

Consumer Drug Stockpiling Pros and Cons

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Some in the medical, public health, and ethics communities have vigorously opposed the desire by consumers to stockpile prescription pharmaceuticals for future use during the next pandemic. Editorials and position statements in opposition to stockpiling have appeared in leading peer reviewed medical journals.^{1,2,3,4} These objections have been widely publicized in the lay press. It is important for individuals desiring to stockpile and their doctors who must decide whether to help them, understand the reasons behind this opposition.

The arguments put forth all have merit and usually have to do with one of several concerns.

- The concern that consumers would use the stockpiled drugs improperly or inappropriately in a fashion that might be wasteful, dangerous, or in the case of antimicrobials increase resistance to the drug
- The concern that widespread stockpiling could result in shortages of drugs for treatment of patients needing them today
- The concern that it is unfair for the affluent to gain access to these drugs ahead of those unable to buy them
- The concern that stockpiling would cost too much
- The concern voiced by the public health community that consumer stockpiling could interfere with their ability to influence who is given priority for antiviral therapy

These concerns have solid foundations and at first blush make sense. A lot of people support them including physicians in private practice who control the prescription pad. While these doctors are the ones who actually have to carry out the policy, most of those making them are not physicians and only a few who are have any direct patient contact.

As a physician in private practice, I can see both sides of this issue but am alarmed by an overlooked but critical flaw in the assumptions underlying these concerns. The arguments err not from a substantive or ethical standpoint. On the contrary, they are all well founded medically and ethically. The problem relates to the fact that their views are valid only if the medical, economic, and government infrastructure remain functional during the pandemic. This is likely to be the case if the pandemic is mild or moderate in severity. Under the conditions of a severe influenza pandemic, there is great risk that this infrastructure may buckle temporarily. If that happens, access to drugs of all types and advanced medical care could become extremely limited.

In the sections below, I provide a detailed analysis of the current concerns over consumer stockpiling and explain how the well intended policies designed to undermine this practice might well result in catastrophic unintended health consequences for patients.

I) Consumers would use the stockpiled drugs improperly or inappropriately in a fashion that might be wasteful, dangerous, or in the case of antimicrobials increase resistance to the drug.

The consumers I have encountered desiring to obtain a stockpile of drugs for use during the pandemic are on the whole, serious and responsible people who have looked carefully at the issue. Many have learned how to use these drugs properly and appropriately and if not are willing to learn. It is anachronistic to maintain that people wishing to stockpile prescription drugs for the pandemic would behave irresponsibly. Our patients are better educated and informed today than ever before. Viewing them in this paternalistic manner is no longer appropriate nor is it accepted in the modern clinical interchange. Physicians acting thus are perceived as condescending by patients, a view that is pure poison to the development and maintenance of a healthy therapeutic relationship.

While some consumers may not use these drugs properly, applying this stereotype to all of them is unwarranted. The person best able to decide whether the patient is likely to use the drugs responsibly or not is their personal physician. This decision should be made on a case-by-case basis by the patient's physician rather than across the board by fiat.

II) Widespread stockpiling could result in shortages of drugs for treatment of patients needing them today

The numbers of people wanting to establish drug stockpiles for use during the pandemic is not large today. True, as the risk of a pandemic rises, more people will come to see the need to obtain a supply of drugs they use everyday for their chronic medical problems as well as those special items held in reserve for use during the pandemic.

All understand the need for patients with chronic medical disorders to continue drug treatment during the 12- to 18-months the pandemic is expected to last. If treatment were interrupted, the incidence of complications of these conditions would surely increase placing an even greater burden on the pandemic ridden healthcare system.

The pharmaceutical industry will have little difficulty satisfying this small additional demand today. Once a person has obtained an adequate drug stockpile, they are no longer in the marketplace for a greater supply. As the need for stockpiling becomes more widely appreciated, more people will wish to do so. These new entrants will take the place of those who have gone before soaking up the marginal drug supply.

Stockpiling occurring in this fashion would be orderly and not lead to shortages of drugs for current use. On the other hand if everyone tried to purchase their stockpile at the same time, shortages would abound. This of course is what will happen at some point in the run up to the pandemic but probably not until the emergency is upon us.

Orderly stockpiling by consumers of drugs taken daily for chronic medical conditions as well as a select few prescription and OTC drugs for influenza treatment is an important way to mitigate the risk inherent in a breakdown in drug availability during the emergency. Instead of opposing this approach categorically, we should be advocating the orderly stockpiling of drugs so that people who need them will not be denied access if the pandemic is more severe than some envision.

III) It is unfair for the affluent to gain access to these drugs ahead of those unable to buy them.

It is doubtful that the majority of consumers will purchase a drug stockpile even if this practice was widely advocated. Most people who wish to obtain a drug stockpile say their primary motivation is to provide as much protection they can for their family from illness during an influenza pandemic. This motivation cuts across all socio-economic groups. While it is true that the affluent can more easily afford the cost of preparing for this emergency, they do not seem to be doing so in any greater numbers than the middle class. All are constrained in their preparations by having to obtain a prescription from their physician. If a person of modest means wishes to use their disposable income for this purpose, this should be their choice.

That the poor have little access to medical care in the first place and no funds to prepare for the pandemic in the second is a great shame. While this condition is deplorable for a nation as wealthy as the US, it is not something that can be rectified quickly. In my view, using this social ill as an excuse to prohibit those desiring to stockpile because it is unfair is misguided. In a perfect world all groups should have access to the drugs they need. In this regard, it is wrong to frustrate the efforts of those who can afford to stockpile drugs in the same way it is that those who cannot afford them are denied access to needed medications. I was taught by a wise man that two wrongs do not make a right, an aphorism that seems applicable here. It is illogical then to take the position that since adverse societal conditions prevents one group of deserving people from

obtaining a needed resource that the same resource should be denied to all groups.

IV) Stockpiling would cost too much

In the event that 10% of the US population stockpiled a 6-month supply of drugs taken daily and those for emergency use during the pandemic, the one-time cost would be about \$14 billion. Since the drugs purchased is intended for future use, when this occurred, the expenditure would be recovered. If the next pandemic was mild or moderate and drug availability remained intact, it would no longer be prudent to maintain a stockpile and patients would consume their stored drugs. This would lower their drug expenditures in the future. The true cost of obtaining a stockpile then is the carrying cost of the inventory between the time it was purchased and consumed. This is a small premium to pay for the value of having uninterrupted drug therapy available to the consumer. Of course, if a severe pandemic results in loss of access to these drugs, the premium paid for carrying the stockpile will pale compared to health benefits derived from patients being able to continue therapy.

V) The public health community's ability to influence who is given priority for antiviral therapy would be undermined if consumers were allowed to stockpile drugs

The well-intentioned plans of the public health community would be impossible to implement without an intact medical delivery system. It is conceivable that the millions of courses of drugs stored in the country's Strategic National Stockpile for use during the emergency could well remain locked up in guarded

federal warehouses or stolen and available only on the black market in the event of a severe pandemic.

The current plan proposed by the US Department of Health and Human Services to distribute these drugs from federal National Strategic Stockpile warehouses to the state health departments and thence to those on a priority list strikes me as too complex to work effectively.⁵ While it is not possible to see the future, it is not difficult to predict a serious influenza pandemic will adversely affect transportation and communications. In a move that could exacerbate distribution of drugs from the National Strategic Stockpile, in an executive order, President Bush has designated the US Department of Homeland Security as the lead agency during an influenza pandemic. There is already conflict between these two agencies over this turf. The US DHS has released their own pandemic plan, which is at odds with the one the US DHHS released in November 2005.⁶ If past performance is any guide to the future, one only needs to consider the way in which the US DHS managed the Hurricane Katrina emergency in August 2005. Of course, that emergency lasted only a short time and was regional in nature. By comparison, a serious influenza pandemic will last 12- to 18-months and affect the entire country at roughly the same time and to the same extent.

Under these circumstances, it is unlikely that those meeting the criteria used by the CDC as eligible to receive priority access to antiviral therapy would receive this drug in a timely manner. To be an effective treatment of influenza, Tamiflu must be started within 48 hours of developing influenza symptoms. It is doubtful that any country in the grasp of a nationwide medical

emergency on the scale of pandemic influenza could effectively coordinate this effort.

Consider the following:

- The US DHHS proposes to transport the drugs stored in the National Strategic Stockpile to the states where they will be turned over to the state health departments
- The state health departments are responsible to distribute the drugs to the county health departments.

This is a fine plan but exactly how do the drugs reach those that need them?

- Will the local health department keep control of the drugs or will they distribute them to area pharmacies or directly to the doctor's offices?
- Are there plans for increased security to guard the drug supply and protect those who control it?
- Will a prescription be required by the agency destined to dispense the drug?
- Who will determine if an individual person meets the CDC definition of someone on the priority access list?
- Will making this determination delay antiviral therapy beyond the therapeutic window making the entire exercise futile?

Implementing a plan this complex might not work even if the pandemic were mild or moderate and would certainly be at risk should there be a severe pandemic. In my view, the only way to ensure that those meeting the criteria for priority use of antiviral drugs established by the public health community would be to provide these people with a personal stockpile of the

medications to keep at home for use in the event they developed influenza. This in fact is the approach take by many doctors for their families and friends and a number of S&P 500 corporations who have purchased Tamiflu stockpiles for use by their employees.

The unintended consequences of the present policy

The longer the medical, public health, and ethics community remains in lock-step opposition to patient stockpiling, the more severe the shortages will be when doctors wake one morning to see the approaching pandemic and break ranks. This is sure to occur, as physicians owe their primary loyalty to their patients. Their patients will clamor for what protection pharmaceuticals will provide from the terror of pandemic influenza. Once physicians begin to think the pandemic is coming soon, it will be very difficult for them to refuse. Depending on the level of panic and chaos in the doctor's office, there may not be much time to instruct the patients in the proper use of the drugs prescribed. Without proper guidance, it is unlikely consumers will use the drugs prescribed appropriately. I have no doubt that this will happen and depending on the timing of the doctor's change of heart, could indeed result in all the worst predictions voiced by those who currently oppose consumer stockpiles. Ironically then, one way to guarantee the concerns of those in opposition to consumer stockpiling becoming manifest is by adhering to their current recommendations.

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

¹ Moscona A., Oseltamivir Resistance — Disabling Our Influenza Defenses. *N Engl J Med* 2005 353;25

² Joint Position Statement of the Infectious Diseases Society of America and Society for Healthcare Epidemiology of America on Antiviral Stockpiling for Influenza Preparedness October 31, 2005; <http://www.idsociety.org>

³ Brett AS, et al., Run on Tamiflu *NEJM* 2005 353,25

⁴ Harvard Vanguard Medical Associates. Avian influenza (bird flu): frequently asked questions. (Accessed November 17, 2005, at <http://www.harvardvanguard.org/flu/avian.asp>)

⁵ The US Department of Health and Human Services Pandemic Influenza Plan. November 2, 2005

⁶ US National Strategy for Pandemic Influenza US DHS 2May2006