year (2001-2002), from $271 million to nearly $3 billion. With a few programmatic and line-item exceptions, this level of funding was sustained, and in fact supplemented through the 2005 fiscal year. By that point, funding for biodefense and preparedness across all federal departments had come to about $7.5 billion per year (Schuler 2005).

As for *Cabinet-level deliberations* on the matter of biological threats, there is little in the public record documenting the ways in which smallpox or other biological agents were considered by the Administration during this time. Interviews with public health officials at CDC and ACIP, on the other hand, suggest quite strongly that, within the executive branch, concerns about smallpox were problematized in the context of concerns about Iraq: respondents consistently reported that the threat of smallpox, in a general sense, was linked to specific information about the possibility that Iraq might have or use biological weapons in what was beginning to look like a likely war in the fairly near term.

In February 2002, HHS, at the behest of senior CDC officials, formally requested that the ACIP take up the issue of smallpox vaccination once again (IOM 2002a). According to a senior CDC official, the administration had already decided to institute some kind of smallpox vaccination program, and apparently had some sense about the scope of it; the idea, then, seemed to be to involve ACIP as a conduit for public input into the already-decided-upon program – without, however, indicating to the public that such a program was definitively in the works and essentially inevitable. The following statement is informative about this process.

> When the committee was engaged around smallpox in terms of a smallpox program, I mean there's I don't think any secret about the fact that that was brought before the committee by [HHS] on behalf of the Administration. I mean, you know, a decision had been made at the highest levels of government that we were going to have a smallpox vaccination program [in early 2002]. So, at that point, the parameters became pretty clear, and the committee handled it as well as they could. They recognized that there was a determination by the Commander-in-Chief, the President of the United States, and his closest advisors, that they wanted to have a smallpox vaccination program based on whatever intelligence they had. And consequently, what we advised, and the Administration followed it, was "okay, maybe you want to have a program and maybe it should be as large as you're talking about, but how about going ahead and using your standard immunization advisory committee to consider the issues, and put it through the regular channels with public meetings and opportunities for public discussion… (CDC official #1)

A cynical read of this statement would be that the ACIP was asked to rubberstamp a public health intervention, desired by the White House on the basis of national security considerations, that was going to go into effect one way or another. A conclusion of this nature is speculative. On the other hand, a

critical read of the statement should help to explain the growing unease felt by many ACIP members: US Commanders-in-Chief are not supposed to will into existence public health programs; rather, they command the nation's military forces. As one former ACIP official noted in an interview, to some extent ACIP is constituted precisely to validate the overseeing agency's (i.e., CDC's) "agenda", suggesting, in the context of smallpox, that this occurred to some degree.

The campaign by which ACIP undertook to solicit public input on the issues surrounding smallpox vaccination was unusual. The committee, in concert with the CDC, held four meetings throughout the country between June 6 and 11, and invited the Institute of Medicine (IOM) to convene an additional meeting on June 15, focusing on the "scientific, clinical, procedural and administrative aspects of various immunization strategies" (IOM 2002a). The information gleaned from this meeting, which included detailed models of hypothetical smallpox outbreaks and various vaccination options, was to be presented to the ACIP's special session on smallpox vaccination options five days later.

The meeting transcripts of the ACIP meeting, held June 19-20, 2002, in Atlanta, provide two sets of rationale for revisiting the smallpox issue. The document notes that "[t]here is no indication the threat has increased since the September 11 attacks, but the perception of risk has [increased], and it is known that the U.S. is vulnerable to enemies with such an attack capability" (ACIP 2002b). The committee's remark about increased perceptions of risk is curious, in part because the committee does not articulate who these perceivers of risk are, and in part because it is the committee that typically makes such determinations. Whatever the risks were, it is clear the ACIP was frustrated that it did not have the means to "know" them the way other government officials "knew" them. Note, for example, the following:

> To make… decisions, the ACIP needs data. Those on vaccine efficacy and safety are in hand, but not for the risk of disease. Does anyone have more information on this that they can share? Without it, should the ACIP even make this decision without that information? Doctor Modlin stated, according to the best information published, presented at meetings, and discussed by Doctor [D.A.] Henderson and others, that ACIP was unlikely to have better estimates of risk than it now had. A higher-level briefing arranged for Committee members may be possible, but he thought that such would be unlikely to alter any decision reached on this day… Some information inappropriate to share in a public forum could be provided, but the bottom line would be the same as the message being received here today. The CDC Director would not place on this Committee the burden of making a risk assessment. The members were informed as best as

> possible under the circumstances that the risk is not zero but is perceived to be low. (ACIP 2002b)

The second rationale indicated by the committee is equally as telling. For some years, experts had begun formulating the dangers of bioterrorism and other "non-conventional" threats utilizing a conceptual schematic other than risk. Utilizing techniques such as scenarios and exercises, the dangers of these agents were linked, conceptually, to the capacities and capabilities of the very public health infrastructure expected to detect, track and respond to them. In June 2001, a key exercise called "Dark Winter" called attention to precisely these capacities and capabilities – or the lack thereof. Sponsored by a central player in bioterrorism preparedness circles, the Center for Civilian Biodefense Strategies at Johns Hopkins University, the scenario was intentionally grim: a smallpox epidemic caused by release of the agent in three shopping malls across the country (O'Toole et al. 2002). The fictitious outcome of the exercise was disasterous: the US faced utter catastrophe given its (then-)present public health infrastructure. The *real* result of the exercise, however, was that public health *vulnerabilities* became widely publicized, both amongst national security types and throughout the public health establishment. As the ACIP came to consider the next round of smallpox vaccination options, the stage had therefore been set to construct a problematic of bioterrorism in which *vulnerability* had guided the logic of response as much as any specific, identifiable *threats*.

The ACIP's June 2002 deliberations were oriented around three main questions: (1) Should the general population be vaccinated?; (2) Which occupational groups should be vaccinated?; and (3) Is ring vaccination the most desirable post-event strategy? The committee transcripts provide an excellent window onto the major areas of deliberation. From the outset, debates about appropriate vaccination strategies were centered on a precarious policy equation: what is the appropriate balance between the benefit derived from vaccination and the risks of vaccination? "Equation" is the precise terminology here, as the committee's decisions were largely oriented around what was ultimately a cost-benefit analysis. Under such a structured calculus of decision-making, a number of assumptions had first to be determined in order to generate any kind of workable policy model. These included: initial attack size (how many individuals initially infected); the "reproductive rate" (how many additional persons infected from the initially infected case; additional rates possible for later "generations" of infected individuals); vaccine efficacy rate; vaccine-induced mortality rate; and various probabilities of release and of exposure (for certain models). Once the models were in place, the committee had a concrete set of options from which to work.

The meeting transcripts of the June 2002 ACIP meetings also indicate, along with the IOM meetings and subsequent report, that a strategy of universal

vaccination was never seriously entertained as a possibility by a critical mass of decision-makers in either a pre- or post-event context. More accurately, the former was ruled out entirely (it was not even an option to the question about whether to vaccinate the general population, pre-event), while the latter was understood to be conceivable as an option only in the direst of circumstances.

In contrast to its recommendations a year earlier, the ACIP's demonstrably conservative approach was held in check somewhat by a push to vaccinate members of certain occupational and professional groups in addition to laboratory workers already handling orthopox viruses. Which groups was a matter of some debate. Some argued that "pre-designated" healthcare providers in relevant occupational and professional groups should be considered for vaccination; it would be such individuals, after all, who would respond and therefore be exposed during an outbreak. Others suggested that a variety of "responders" of all stripes and sizes should be given consideration, beyond an emphasis on designated smallpox response teams specifically, or (specified) healthcare providers more generally. Cogent arguments were made all around, and debate was apparently passionate (CDC official #1). Ultimately, the ACIP honed in on members of outbreak response teams at federal, state and local levels, as well as some hospital healthcare providers (at predesignated smallpox receiving hospitals), to receive the vaccine.

Around this time, the first salvos in a war of numbers erupted, specifically over how many individuals were to make up the two broad groups of professionals for whom the vaccine was recommended. In a press conference announcing the ACIP's recommendations, Chairman John Modlin noted that somewhere between ten- and twenty-thousand individuals would be vaccinated. A few weeks later, two Administration officials made estimates well over an order of magnitude higher than that. Respected smallpox expert D.A. Henderson, and Jerome Hauer, both senior officials at HHS, mentioned a number – five hundred thousand – around which an inordinate amount of debate would subsequently revolve. It seems clear from this alone that the advisory committee and the Administration had two very different views about what a smallpox vaccination program should look like. Information elicited from various officials supports this interpretation (CDC officials #3, #6 and #8; ACIP member #1). The administration made no secret over its disappointment with the ACIP's June recommendations, at least in private. In public there was simply respectful disagreement, but no one involved had any illusions about the extent of ACIP's reach: it was an advisory committee only, and its recommendations went to the CDC, not to the Cabinet.

The main source of disagreement voiced publicly had less to do with envisioned smallpox response teams – there was general agreement on that account – and more to do with which hospital healthcare providers should be vaccinated. The ACIP had based its recommendations on the notion that

infected individuals or suspected cases would report to hospitals designated by state officials in their respective, and in some cases not-yet-formulated bioterrorism response plans. In effect, only a small percentage of hospitals in any given region were expected to be so designated; consequently, a figure averaging around 15,000 in total was aired as the number of individuals likely to be called upon to be vaccinated (voluntarily, of course). Importantly, such assumptions were based upon projected vaccination rates vastly higher than what would ultimately be the case.

Critics of the recommendations pointed to what were felt to be flawed assumptions about how potentially infected individuals were expected to behave in an emergent crisis. Specifically, it was noted, with supporting evidence provided by the events of 9/11, that sick individuals tended to go to the nearest hospital. The implication was that every hospital was vulnerable precisely because the entire population was, in effect, vulnerable as well (both in the sense of being immunologically naïve and because smallpox could appear and reappear anywhere in the country). The ensuing logic is not difficult to follow: because of this, select healthcare workers at every hospital in the United States should be vaccinated. Hence, the 500,000 number.

Although this number followed an internally consistent logic, it is remarkable that there is little evidence in the ACIP transcript record indicating that anywhere near that number would actually agree to, or demand, vaccination. To the extent that this issue was discussed in public deliberations, it was heavily moderated by concerns (especially amongst physicians and other healthcare providers) about the conditions under which such vaccination should take place. In interviews, CDC officials noted that adequate discussions regarding "the public," including which groups were presumed to constitute this public and which amongst these were envisioned to be willing vaccine recipients, had been largely understudied and underdiscussed during the bulk of CDC/ACIP work on vaccination strategies and recommendations (CDC officials #1, #3, #8) Although studies would later indicate a general willingness amongst specific healthcare providers to be vaccinated (Yih et al. 2003), post-SVP surveys found this not at all to be the case: rates of *actual* vaccination were substantially lower than *expressions of willingness* to be vaccinated (GAO 2003; Kemper et al. 2005; Taylor et al. 2005; Wilson 2005).

Throughout the summer and into the fall of 2002, the ACIP continued to work on the smallpox problem. According to one member of the committee, when word got to the ACIP that the Administration was honing in on 500,000 vaccinees, a number of individuals on the expert panel became very nervous (ACIP official #1). The Dryvax vaccine had, of course, known side effects, and estimates of illness and injury associated with the vaccine had been well-documented in the medical literature for several decades. One source of unease on the part of some ACIP members and CDC officials had to do with

what was seen as the inevitability of injury from the vaccine alone – without a single case of smallpox in the population (CDC official #8). Although few, if any, explicitly invoked the language of medical ethics in working through such a vaccination strategy, it is clear that the risk/benefit calculus adhered to by members of the public health and health policy communities was governed by an ethics which tolerated vaccine-induced illness only in certain contexts, none of which included zero-incidence of disease in the population – let alone the world.

It was in light of these debates that in October 2002 the ACIP, in an unusual move, amended the smallpox vaccination recommendations it had made stemming from its previously held (June) meeting (ACIP 2002a).[13] Recall that the latter meeting produced a general recommendation regarding the vaccination of select healthcare providers at a small number of hospitals envisioned to receive smallpox patients. By October, the committee had decided that *all* hospitals were at some risk of smallpox exposure (because all individuals were at *some* risk), and therefore up to two "teams" of healthcare personnel at each hospital should receive the vaccine. Other modifications to the recommendations focused on which occupational groups should constitute a hospital response team; a determination of contraindications for individuals with skin problems, as well as immunocompromised states; and various other clinical and procedural issues.

The October recommendations provided the first clear indication that the ACIP had begun to align its thinking towards some kind of "preparedness" rationale. In the context of smallpox specifically, it is not altogether clear, but it is unlikely that such a rationale had been substantively circulated as the principle logic guiding public health authorities, nor was it ACIP's job to do so. Or was it? The kind of preparedness the committee seemed to have in mind shifted away from the "out-the-door" response approach that the CDC had planned for a year earlier, and which reflected the *modus operandi* of the agency's well-known Epidemic Intelligence Service. Instead, the committee focused on building out capacity to respond at a national level; that is, on laying a foundation across the nation, irrespective of greater or lesser risks to any one region or city, aimed at establishing an in-place infrastructure of trained, already-vaccinated personnel. Chairman Modlin noted in an October press briefing the following.

> In order to minimize the clinical impact of inadvertent inoculation, should it occur, the ACIP recommends that all persons who administer smallpox vaccine be vaccinated beforehand. Vaccination of this group will also contribute to preparedness for

[13] The October recommendations are no longer available as they were modified in an April 2003 publication. A summary of the October recommendations can be found at www.immunize.org/acip/acip1021.pdf

> smallpox response. Should smallpox release occur, the development of a cadre of vaccinated, experienced vaccinators who could immediately be deployed for outbreak response. (CDC 2002)

This early formulation of what should constitute smallpox preparedness (as opposed, importantly, to bioterrorism or general public health preparedness) did not, notably, hone in on specific numbers of individuals envisioned or expected to be vaccinated. More to the point, the by-then-famous 500,000 number had been deemphasized as a standard to be met by state and local officials. Rather, the number was viewed as something of a best case, should a certain number of healthcare providers, say 100 per acute-care hospital in the US, be vaccinated. The following comments by the ACIP Chair and by the Director of the CDC's National Immunization Program (NIP), Dr. Walt Orenstein, illustrate these tensions in a telebriefing to the press.

> DR. MODLIN: … [T]he objective of our recommendations is to assure that there are an adequate number of health care workers to provide care for the first wave of smallpox victims and that we are not focusing on a specific number, a target number of individuals to be immunized, but rather the objective is to identify and to suggest that there be a sufficient number of health care workers in different categories that we've just talked about to provide care in many, if not most, of the acute-care hospitals in this country. It turns out there, there are approximately 5,100 acute-care hospitals in the United States, and if--a big if--all of them were to take part in this program, we would estimate that there might be roughly, and I want to emphasize very roughly approximately 100 health care workers into those hospitals that might be needed to be vaccinated in order to meet that objective, and so if you do the math, that number comes up to about 500,000 health care workers. However, we fully intend that there will be considerable differences between, and different needs, and different assessments of needs of numbers of health care workers from hospital to hospital and from location to location, and we intend that there be some flexibility. It may very well be that it's far better to leave the decision, in terms of the actual number of health care workers in any one hospital left up to not only the local public health authorities, but the people who are ultimately making the decisions in those hospitals themselves. They know their staff far better than we do.
>
> DR. ORENSTEIN: I just want to emphasize, again, the goal is a cadre of people who could care for the first several patients in the first seven to ten days on a 24-hour basis. Hospitals have a lot of

> experience with figuring out what staff they need to care for patients who would be in isolation rooms with negative pressure, and so that's why we're a little uncomfortable with trying to name an actual number for you; that, in fact, the number will come from the hospitals if they decide what staff are needed to cover these patients… (CDC 2002)

Officials at HHS, who only a few weeks previously had floated a number on the order of 10 million or so, must not have been all that pleased with a joint-announcement that numbers were *not* what was important in putting together a smallpox vaccination/preparedness program. Clearly, the basic question of what should constitute preparedness had not been resolved at the level of senior policy-makers; too many divergences still existed between those espousing a conservative, incremental approach based on a limited vaccination program, and those pushing for something much bigger. Despite claims to the contrary, the fight over preparedness was, at this stage at least, a fight over numbers. How else, after all, could preparedness be measured?[14]

Additional conflicts and ambiguities arose in other areas as well. A number of CDC and ACIP officials interviewed for this project have suggested in more or less unambiguous terms that deterrence – what one official described as taking the disease "off the table" (CDC official #8) – lay at the heart of the Administration's push to get smallpox vaccination up and running. With anthrax already "out there", a war with Iraq in the works (Woodward 2004), and a dawning realization that smallpox was one of the few Category A agents about which federal and public health authorities could actually do anything in an organized, concerted way, the line coming from the White House was that a vaccination program was not only prudent as a protective measure, but as a strategic deterrent as well. A few respondents have commented that the Office of the Vice President was particularly keen on such an approach, a finding that jibes with publicly-available reporting on the Administration's various positions with respect to war (CDC official #8).

For public health officials tasked with building out some kind of smallpox vaccination program, this orientation towards deterrence was wholly unfamiliar as a programmatic aim. In no way, according to respondents, did it look conceptually analogous to disease prevention, owing to the crucial difference that smallpox vaccination-- and hence a logic of deterrence – was sure to harm a small number of people while providing no quantifiable benefit recognizable as such by officials traditionally tasked with public health interventions. This outcome was unpalatable for a few senior and other CDC officials, who quietly resigned or were otherwise reassigned to non-smallpox-related tasks.

[14] This is precisely the question public health officials were grappling with; answers were, in fact, soon to be forthcoming.

As October and November came and went, there was a good deal of anxiety about what the executive branch – read: the President – would decide with respect to the scope of a smallpox vaccination program. The Dryvax vaccine had been relicensed by the FDA, allowing for more flexibility in its administration, and in addition the vaccine was licensed for dilution if necessary. Coupled with Aventis-Pasteur's (A-P) offer, accepted by the US, of additional (but old) stocks of vaccine, the country had substantially greater quantities of vaccine compared with just one year earlier. With dilution, there were enough doses of smallpox vaccine for everyone in the United States, with substantial room to spare. Acambis's vaccine, ostensibly a measurable improvement over both Dryvax and the A-P vaccine, had not yet even been included in the equation, although it, too, was beginning to be made available in large quantities, albeit (still) under an IND. With doses in these quantities coming "on line," the parameters for what (could) constitute an effective response as articulated in official discourse might have been expected to (actually) change the nature of the discussion, although as events were to unfold, it seems the initial orientation towards a limited pre-event vaccination program remained firmly in place.

December 2002 was a busy month for federal, state and local officials anticipating the announcement of some kind of smallpox vaccination program. It was in this month that the CDC requested, and received, virtually all of the United States' 62 public health jurisdictions' (states, territories and stand-alone urban areas) plans, first for mass vaccination programs for their respective populations, and then for what their pre-event programs would look like. There is some irony to the fact that pre-event plans were due to the CDC before any official announcement was made regarding the scope of the pre-event vaccination program being considered. As indicated earlier, however, the Administration's thinking on the matter, and its decision to press ahead, was not really a secret at DHHS or CDC.

States submitted plans that looked vastly different from one another. An online article in the excellent CIDRAP News (online) cited an Associated Press report indicating, for example, that Louisiana had plans to vaccinate upwards of 20,000 people, while Georgia submitted a figure two orders of magnitude lower (Roos 2002). Georgia, however, had a population roughly twice the size of Louisiana, and arguably possessed a metropolitan target (Atlanta) equally as attractive as Louisiana's Big Easy, New Orleans.

The very existence of "disparities" in numbers, types of personnel, which hospitals, etc., between states, provides a window onto an interesting tension in preparedness efforts – although by this I do not mean to suggest that the tension is limited to preparedness alone. The tension is this: does the constitution of a preparedness program require a kind of uniformity and standardization across spaces of activity (such as states), or can a logic of

preparedness entail a kind of flexibility that transcends, in this case, state boundaries and the political need to keep such states "equally" prepared? In a way, this tension does not, exactly, match the empirical case: there were no calls, per se, for states to meet some type of equal or proportionate level of preparedness; the discourse of public health was quite clearly demarcated by a devolution to states in matters pertaining to public health – and at this point, the vaccination program was very clearly kept within the machinery of the traditional public health apparatus. Consequently, the CDC deferred to states (and extreme variations in planning between them), approving or conditionally approving virtually every pre-event plan that came through its doors. Despite all this, the point remains: Could an emergent rationale of preparedness "map" onto pre-existing divisions, or units, where the activities and practices constituting it were to take place? That is, could there be a workable arrangement between the kind of preparedness rationale that was getting articulated, and practices based in traditional political-jurisdictional spaces (i.e., states, counties, etc.), where traditional public health was accomplished?

On a related note, one might ask whether at this point in the planning process, "preparedness" as it was being put into practice actually matched the nascent articulation of a necessary strategy to counter perceived vulnerabilities in the United States' public health apparatus(es). In other words, one might conclude that something of a disjuncture had begun to form between the notion of preparedness as an orientation towards an uncertain future (involving uncertain threats of uncertain magnitude and probability, but with various identifiable vulnerabilities to critical infrastructures already known), and the notion of preparedness as a kind of ramped-up public health program. In short, preparedness as articulated (whether BT or smallpox or under some other name) looked increasingly less like a newly emergent normative and technical rationality (which would guide practices and strategies such as vaccination, surveillance, etc.), and more like a beefed-up public health intervention.[15]

Vaccination recommendations, the ACIP and the risk/benefit balance

Although its multiple histories are too complex to delve into here, the nascent federal public health apparatus in the United States, having oriented itself towards communicable disease for much of its early history, found itself in a good strategic position by the early- to mid- 20th century to incorporate mass immunization as a technique appropriate to its charge. This coupled with the emergence of routine (typically childhood) immunizations opened up a space for those properly positioned to adjudicate its benefits, leading ultimately to a form of deliberation which would produce recommendations about which

[15] See Collier and Lakoff (2006) for a discussion of preparedness in this context.

vaccines should be given, utilizing which kinds of techniques and practices, and under which kind of schedule(s).

The initial use of vaccine in the United States was accompanied from the start by perceived needs to survey the extent to which certain communicable diseases were an "actual" problem, for example in a geographic area such as a municipality or a State, as well as the extent to which immunization would play a role in altering observable disease incidence in such areas.[16] These specific issues were raised in the context of intense controversies within the scientific and medical communities at the time regarding the utility of incorporating statistical measures into public health practice – itself a nascent field balancing the "old" and the "new" public health, as well as a divisive skepticism regarding the increasingly popular, and related, field of bacteriology with the germ theory of disease. As regards early vaccination efforts, most were assessed empirically through a kind of trial-and-error method, or through the reported observations of private physicians administering vaccines who, especially in the early mass vaccination campaigns of the 20th century (for example, utilizing diphtheria antitoxin), were relatively few in number and largely suspicious of public health and state medicine on the one hand, and rather revolutionary technologies on the other (Hammonds 1999). As statistical methods and the specialty of epidemiology gained a foothold in public health practice in the early 20th century, studies of the effects of immunization grew amenable to analyses incorporating these practices. While this did little to alter the likelihood that controversy or debate would accompany any given vaccine – the legacy of antivaccination movements still resonated amongst some parents, and physician-skeptics of vaccination were still vocal – it did change the character and the setting of these debates. Most notably, debates had begun to be cast as issues of *efficacy*.[17]

More importantly, perhaps, by the mid-20th century, the issue of *safety* had become an object of intense scrutiny as a matter of public health and immunization practice (Etheridge 1992). Specifically, although childhood disease incidence by this time had begun to wane substantially, just after mid-century newer vaccines – in particular the Sabin oral polio vaccine (OPV) – generated intense controversy as experts, clinicians, policy-makers and the public began to wonder whether (the risk of) *actively inducing disease* in individuals was worth the price of reducing or eliminating that disease – especially as compared with proven safer vaccines. For socially disadvantaged

[16] "Initial use" as discussed here does not include colonial or early American efforts at immunizing against smallpox through the practice of variolation. Unless indicated otherwise, "early" practices refer to practices subsequent to the emergence of bacteriology and the initial configurations of the "New Public Health" circa the turn of the century (see, e.g. (Rosen 1993).

[17] I use this term to indicate scientists' and practitioners' concerns about the effectiveness of drugs and vaccines; contemporary associations with the term (the FDA's mission and such) is not implied here.

and marginalized groups, angst over such decisions was considerably less apparent; prisoners and other institutionalized individuals had, of course, been routinely subjected to medical and pharmaceutical experimentation of all kinds, including disease induction and non-treatment. Nevertheless, as a matter implicating a much larger, and more socially accepted population (*qua* a statistically and socially defined population), the risk-benefit calculus starting to take shape *en masse* in the area of public health took on a specific form, namely, one built on an explicit acknowledgement that mass vaccination of the nation's yearly cohort of children could constitute a perpetually iatrogenic practice, sanctioned by a state- or quasi-state apparatus such as the CDC or the soon-to-be-formed ACIP.

The polio vaccine debates during mid-century were contentious, ugly and political, and lasted for years. The apex of the debates, which followed years of public barbs between two 'giants' of medicine, Albert Sabin and Jonas Salk, was precipitated by a particularly disturbing development, in which one of the manufacturers (producing the live vaccine) distributed a particularly virulent product; consequently, a large number of children receiving the vaccine contracted polio, many becoming paralyzed. Although arguments about the pros and cons of both the live and inactive vaccines had been going back and forth for some time – largely in the public's view – it was only at this point that the Surgeon General's office pressed hard for the creation of an "independent" body to adjudicate issues of safety and, eventually, recommend schedules for immunization. The Advisory Committee on Immunization Practices was formed in 1964, notably after the polio vaccine "crisis" was resolved amongst officials in Atlanta and Washington.

Of particular relevance here are the subsequent debates, some forty or so years later, around the exact same vaccines. Whereas at mid-century, polio was endemic in much of the world, including, technically, the United States, by the last quarter of the century disease incidence had declined dramatically. As very few cases of "wild" polio (as the naturally-occurring disease was known) appeared each year, the case was once again being put forward that recommending continued use of OPV was poor medical practice and, in fact, unethical. The chief tension in the decision calculus was: should a vaccine be recommended to continue preventing disease, when a) the disease in question was extremely rare; b) the vaccine being used unquestionably *caused* not just illness, but, in this case, *actual paralytic polio* <u>in more individuals</u> than those acquiring the "wild" type, and c) a safer vaccine existed, which did not cause the disease. Adding to the mix of what was already a complicated set of factors to consider, OPV was considered by a majority of practitioners and experts to be more efficacious in preventing polio than IPV.

The main point in illustrating this tension is to highlight the kinds of thinking to which the ACIP would orient itself in the coming years and decades. The

committee's "take up" of vaccine-related issues has hinged largely on the extent of disease in a population – and, crucially, the extent of disease projected for a population without vaccination. In other words, a fundamental variable – disease incidence – in the form of concrete numbers, or ranges thereof, formed the basis for generating calculations which experts then compared with alternative future possibilities, or scenarios: disease incidence without vaccine, numbers of likely side-effects, etc. Knowledge about disease incidence, potential disease incidence with and without vaccination, and likely side-effects, formed a "grid of intelligibility" (Dreyfus and Rabinow 1982), which tended to boil down to a numbers game: the most favorable numbers usually dictated the policy. The experts, in other words, were convened to produce (or solicit the production of), and then scrutinize, the numbers.

It is a matter of the utmost importance, then, in doubling back on this genealogical tracing – back to "the" problem of smallpox in 2002/2003 – that by virtually every account in the public record, there was no meaningful numeric estimate of the possibility of a smallpox release. To state it a different way, within the framework of understanding to which both health *and* security experts were accustomed, namely, through practices of risk and threat assessment, making sense of this specific danger through the meaningful production of (knowledge about) risk was impossible. "The threat is low, but not zero" constituted a novel and challenging presentation of risk, with which public health officials had little familiarity and virtually no expertise.

Diagnoses

The task of this chapter has been to present a select overview of the ways in which certain vaccination options became "thinkable," "knowable" and "doable" in the context of the emergence of smallpox as a contemporary biological threat, culminating in the Smallpox Vaccination Program. What remains is to make some sense of the observations presented, although not as matter of adding yet another pronouncement, or judgment, on top of the impressively large list of previous pronouncements (GAO 2003; Kuhles and Ackman 2003; IOM 2005; Wilson 2005), which, as far as they go, consisted of reasonably plausible explanations of the barriers to the SVP as conceived. What follows, then, are a set of provisional diagnoses out of which additional, explicitly policy-relevant interventions might be generated. These diagnoses are formulated along two general lines.

The first of these is what Luhmann (1993, 1998) has termed "second-order observation," which describes techniques by which an observer/analyst, through a kind of relentless, iterative process of engagement and inquiry in the field, produces a set of reflections on the broad set of assumptions and conditions which guide thought and action (by "first-order" observers) within

the field of activity under study. The practice of diagnosis is also informed by the work of Michel Foucault and other scholars who have taken up the notion of "problmatization" (Foucault 2006; Rabinow 2003; Rabinow and Rose 2003). In short, problematizations consist in "discursive and non-discursive practices that make something enter into the play of true and false and constitute it as an object of thought" (cited in Rabinow and Rose 2003, p. xviii). The following diagnoses are meant to provide a set of considered reflections on the emergence of recent smallpox vaccination thinking. This thinking constituted a central component of a problematization. This problematization can be engaged with as a set of related questions: Which practices provided a space to understand the disease as a certain kind of threat and not something else – employed, as they were, to generate the very possibility of knowing which responses were or were not possible?

Diagnosis #1

Far from being a kind of inevitable outcome of new and dangerous threats in the world, the previous sections have shown that specific practices related to vaccination, including recommendation practices grounded in specific techniques of calculation, lay at the center of experts' capacities to formulate a workable problematization of smallpox. Within the domains of public health and national security, similar kinds of techniques, including risk and threat assessments and risk/cost-benefit evaluations, are employed in such a manner as to estimate the likelihood and magnitude of future outcomes, as well as the extent to which proposed interventions would be favorable relative to their costs. This orientation towards what Lee Clarke (2006) has called "probabilistic thinking" has served a clear function in these and many other domains, namely, as a mechanism by which (ostensibly) to allocate scarce resources "rationally" to a variety of competing needs.

Much of what constitutes public health is built on this model, particularly as regards infectious diseases. As the risk of disease increases for a given population, various interventions are increasingly considered (possible), their costs and benefits weighed. If the likelihood of disease incidence, including an outbreak, rises, so too does the risk of not doing anything, according to the logic of the model just presented. In just such a case, benefits will tend to outweigh risks. Conversely, as potentially dangerous objects are transformed by these mechanisms of calculability and understood to be increasingly *less* likely, the costs associated with interventions tend to go up, often dramatically, while benefits – understood as averted, mitigated or treated cases of illness, or death – are either few and/or appear less likely.

For a host of reasons, the formulation of smallpox as a biological threat constituted a problematization of a particularly challenging type. It was, after all, a disease that had been eradicated some twenty years earlier. Its ontological

basis – that is, the conditions which facilitated its constitution through thought as a real object, let alone a real threat – was therefore grounded in a variety of elements apart from its actual observation. It came to exist as real by virtue of sets of (other kinds of) observations from which could be deduced its very possibility, not only as an object, but as a dangerous one at that. A crucial step in this process, it seems, lay in its transformation from a thinkable (dangerous) object, to one in which something like a "knowable" risk was attached. By knowable, I am referring to that which understands a thing by virtue of its potential to be, typically in terms of its quantifiable/quantified likelihood or probability. In this case, of course, the extent to which the risk of smallpox was quantified posed particular problems. "Low, but not zero" – the official *public* estimate of risk – came to take on a peculiar significance, and required a level of interpretation not typically found in most other systemic public health assessments. Such a risk was open to a number of interpretations. What is one to do – what is one *supposed to do* – with that kind of information? These are very separate questions, and the latter in particular – as a kind of reflexive ethical inquiry – seems not to have been central to vaccination deliberations. One might therefore feasibly hypothesize the utility of incorporating such a question into early decision-making activities.

A cottage industry of risk analysts, disaster preparedness experts, psychologists, and others have produced an array of theoretical work and conceptual grids around the issue of low probability-high consequence events (see, e.g., (Kunreuther 1992), for an excellent primer on the topic). The concept did not appear with smallpox. Nevertheless, it appears that part of what came to constitute smallpox as a threat to be dealt with had very precisely to do with its formulation in these conceptual terms. Since the risk of smallpox given was extraordinarily, even unquantifiably, low, the conditions for producing any meaningful understanding of the benefits of a public health intervention (i.e., vaccination) became uncomfortably narrow. How, in the context of the public health "system" (again in the Luhmannian sense), could there be any meaningful conceptual grasp of the benefit of vaccination, when, according to the very techniques of that system, there existed, by definition, virtually no risk? At its most extreme, and to be fair it was not articulated as such, pre-event vaccination could be construed as all cost and no benefit.[18] As strategizing about smallpox vaccination options got underway, all that was certain was that, given the implementation of *any* pre-event vaccination program, some (probably small) number of individuals was going to get sick from the vaccine,

[18] By virtue of the lack of any meaningful risk estimates, experts had to rely on an additional set of techniques with which to orient their thinking. As discussed above, this included the generation of possible scenarios and models of smallpox attacks. These models were based on a wide variety of assumptions – too great to list here (but see IOM (2002a))-- as well as widely varying ranges of risk estimates. With these models and those of the CDC, the ACIP and other experts were provided with necessary information to evaluate cost/benefit analyses. By "necessary" I refer to the form that the information took, namely, quantified (albeit guesstimated) data.

and possibly die, without the benefit of related information about how many cases of smallpox would be averted or rendered less severe. Clearly, how benefits were to be gauged would become central to the smallpox vaccination process, although articulated answers (to this question) were sparse.

This analysis begs the question: if it was logically difficult to gauge the benefit of a vaccination program according to the standard calculus of cost/benefit techniques (other than through an understanding of "benefits" as derived via plausible, but hypothetical models and scenarios), then by what criteria could experts decide that a certain strategy of vaccination was appropriate? And for whom? The first diagnosis begins with the observation that risk assessment and risk/cost-benefit practices – even when exercised according to internally consistent and sound models and scenarios about likely future events – are conducted according to a calculus within which what is thought (literally) to be actionable is based in a rational-choice logic, whereby costs and benefits are known according to specific counts of disease or injury. The strong claim here is that knowing a thing in such a manner, and acting according to the most favorable numbers, seems to operate in an uneasy relationship with the normative and technical rationalities of preparedness, which by the logic governing it, works outside such calculative practices. Such practices are employed for different purposes, to different ends; they do not seem to articulate with(in) the rationality of preparedness.

Such a diagnosis would be at odds with some respondents' claims that had the "true" risk of smallpox been known (or properly communicated), unadulterated by political interference or hindered by the requirements of secret intelligence compartmentalization, then the public health system would have been able to carry out its functions in a more judicious, effective manner. Such a claim sidesteps the point that even in this instance, the decision reached, while certainly appearing more acceptable within a logic of population-level health, would nevertheless have been oriented towards something other than preparedness as it was variously articulated.

Another implication of this claim challenges the notion that "public health" was fundamentally ill-equipped to tackle what came to be framed as an issue of "national security." Which other than the system of public health can speak to the nuances of a classic public health intervention such as a vaccination program? Recourse to an explanation holding that public health adheres to a different set of values than those of national security, and therefore is ethically beholden to "do no harm" (unlike national security, which is not proscribed by such an orientation), would seem to obfuscate the issue. Public health officials would have had no hesitations about recommending a *pre-event, universal vaccination program*, had information been presented suggesting that a smallpox release was even modestly, say ten percent, likely (CDC official #8) – let alone imminent. Such a decision would have entailed accepting the risk of

substantial adverse events, including a number of deaths, across the entire population. Rather, it appears that the emergence and increased employment of the risk/cost-benefit model in adjudicating immunization decisions has built into its very operation an emphasis on risk aversion. That is, after all, the chief reasoning behind its development and use. As risk estimates and risk/benefit calculations increasingly work with relatively low magnitude risks for many infectious diseases – often 1 case in ten or one hundred thousand, even occasionally into the millions – every adverse event, every case of induced morbidity or mortality takes on a new meaning: lower numbers of these cases are increasingly unacceptable, owing to lower counts of disease incidence. As officials, in thinking through various ways of understanding what should constitute an appropriate response, worked to categorize the state of zero incidence smallpox as "pre-event," so too did they describe a world in which an immunization program would produce, in essence, only risk(s). The benefits would have to be understood according to some other logic, some other mode of understanding – but that was not forthcoming.

Diagnosis #2

In a number of reports issued both during and after the SVP's implementation, the Institute of Medicine noted that the program had somewhat ineffectually linked up actual vaccination efforts with its articulated aims of, at various points, either general bioterrorism preparedness, smallpox preparedness, or both (IOM 2005). Had such aims been *clearly articulated*, the reports went on, the program stood a better chance of benefiting from more effective implementation. Moreover (again according to the IOM), had vaccination activities been undertaken in the context of a preparedness program oriented towards the augmentation of *capabilities* to handle a public health emergency – as opposed to specific threats – the overall program may have fared better than it did. Perhaps.

The evidence is fairly convincing that there was a good deal of room for improvement in implementing the Smallpox Vaccination Program. Issues like compensation for vaccine-induced injury (variable between states, but generally low) and program funding (there was no special appropriation for several months), were, according to most published accounts and study participants, grossly underestimated by senior officials in HHS and the Administration, and perhaps CDC as well. Moreover, issues of liability and adverse events seemed to plague program officials since nearly the start of the program. Improvements in all these areas would almost certainly have boosted the numbers of individuals vaccinated, although it should be clear that a push for higher numbers in all likelihood would not have correlated with a "greater" state of preparedness in practice.

Two related points can be made in light of this, constituting the second and final diagnosis. These points can be summed up in a phrase: "There is preparedness, and there is preparedness." Officials, experts and policymakers have for several years decried the fact that however preparedness has been defined in principal, it has not been satisfactorily operationalized. The various frameworks and metrics meant to give some definition, some measurability, some sense of knowing what preparedness is and whether one (jurisdiction, state, etc.) is prepared, have met with a fair degree of controversy. This case study has illustrated just one of several debates in public health and disaster management circles regarding how to put preparedness into practice. In this case, one issue (amongst many) was the issue of numbers: should the numbers of individuals vaccinated count as preparedness, or not? How about the number of vaccines? The number of hospitals with vaccinated staff? Or plans? Whatever the metric, the point is that all of these kinds of "preparedness" (oriented to specific risks and threats) seem to be partially if not wholly disarticulated from the *rationality* of preparedness, which is oriented towards uncertain futures and the unknown. This is not, of course, to say that none of these activities are not important or necessary. Naturally, putting (vaccinated) people and infrastructure in place is central to the preparedness enterprise. Still, in developing smallpox vaccination options and in implementing the SVP, there seemed to be a telescopic view of what constituted vulnerabilities to be addressed and capabilities to be enhanced. Vulnerability was understood in a strict sense to mean: an immunologically-naïve population's vulnerability to (acquire) smallpox, or in relation to this: a jurisdiction's vulnerability (according to degraded or absent capabilities) in responding to a smallpox outbreak. Capabilities were understood in a strict sense to mean, amongst other things, the capability to conduct ring or mass vaccination operations; or to surveil a particular population, or run diagnostic tests, etc. All of these needs were framed largely as a function of whether an adequate number of smallpox vaccinations had been or could be given to appropriate individuals. In other words, vaccination was the preliminary step necessary by which to facilitate necessary (additional) public health measures. While all these are clearly important operational questions utterly germane to the issue of smallpox, it seems that they are not fully congruent with the preparedness rationality.

To orient towards an unknown future, even if that future is understood with respect to a specific infectious disease like smallpox, is not only to provide, pre-event, for the possibility of a massive organized response (ala stages 1 and 2 of the SVP) through vaccination (and surveillance, detection, laboratory work, communication infrastructure, etc.); rather, the logic of preparedness would demand that *all* of the elements and nodes in a preparedness assemblage be rigorously examined for vulnerabilities, with apparent "blockages" remedied or mitigated as part of configuring the assemblage itself. As experts from CDC and ACIP (very understandably) adjudicated vaccination options, the mold of preparedness, whatever the type (bioterrorism, smallpox, public health), had

already been cast: Preparedness would articulate according to a logic with roots deeply entrenched in previous public health campaigns and long-standing practices. Risks and benefits would be weighed, contraindications would be determined, dosages would be settled upon, and eligible populations would be established. Other elements and practices having to do with, for example, hospital and clinic staffing, compensation for injury or illness, family issues, or liability were, in the early planning stages, only ancillary to "proper" considerations about smallpox vaccination and preparedness. They became issues to consider or redress largely only after they emerged as operationally problematic. According to a preparedness rationale, however, these should not be understood as "barriers" to an effective program; they are not objects *external* to preparedness that simply get in the way of its successful implementation. Rather these issues, and the relationships they reflect between different groups, different levels of government, and different centers of activity, are fundamentally just as central to a preparedness assemblage as more traditional measures and public health interventions. It is therefore not unreasonable to conclude that the "social organization of preparedness" – since it is ostensibly "aimed" at vulnerabilities – should seek to reconceptualize what constitutes a vulnerability and to treat *all* vulnerabilities (e.g., Worker's Compensation issues, staffing, family concerns) with equal concern and effective prevention and mitigation techniques.

The second half of this diagnosis reiterates the point that the SVP was not, strictly speaking, an exercise in (the logic and rationale of) preparedness, through the presentation of an analogy. To some extent, vaccination strategies have historically mirrored military thinking and strategies. A threat is identified and its movements tracked. Where it appears to be making headway, defenses are erected to blunt the attack or, in best case scenarios, to prevent it or neutralize it altogether. Where a threat appears, the walls go up. In some respects, the logic of traditional vaccination reflects our understandings of biology, immunology and pathophysiology. If individuals or a population are immunologically naïve (in other words, vulnerable), they are, in some intuitively logical sense, "defenseless" unless the body's (or populations') defenses are somehow augmented.

Despite its unusual circumstances and risk profile(s), and in addition despite the demand for new forms of understanding and response to this and other threats, the SVP was an entirely familiar and recognizable public health intervention. Familiar institutional apparatuses were employed, utilizing familiar techniques to understand a specific threat and specific risks, and familiar interventions were designed to respond to those threats. A strict interpretation of the preparedness logic would suggest that such an undertaking, while perhaps necessary in the short-term given the emergence of smallpox as an immediate threat requiring an urgent solution, tends to focus efforts away from broader sets of vulnerabilities and capabilities which are not, per se, agent specific. For

all the emphasis in recent years on "dual use" public health activities and "all hazards" approaches, the SVP was very much an agent-specific program. The infrastructure built around it, the program itself, and its residual elements in the public health and healthcare communities seem not to have generated much in the way of new forms of organizing for, or understanding, unknown biological threats or future catastrophic health emergencies involving biological organisms. Public health officials and others on the ground who have in many respects been working under a mandate of smallpox preparedness should be applauded for their efforts, and should not read the previous statement as a criticism of their work. Unquestionably, the US is more prepared now than it was in the event of a smallpox outbreak, both despite and because of the work that went into smallpox vaccination thinking (and vaccine development) before, during and after the SVP. It is a sign of successful thinking and successful organization that this is the case, and any argument to the contrary should be greeted with a degree of skepticism. This chapter's critique of smallpox preparedness efforts must therefore be understood in this context. In the broad sense of the term, the US is largely prepared for a smallpox outbreak. The US has not, however, effectively oriented itself towards preparedness, in terms of the latter's rationale and logic.

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