

Comments on the Draft Guidance on Allocating and Targeting Pandemic Influenza Vaccine

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We commend the Departments of Health and Human Services (HHS) and Homeland Security (DHS) for their ongoing efforts to provide informed and ethics-based guidance to our federal, state and local governments for the allocation and prioritization of pandemic influenza vaccine during the next pandemic. A rigorous and inclusive process has been embarked upon by the agencies and specifically the federal interagency working group to draft guidance that will target administration of the early production of pandemic vaccine to minimize levels of illness, death and disruption to our society and economy. However we believe the underlying assumptions for this guidance are flawed and the current process will not provide us with the guidance needed for vaccine allocation during the next pandemic. To date, the HHS and DHS process has not recognized and addressed the realities of the global, just-in-time economy which has neither surge production nor distribution capacity for many of the critical products and services that all residents of our country require to support their daily lives and their current health status. In short, a minor disruption in a single ingredient, part, chemical constituent, packaging material or transportation mode means that this product will quickly be unavailable. We consider the supply chain for such a product to be extremely vulnerable, a condition common to most products and services we utilize today.

The defining aspects of influenza pandemic preparedness in this unprecedented economic environment, including vaccine manufacturing and distribution, has been described previously by one us (MTO) (1, 2). Specifically, we have defined critical-product continuity as the determination of those private sector products and services that our country routinely requires that must be available during the duration of a pandemic in order to minimize potentially catastrophic collateral health and security consequences and the subsequent comprehensive actions that must be taken by both governments and the private sector to ensure their availability (3).

We believe that the basic ethical principle of utility, which requires that one act to maximize aggregate welfare (illness, death and disruption to our society and economy), will not be best served by the current approach for vaccine prioritization and allocation. This concern extends to residents of all ages. In particular, we believe that HHS and DHS must determine a priority list of critical products and services that, should they be unavailable during a pandemic due to disruptions in international trade and travel, will result in significant morbidity and mortality.

For example, in the health care delivery system during the next pandemic, regardless of where routine and influenza-related patient care takes place or how many health care providers actually come to work, we will need even more drugs such as antibiotics;

medical devices and other products such as needles, syringes, IV bags, gloves, and masks; and routine laboratory and diagnostic tests. Yet today most of these products have supply chains and production locations outside of the United States. For example, over 85% of all pharmaceutical products used in our country are made outside of the US and have “long and thin” supply chains. Many of our larger hospitals now receive delivery of these drugs three times a day. Most hospitals now have no more than two days of oxygen on hand for ventilator use. The private sector manufacturers of industrial and medical chemicals, including oxygen, have an extremely limited capacity to stockpile such chemicals and are heavily dependent on electricity to produce them. In addition, without supplies of diesel fuel and approved transportation vehicles it is impossible to deliver chemicals like oxygen to hospitals or other health care locations. Finally the workers in the oxygen manufacturing facilities and those that transport it become essential to ensuring the oxygen supply chain remains intact. So, despite all of the recent discussion and consultation on who will be provided one of the limited ventilators during a pandemic, no one has considered the requirements, specifically the provision of “early vaccine” to those who ensure that there is electricity, oxygen production plant workers, diesel fuel and delivery drivers.

According to the draft guidance on allocating and targeting pandemic influenza vaccines released on October 17, 2007, one of the top objectives of the programs is to “protect those who are essential to the pandemic response and provide care for persons who are ill.” We believe that to date HHS and DHS have not determined who these workers will be during a pandemic. In large part this is due to the fact that we have not identified the critical products and services we need to ensure during the next pandemic regardless of the severity.

While the guidance allocates a portion of the projected vaccine supply to those who maintain essential community services, it does not adequately address the risk associated with losing specific aspects of the critical infrastructure (CI) during a pandemic. The prioritization of the CI, specifically the tiers in which they are categorized, needs to be reconsidered so that the limited vaccines can protect the health of the most residents of our country regardless of the cause of their illness or death during the pandemic. For example, in the current guidance millions of toddlers will receive pandemic influenza vaccine before those who provide electricity and transportation. While we understand the need to vaccinate vulnerable populations during a pandemic, the consequences of having the CI fail would be catastrophic to children and adults alike. Thus the CI needs to be reprioritized with this and the concept of utility in mind.

A pandemic in today’s world would cause tremendous problems for all business sectors, not just the CI sectors. Almost every business in the US relies on a just-in-time supply chain; it’s the most economical choice. These supply chains are very fragile, as they depend on their suppliers, who often supply them just in time. If just one key input is delayed or missing, an entire process may come unraveled.

The HHS and DHS analysis of potential critical product and services must look at every aspect of a given product or service supply chain to determine the weak, yet necessary, links that must be preserved if that product or service is to be available. The results of such an analysis will be very instructive in helping to determine the criticality of that product or service during the pandemic and the subsequent vaccine needs in order to support the workforce that ensures that supply chain requirement is met. This will

inevitably lead to recommendations that early vaccine distribution occurs to workers outside of the US. As noted above, almost all of the antibiotics and a growing proportion of insulin used in the US are manufactured offshore. Will a child be better off during a pandemic if he or she receives vaccine before those who manufacture and distribute a variety of lifesaving drugs (including the assurance of an adequate electricity supply to enable such manufacturing?) We are not aware of any agency, organization or individual that has attempted to estimate the collateral damage (illnesses and deaths) that would occur due to lack of availability of critical products—damage that potentially could be modified by distributing early vaccine to support their supply chain rather than supplying this same vaccine to children in general. This analysis needs to be completed as soon as possible to adequately inform us of the consequences of the choices we are making with the current vaccine allocation scheme.

Allocating vaccines to workers ensuring the supply chain of important goods and services is not an easy task. What goods or services are so critical to the US that they should have vaccines allocated to ensure the continuation of those services? No one currently has the answer to that, but we believe such a list can be determined. Those products and services that are crucial for sustaining life (energy, water, food, pharmaceuticals, etc) must be maintained during a pandemic. The National Infrastructure Advisory Council's (NIAC's) working group on pandemic preparedness suggested that the US develop a "national prioritization scheme for goods and services." We strongly support this recommendation made almost a year ago. It will be impossible to ensure that critical supplies and services are maintained during a pandemic if they are not identified before a pandemic so strategies can be developed to ensure their continuation.

The CI plays a vital role in every aspect of the US economy and is extremely interdependent on other infrastructure. The NIAC 2004 report on these interdependencies highlighted the risks to the 17 CI if just one has problems functioning. This 2004 report made it extremely clear that the energy sector is critical for all other sectors, but the energy sector is dependent on other sectors to continue to operate. This level of interdependency makes the entire CI extremely vulnerable to a pandemic, as it will affect the entire country at the same time and there will be widespread work absenteeism. Most CI are currently staffed at levels aimed to be the most efficient—in essence, the fewest people necessary. During a disaster, this common business practice is typically mitigated by redundancy in other locations or by other staff trained to replace individuals critical to the workforce. This has typically worked well for almost all disasters the CI has faced, but we have not experienced a pandemic in modern times.

In summary, we strongly recommend that HHS and DHS reevaluate the priority levels outlined in the draft guidance and take into account the realities of the critical product and service supply chains our nation depends on and the foreign workers who maintain them. Those providing critical products and services and maintaining important supply chains will in many instances perform roles during a pandemic equal to the critical roles of those who provide homeland security and medical care. These workers should be given equal consideration with regard to the vaccine allocation status.

We recommend:

- Continued efforts should be made to identify and quantify personnel essential for maintaining critical product and service supply chains, on both US soil and abroad.

- Continued efforts should be made to identify goods and products that are critical to the US.
- Personnel critical to maintaining these supply chains should have priority over the general population, including children.

1. Osterholm MT. Foreign Affairs; 2005 Vol 84:24-37.
2. Osterholm MT. Foreign Affairs; 2007 Vol 86:47-57.
3. Osterholm MT. Testimony before the House Committee on International Relations. Dec 7, 2005.