
Setting Expectations for the Federal Role in Public Health Emergencies

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I would like to begin by discussing the legal and administrative framework of the role of the federal government in public health. At the heart of it is, of course, the Constitution. At the Department of Health and Human Services (HHS) we depend, as does much of the federal government, on our power to regulate interstate commerce. Since the Supreme Court in 1942 removed essentially any restraint from the meaning of interstate commerce in *Wickard v. Filburn*,¹ the federal government has been regulating with wide latitude, in spite of small and, arguably, equivocal reverses in recent years. However, even though the Supreme Court no longer provides any real constitutional check on the federal government's interstate commerce power, some other restraints persist. For example, many parts of the health system have traditionally been deemed inherently state functions, such as the licensing and disciplining of doctors, nurses, and pharmacists, as well as the practice of medicine itself. The federal government has hesitated to tread across these areas, for fear of disturbing long-established patterns of regulation that work effectively at the state level.

The constitutional right of citizen groups and businesses to petition the government is another check on the federal government. For example, even during the potential outbreak of monkeypox in 2003, for which we needed to prevent the distribution and sale of prairie dogs, in crafting the ban we needed to work carefully around the prairie dog lobby's potential concerns. In fact, there is virtually no group in America that is not organized and striving to be heard by the

government. This is, of course, as it should be, even if it sometimes makes life uncomfortable for those of us representing the federal government.

While the 10th Amendment is unfortunately forgotten by many, we at the Department of Health and Human Services are bound to carry out only that which is delegated to us. We do not have a plenary power to regulate. We cannot just establish power for ourselves, and we have to defer to the states when they have a system in place. For example, HHS does not generally run hospitals, administer vaccines, provide physicians or nurses, or establish quarantines. In fact, most of my presentation focuses on what powers we do not possess.

Section 247d of the U.S. Code and Section 319 of the Public Health Service Act gives the Secretary of Health and Human Services a great deal of authority in the event of a public health emergency. It says:

If the Secretary determines, after consultation with such public health officials as may be necessary, that –

- (1) a disease or disorder presents a public health emergency; or
- (2) a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists, the Secretary may take such action as may be appropriate to respond to the public health emergency, including making grants, providing awards for expenses, and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder as described in paragraphs (1) and (2).

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Obviously, this cannot mean that the federal government can do whatever it wants simply by declaring a public health emergency. Herein we find the distinction between authorization and appropriation. Just because part of the federal government has statutory power to do something, it cannot practically do it if it lacks the funds. For example, in a public health emergency, the Secretary largely cannot use money that already has a dedicated use – and the Public Health Service Act acknowledges this. The Secretary cannot just shut down Alzheimer’s research at the National Institutes of Health (NIH) in order to hire nurses to respond to an earthquake in California; NIH research has its own money set aside by Congress in the budget bill, and, with small exception, not even the President, much less the Secretary, can re-appropriate that money or sequester or otherwise switch it around once the budget bill is signed. In other words, the HHS budget, as enormous as it is, is not a big checkbook to be drawn on by the Secretary as he sees fit. As an aside, while the Secretary can draw from the Public Health Emergency Fund, it is a dry hole, since Congress has never actually put any money into it.

The public health emergency declaration does allow use of some waivers of programs and other powers, but despite what some people think, it is nowhere near as sweeping as a declaration of martial law. The health laws are just not the right place to look for that. As far as this topic goes, it is better to look at the Posse Comitatus Act,² the Insurrection Act³ (which has been tediously renamed), and others, and not to our health laws, tempting as it may seem.

What does this all mean, from a practicable perspective? How are we acting under our authority? I will explain by discussing several of the most significant public health challenges we are faced with. Some of the threats we at HHS are charged by the President and Congress to prepare against are manmade, like bioterrorist attacks. Some are natural, like pandemics. I will begin with bioterrorism, an area that our friends here at the Centers for Disease Control and Prevention conduct a great deal of work on.

Bioterrorism is a terrifying concept, and the idea for using biological agents to spread disease and death is an old idea. While it is fortunately more feared than practiced, and security specialists are more concerned with nuclear and radiological devices, it should be noted that the only uses of advanced terrorism devices have been bioterror ones: the anthrax attacks of 2001.

Since September 11, 2001, we have taken a number of steps to prepare against the threat of a bioterrorist attack. Thirty days after the attacks, we put forward the Bioterrorism Act of 2002,⁴ which developed critical new bioterrorism authorities for the HHS and

gave the Department broad new authorities to protect the nation’s food supply. The Act also allowed us certain critical waiver and response capabilities across a broad range of our programs so we could react and be more responsive in an emergency. These capabilities are focused around two main areas that use Congress-appropriated funds: assisting and encouraging states and communities in their preparedness efforts, and building up our knowledge, infrastructure, and material. Examples of related steps are that:

- We have provided more than \$7 billion since 2001 for state and local preparedness.
- We have increased our spending on bioterrorism and counterterrorism activities from \$273 million in 2001 to a requested \$4.3 billion for next year.
- Through Project Bioshield, we are providing new tools to improve medical countermeasures protecting Americans against a chemical, biological, radiological, or nuclear attack.
- We have worked with every state to develop response plans.
- We are piloting a Cities Readiness Initiative to upgrade capabilities for the rapid distribution of antibiotics across large urban areas during emergencies.
- We have expanded and enhanced our Laboratory Response Network to aid in detection and surveillance.
- We have built stockpiles of needed drugs and supplies.

But, in my opinion, the most significant threat to public health that we face today is not a bioterrorist attack but an influenza pandemic, the current possibility being known as “bird flu.” The issue of pandemic preparedness is a timely one, because we are overdue but under-prepared for a reoccurring natural disaster such as a pandemic. Pandemics are a biological fact, as history has shown us time and time again. We know that viruses and bacteria are constantly mutating, adapting – and attacking. And when pandemics strike, they not only cause a great deal of sickness and terrible loss of life, but they reshape nations.

Why are we so concerned right now? This is a good question, since H5N1 virus infection, the one that scientists are most worried about, is currently a bird disease. The problem with this strain of influenza is twofold: it is new and it is deadly. H5N1 has not developed sustained or efficient human-to-human transmission, but it has already infected 313 people and killed 191. That is a mortality rate of over 60 percent. In contrast, the 1918 pandemic had a mortality rate of at most 6

percent. And our epidemiologists tell us we are overdue for another pandemic.

When it comes to pandemics, there is no rational basis to believe that the early years of the 21st century will be different than the past. If a pandemic strikes, it will come to the United States and to communities all across the world. Of course, a pandemic might not happen for years or even decades. There is a certain cynical but natural view that this alarm about the bird flu is all hysteria. And there is a certain political calculation that would instruct us to do nothing. Tony Abbott, the health minister of Australia, said, "In the absence of a pandemic, almost any preparation will smack of alarmism. If a pandemic does break out, nothing that's been done will be enough."⁵

However, we are convinced that, whether or not we are facing an imminent pandemic, we should be better prepared for a pandemic. A century ago, America's health system was much less sophisticated in general, but its capacity for dealing with mass infectious disease was much more robust. Waves of disease were expected, and sanitariums, mass public health programs, quarantines, and adult immunization programs were more common and more widely accepted.

Another thing that the previous age of public health has us beat cold on is local preparedness. And local preparedness must be the foundation of pandemic readiness, because in case of a national pandemic, there is going to be no unaffected area from which to draw health workers and others to take care of patients in affected areas; thus, at some point in a pandemic, every local community has to make do with its own resources. In emergency preparedness, we usually think of and exercise single short disaster scenarios, like a hurricane. But as terrible as a hurricane can be, as, for example, was Hurricane Katrina, it is physically an event primarily of regional significance. It had a regional impact, it was limited in time (in spite of the continuing repercussions in the region), and volunteers and supplies from around the world poured into the area. Think instead about a pandemic: it will have a sudden, national impact. It will not last for a couple of days, but rather for months or even over a year, in multiple waves. Instead of people racing to the affected area to provide comfort and assistance, people will be staying home, many afraid to go into the affected area to lend help and support. It is a different construct for which we have to prepare.

And if none of us prepares, as a pandemic outbreak spreads, and outbreaks in communities reach their peak, the disaster will spiral downward, affecting everyone, everywhere. Due to the ubiquitous nature of a pandemic, it is dangerously unrealistic to expect the federal government to be able to swoop in and

fix everything. That is why it is important that every community have its own plan and be able to rely on its own resources as it fights the outbreak or anticipates an imminent one. That is why it is vital that we understand the role of the federal government versus the role of states and communities when it comes to pandemic readiness.

We have delineated our role as the federal government to include five main objectives:

- Disease monitoring,
- Stockpiling countermeasures,
- Developing vaccines,
- Establishing communications plans, and
- Setting up local plans.

First, disease monitoring. HHS Secretary Leavitt uses a metaphor when describing this goal. Think of the world as a vast forest, thick with underbrush and dead trees. It is very vulnerable to fire. A single spark can burst into a great inferno that is extremely difficult to put out. But if you are there right after the spark ignites so you can extinguish it, you can limit the damage. We believe that could be true with a pandemic. If we are able to discover the spark quickly, there is a chance we can extinguish it and stop a pandemic. Therefore, we are building a network of nations to cooperate in disease monitoring. Likewise, we need communities in the United States with sophisticated systems to watch for the emergence of disease.

Second, we must have stockpiles of anti-viral medications and other supplies. We are building up supplies of antivirals such as Relenza and Tamiflu and subsidizing our states' antiviral purchases as well. There is a nuance when it comes to stockpiling countermeasures, however. People imagine an airlift, probably by the armed forces, of medicines from a large federal stockpile. The federal government steps in and saves the day! Unfortunately, our readiness exercises have shown us that stockpiles are not the problem. Distribution is the problem. Unless you can get medicine to those who are sick within 24 to 36 hours, the size of your stockpile will not much matter. And, as the experience of 1918 showed, soldiers who might be carrying out those airlifts get sick just like everyone else.

Parenthetically, if I seem like I am belaboring the military point, it is because it is always the first recourse of people wanting to wish away this distribution problem, and no expert in this area that I know of thinks the military can solve this problem. Many people seem to think that in any disaster, the federal government can simply step in and fix everything. That is an unrealistic worldview, however. Instead, when it comes to distributing stockpiles, it is the state

and local plans that will spell the difference between defeat and victory. Thus, we have been working to help states set up distribution plans and to investigate how to partner with additional groups like the U.S. Postal Service.

Third, we need vaccines. Fortunately, a vaccine that produces an immune response in humans was developed last year and approved by the FDA. We are testing it, and getting through the bumps in the road on that. Of course, we are working on this vaccine with no assurance that H5N1 will be the virus to develop into a pandemic, but we need to be as prepared as we can. We are also spending several billion dollars to improve vaccine and antiviral production capacity, purchase vaccines and antivirals, and conduct research on new production technologies.

Fourth, preparedness needs to include communications plans as well. We all need the capacity to inform people without inflaming them, so there is not panic. In this area, SARS was a wake-up call. Across the world, only 8,000 people got sick, with 800 of them dying, but it paralyzed the Chinese and Canadian economies for several weeks and caused several billion dollars worth of economic disruption.

The fifth – and most important objective – is that every state, every Indian tribe, every city, every school, every business, every church, and every family needs a plan that addresses the unique challenges they would face. During a pandemic, there will not be any unaffected areas from which to draw health care workers to take care of patients in affected areas, so at some point in a pandemic, every local community has to make do with its own resources. And when it comes to pandemics, any community that fails to prepare – expecting that the federal government can or will offer a lifeline – will be tragically wrong. Leadership must come from governors, mayors, county commissioners, pastors, school principals, corporate planners, the entire medical community, individuals, and families. For when a pandemic comes, we believe it will hit everywhere in a short period of time.

All governments have plans established to ensure continuity of government in case of a decapitating event, like an assassination. Many governments also have plans to ensure continuity in the event of a degrading event, like a pandemic. But how many cities, businesses, or schools have plans for fighting outbreaks with their own resources when as many as 30 to 40 percent of their workforce are absent for 6 to 8 weeks? If none of us prepare, then as the pandemic spreads and outbreaks reach their peak, the consequences would cascade. Medical centers would be overwhelmed. Schools would close. Transportation would be disrupted. Food and fuel would run

out. There would be power and telecommunications outages.

Therefore, to help mobilize the American people in their planning efforts, we are making available extensive information resources including planning guides and checklists targeted toward specific groups. We have released more than a dozen so far, to help businesses, schools, health care services, to individuals and families, and many more categories. We have adopted a comprehensive approach with these guides, and they cover everything from assigning a person responsible for coordinating preparedness planning, to developing an education and training program to ensure that everyone understands the implications of pandemic influenza, to determining how vaccines and antivirals would be used.

We will continue to release guides as we develop them. These checklists and plans, along with a great deal of other useful material, such as hundreds of pages of technical guidance we have provided to state and local health officials and providers, can be found on the Web site <www.pandemicflu.gov>. Pandemicflu.gov serves as our government's one-stop access point to pandemic and avian flu information. And, since all the information is online, anyone around the world is more than welcome to use them. As countries, states, local groups, and individuals carry out preparedness activities, they may find weaknesses in our plans – and we need to discover these while we still have the time to correct them.

There is the possibility that a pandemic might not happen for years or even decades. Some people may think that our preparation is a waste and that we are being alarmist. In reply, I can only say that these people are right – until they are wrong. And the consequences of them being wrong are greater than the consequences of us being wrong. We probably cannot prevent a pandemic. But preparation can delay its onset. Preparation is likely to reduce the peak of a pandemic to a level that is much less overwhelming than it could have been, bringing it down to a number of cases that could be cared for. Preparation is likely to save lives.

Even if it is a long time before a pandemic strikes, there are real benefits to preparing now:

- We would have established new vaccine technology,
- We would have the capacity to manufacture vaccines much more quickly than we currently do,
- Annual flu would be much less of an issue, and
- We would be better prepared against any medical disaster or health crisis.

Over the past few years, we have been confronted with a variety of disasters, from hurricanes to bird flu to terrorist attacks. We have learned a great deal about what response efforts do and do not work. We are implementing all of the reports that have been issued, and are working to patch the flaws in the system.

But one fundamental flaw persists in the public imagination: people seem to think that, if only it were properly administrated, that the federal government should – or even could – push state and local authority aside in the aftermath of any disaster. This is neither federal doctrine nor realistic – there are limits to what bureaucrats, even highly-trained bureaucrats, can do. To tie this back to the point I made earlier, the federal government is constitutionally one of plenary state power, with federal authority primarily depending on one clause of the Constitution and one set of Supreme Court decisions for its wider powers. Even though there are also statutory powers, which give us broad authority, they are not paired with appropriations to implement them.

Therefore, when it comes to emergency preparedness, though unforeseen by the founding fathers, the Constitution and all sense of practicality agree: there

must be a balance of federal and state roles, with the states virtually owning entire responsibilities in this area.

We may never perfectly balance the role of the federal government against the obligations of states and communities in preparing against all possible disasters. But each day that we prepare, each day that we hash out these questions while we have the luxury of time, we make ourselves more ready and more capable of an effective response.

We are not prepared yet. But we are more prepared today than we were yesterday. And, with enough people aware and engaged, we will all be more prepared tomorrow than we are today. Thank you.

References

1. *Wickard v. Filburn*, 317 U.S. 111 (1942).
2. *Posse Comitatus Act*, 18 USC 1385 (1878).
3. *Insurrection Act*, 10 U.S.C. § 331 - 10 U.S.C. § 335.
4. *Bioterrorism Act of 2002*, 42 USC 201 et. seq.
5. Tony Abbott, Minister for Health and Ageing, *Bracing for the Worst*, country report for Pandemic Flu Conference, Ottawa, October 25, 2005, <[http://www.health.gov.au/internet/ministers/publishing.nsf/Content/95038345EFC1995CCA2570A60081A274/\\$File/ABBSP251005a.pdf](http://www.health.gov.au/internet/ministers/publishing.nsf/Content/95038345EFC1995CCA2570A60081A274/$File/ABBSP251005a.pdf)> (last visited November 29, 2007).