

Supporting Consumer Drug Stockpiling

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There are a number of unintended adverse consequences that accrue if physicians deny their patient's request for help in obtaining a stockpile of drugs for use during the coming influenza pandemic. While no one can say when the next pandemic will occur, we are presently overdue and H5N1 bird flu seems to be shaping up as the likely candidate. Its resemblance in many regards to the devastating 1918 Spanish Flu and the fact this virus looks to be on the verge of becoming pandemic are adequate reason to take this threat seriously.

What patients need and why

There are two types of drugs patients need to stockpile now in order to be adequately prepared to cope with the possibility of a severe pandemic. Stockpiling is reasonable because the risk a severe pandemic could temporarily block ready access to both physicians and to pharmaceuticals. It makes sense for patients to secure an adequate supply of the drugs taken daily for chronic disease as well as a select few held in reserve for treatment of influenza during the pandemic. It is ironic that the concerns expressed by those opposing consumer stockpiles along with a variety of excess adverse health outcomes are much more likely to develop if physicians refuse to help their patients obtain the drugs needed to sustain them during the pandemic. Support for this view is provided in the following analysis.

Stockpiling a 6-month supply of regular medications

Preventing consumers from establishing an adequate stockpile of drugs they rely on day in and day out places patients at greater risk of harm should the pandemic be so severe that it affected the

conventional supply chain. If patients were suddenly without their regular medications and had no effective treatments for the symptoms or complications of influenza, it is not hard to envision the consequences. The incidence of catastrophic health events like myocardial infarction, cerebrovascular accident, bacterial pneumonia and sepsis would all rise in this group.

At this point, only a few patients desire to obtain a drug stockpile and even fewer physicians' support these efforts, a circumstance that is likely to change as the pandemic becomes increasingly likely.

Patients making preparations for pandemic influenza are quite serious about doing it right. They have studied the issue and planned their strategy. Stockpiling a 6-month supply of the drugs they take daily for management of their chronic medical problems is a rational way to insure that therapy for these serious disorders can be continued in the event that a chain of pandemic related events interrupts routine pharmaceutical manufacture or delivery.

Stockpiling drugs for treatment of pandemic influenza

Helping patients have an adequate supply of medication on hand useful in the treatment of influenza together with clear instructions for when and how to use them is also a responsible act for the primary care physician. Ideally, this stockpile would include the antiviral agent Tamiflu, and medications for nausea, pain, cough suppression, anxiety, and an antibiotic with good coverage for the bacterial causes community acquired pneumonia. For instance, the Flu Treatment Kit I recommend in *The Bird Flu Manual* contains oseltamivir, promethazine, hydrocodone, diazepam, and the antibiotic azithromycin. I also include probenecid for use as a Tamiflu dose multiplier. Probenecid inhibits renal excretion of oseltamivir by 60% in the same way it does with penicillin having

the effect of doubling its peak serum level and increasing its half-life by 2.5 times above that seen without concomitant use.

Pandemic threats to the pharmaceutical supply

Today all pharmaceutical companies, wholesalers, and retail pharmacies have implemented the just-in-time method to control inventory. This management technique keeps inventories lean freeing up operating capital for other purposes. A demand spike, especially if prolonged for any drug will result in a short-term shortage until the manufacturer can scale up production sufficiently. Most drug makers can increase production quantities without the need to add equipment or staff. There is an upper limit that can't be exceeded without sacrificing quality. To meet demand beyond this level requires the addition of manufacturing facilities and staff as was done in 2005 by Roche to meet the huge increase in demand by countries seeking to add Tamiflu to their national strategic stockpiles.

During an influenza pandemic, the vast increase in demand for both OTC and prescription drugs useful in the management of flu will lead to prolonged shortages in a large number of these products. This includes OTC drugs for treatment of pain and fever like aspirin, acetaminophen, ibuprofen, and naproxen, cough syrup employing dextromethorphan, antihistamines like diphenhydramine, and decongestants like pseudoephedrine. These products will fly off the drugstore shelves faster than they can be replaced. Manufacturers will be operating at full capacity to meet this demand but at some point, flu related absenteeism or a lack of raw materials could affect their ability to produce or deliver their products.

These same dynamics apply to prescription drugs, especially those useful in the treatment of influenza, its symptoms and complications. Obviously the antivirals Tamiflu and Relenza will

be remain in continual short supply beginning even before the actual start of the pandemic and extending during the entire 12- to 18-month pandemic period. Narcotic containing cough suppressants and pain relievers, antiemetics in the phenothiazine class, prescription antihistamines, and oral and IV antibiotics will all be in continuous short supply or temporarily unavailable.

Disturbingly, few know that more than 80% of the raw materials for drug manufacture and in some cases the finished pharmaceutical used in the US are imported, mainly from the EU and Asia.¹ Disruptions in collection and processing these raw materials in the country of origin, their diversion to regional manufactures or distributors to meet increased local demand, or interruption in the transportation or distribution of these materials to or within the US are all easily predicable consequences of a severe pandemic. This can only aggravate shortages of the drugs that will predictably already exist in the US due to significantly increased demand.

Dependence on disposable medical supplies



Shortages of a wide variety of disposable medical supplies will also plague the delivery of quality healthcare and affect safety. The N-95 respirator mask has gotten most attention in this regard but this is just the tip of the iceberg.² The supply of everything from latex gloves, shoe covers, syringes, hypodermic needles, sterile saline for IV drug preparation, to the polyethylene IV tubing and intravenous catheters used to

administer drugs and fluids will become terribly scare and very quickly after the onset of the pandemic. After initial shortages

develop, intermittent re-supply can be expected to occur in the beginning months of the pandemic but the deliveries will never meet the increased demand. There will not be enough time to add manufacturing capacity even if this was warranted from a long-term business prospective, which it is not because manufacturers see that the increased demand will last only as long as the pandemic.

Manufacturers of disposable medical equipment and supplies will be able to ramp up production in the same way as pharmaceutical companies, but only so long as their employees remain healthy and their raw material suppliers can continue to deliver. In the event of a severe pandemic, worldwide influenza related conditions are likely to reduce or even halt production. These conditions include absenteeism of the plant workforce, inadequate supplies of raw materials, and loss of critical inputs required to operate the plant such as reliable electric, natural gas, or water utility service. Civil disorder or the threat thereof could also result in plant closure.

If these conditions develop it is easy to predict they will be extremely disruptive to the operation of the healthcare economy including provision of direct patient care and those responsible for the manufacture of drugs and medical supplies.

Medical first responder and healthcare worker absenteeism

A further complication is the growing uncertainty that medical first responders and healthcare workers will remain at their posts during the pandemic.

First responders

The lessons learned by first responders to the 9/11 tragedies in New York City remain fresh in the minds of their colleagues everywhere. The collapse of the buildings killed hundreds of first responders but many more who survived have become disabled due to inhaling the toxic air at the disaster site during the rescue attempt and ensuring weeks spent recovering the deceased's remains. The US EPA made public statements declaring the air within the vicinity of the disaster was safe. Subsequently we have learned that these declarations were false. The medical first responders and rescue crews believed them and remained at work for weeks.

Some are now disabled with pulmonary fibrosis and other respiratory disorders and are no longer able to work. Others have been fired with some being abandoned by the authorities. The front of our healthcare system in every city across the US is composed of these same first responders. Given this experience, one wonders what their reaction will be when asked to risk their health during a severe influenza pandemic?

Healthcare workers

The healthcare system needs all its workers to operate properly, not just the allied technicians and medical professionals. In hospitals, this includes the clerical, janitorial, IT, facilities maintenance, nursing aids, kitchen, and security staff who do all the heavy lifting needed to keep the facility open. These are the people that pay the hospital's bills and collect its money, keep the hospital clean and sanitary, keep the computers running, maintain and repair the physical plant, bath the patients, change their bed linen, and help patients use the bedpan. They are those who prepare and deliver food to the patient's rooms and feed the staff. They are responsible for patient and hospital staff security and

safety. Despite the fact that these healthcare workers are some of the lowest paid in the economy as a whole, no hospital could remain functional without them.

The sacrifice of those who serve

Hospital workers, medical first responders, and the ancillary and professional medical staff will by virtue of their work be repeatedly exposed to the influenza virus irrespective of the precautions taken. They will carry the virus home with them exposing their families and friends. As was seen during the 1918 and 1957 pandemics, people in these professions are predicted to have the highest clinical attack rates and case fatality rates of any group during the coming pandemic.

Most health care workers are presently unaware of their increased health risk despite being well known within the public health community. This fact and because it is in the public interest that healthcare workers and first responders live to provide care for others is why these groups head the CDC's priority list for access to scarce drugs and vaccines during the pandemic. Unfortunately, the same protection does not extend to the families of healthcare workers or first responders. No doubt, as the pandemic approaches and certainly once it arrives, this fact will become better known.

Healthcare workers and medical first responders are among some of the most dedicated people in our society and many will remain at their posts irrespective of the risk, but not all. It is easy to see that healthcare workers in every category will be significantly reduced due to the combined effects of illness and death due to influenza and to those who resign their position or simply fail to return to work due to concern about becoming ill themselves and/or infecting their family members. While volunteers can help keep the hospital clean, prepare food, and bath patients, when it

comes to highly technical roles in the laboratory, respiratory, radiology, or ICU there will be no relief.

As soon as physicians, nurses, and healthcare administrators come to a more realistic appraisal of the conditions that could emerge during a severe pandemic, the sooner they can begin planning appropriately for it.

Preparing for this pandemic makes a lot of sense despite the fact that most hospitals and few doctors have done very little so far. Those that plan now will be in a much better position to weather the storm when it comes and recover more quickly once it is over.

This essay was written to foster insight into the risk our highly structured and technology dependent healthcare and health economic system faces from a pandemic event. The widespread use of just-in-time inventory methods up and down the supply chain means that no one has more than a few days or weeks supply of anything on hand at any one time. Globalization of the supply and manufacturing chain is another factor increasing our vulnerability. As appreciation of these risks increase, it becomes apparent that taking steps to prepare for the possibility of a disruption in the supply of drugs as well as a whole host of other healthcare materials and supplies becomes a rational act.

Those who accept this analysis will also see that there are actions that can be taken to help reduce the consequences. One of these actions is for people to obtain a stockpile of their regular and influenza treatment medications for emergency use. Patients are not able to do this easily without the help of their physicians. It is my hope that physicians will see the value of helping their patients prepare for the coming pandemic in every way possible including supporting their effort to obtain a stockpile of necessary drugs.

For more information on pandemic influenza visit
www.BirdFluManual.com.

¹ Michael Osterholm, PhD, Director of CIDRAP in testimony before the US Congress in December 2005.

² Reusability of Facemasks IOM Apr2006