

**Stockpiling Antiviral Drugs for Pandemic Influenza: The Key Ethical Principles<sup>1</sup>**

**Prepared by  
Ethics Subcommittee of the Advisory Committee to the Director,  
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November 28, 2007**

The National Strategy for Pandemic Influenza emphasizes that planning and preparedness are shared responsibilities of all levels of government, businesses, and individuals. This concept of “shared responsibility” has been proposed for the purchase and stockpiling of antiviral drugs in preparation for pandemic influenza. Antiviral drugs for the treatment of persons who become ill during a pandemic have been purchased and stockpiled by the federal and state governments. A working group that included representatives from government and public health recently recommended that pandemic antiviral drug strategies be expanded to also include prophylaxis (preventive use) for healthcare and emergency service providers and for household contacts of persons who have pandemic illness. Businesses also are encouraged to consider stockpiling antiviral drugs for their critical employees as a component of a comprehensive pandemic plan.

The Ethics Subcommittee of the Advisory Committee to the Director, Centers for Disease Control and Prevention offer these comments on key ethical considerations relevant to decision making about stockpiling antiviral drugs. We did not consider a specified definition of “shared responsibility” realizing that the scope and meaning of the concept of shared responsibility is dependent upon first determining among what groups responsibility for purchase of antiviral drugs may be shared. The candidates are: A) the federal government; B) tribal, state, and local governments; C) public sector organizations (public hospitals, police and fire departments); D) private sector organizations (health care organizations, industry, non-profit organizations); E) insurance companies; F) manufacturers of antiviral drugs; and G) individuals and families. The alternative to this concept of shared responsibility is to have the federal government assume full responsibility for purchasing antiviral drugs for a pandemic influenza response.

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<sup>1</sup> This document was reviewed and approved by the Advisory Committee to the Director, Centers for Disease Control and Prevention on May 1, 2008.

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## Key Ethical Principles of Stockpiling Antiviral Drugs

Shared responsibility for the purchase of antiviral drugs among some or all of the above candidates gives rise to the question: how to prepare for pandemic influenza as a public health emergency in a way that is consistent with ethical principles? An exhaustive analysis of the concept of shared responsibility would require examining the likely consequences of all permutations and combinations of the above candidates as purchasers, and seeing how ethical principles apply to those consequences. That analysis is well beyond the scope of this document. Instead we focused on addressing the key ethical principles that should be considered by decision makers who will be charged with assigning responsibility for the purchase of antiviral drugs. These key ethical principles are – effectiveness, efficiency, equity, reciprocity, and autonomy.

**1. Effectiveness:** what arrangement for the purchase and distribution of antiviral drugs will result in the best overall public health outcome? This is an illustration of the utilitarian principle that mandates actions or policies that maximize benefits for the greatest number of people. In the context of pandemic influenza preparedness, this would mean ensuring that antiviral drugs are stockpiled and can be appropriately deployed during a pandemic as recommended in order to maximize health benefits and minimize disease impact for society as a whole. Whereas prophylactic use of antiviral drugs provides an individual benefit, it also provides community benefits. Protecting healthcare workers and emergency responders contributes to maintaining health and safety for the entire community. And results of mathematical models suggest that protecting household contacts of ill persons reduces the transmission of influenza in communities reducing the overall number of persons who become infected.

**2. Efficiency:** what is the least expensive and quickest arrangement to achieve the desired ends? In the context of pandemic influenza preparedness, this principle would call for 1) purchasing the drugs at the cheapest possible price, 2) minimizing costs associated with maintaining a stockpile and distributing the drugs, 3) extending the shelf-life of the drugs to reduce the need for periodic re-purchase, and 4) limiting the quantity of drug purchased to what is necessary to achieve public health objectives. There is often an overlap between efficiency and effectiveness: approaches that reduce costs may allow more drugs to be purchased better achieving public health outcomes and reducing “opportunity costs” where funds applied to antiviral drug purchase and stockpiling are not available for other beneficial uses. Nevertheless, the most economical solution may not be the most effective for public health outcomes.

**3. Equity:** how to ensure fairness, making sure that that the uninsured, the unemployed, the poor, the homeless, and any marginalized groups or persons geographically isolated in rural communities have equitable access. The principle of equity is often in tension with the principle of efficiency, since it will probably cost more money and take longer to ensure equitable access to antiviral drugs for all these groups. Equity is likely consistent with effectiveness; for example, the unchecked spread of influenza in poor neighborhoods would spill over increasing disease in more affluent areas and

## Key Ethical Principles of Stockpiling Antiviral Drugs

overburdening healthcare facilities reducing the availability of resources for all in the community.

4. **Reciprocity:** those who assume occupational risks are entitled to greater protections. The American Medical Association Code of Medical Ethics states, “A duty to serve overrides autonomy rights in societal emergencies, even in cases that involve personal risks to physicians.” If healthcare workers are expected to work during a pandemic, benefiting their communities, access to recommended protective measures should be assured.

5. **Autonomy:** individuals should make their own health related decisions when those decisions do not adversely affect the health or safety of the community generally. Promoting autonomy for individuals and organizations with respect to antiviral drugs also may contribute to a more effective pandemic response by promoting planning and preparedness generally

As stated above, it was not our intent to conduct an exhaustive ethical analysis of the concept of shared responsibility. Instead, we start by addressing the following considerations.

1. Equity requires that individuals who cannot afford to purchase antiviral drugs nevertheless have access to them. This means that purchases should be subsidized or provided free of charge for those who cannot afford them. Which one of the sharing partners should do this? How is the ability to afford determined?
2. The same question of equity arises for public or private sector organizations with limited financial resources and/or competing needs. Purchases would also have to be subsidized for these organizations.
3. Effectiveness may require that access to antiviral drugs be assured for health care personnel who assume increased occupational risk. Since healthcare workers are necessary to treat others who get sick, the best overall outcome (reducing the impact of pandemic influenza) is likely to be achieved if these groups are provided with antiviral drugs for prophylaxis. Providing medications free of charge or at lowest cost is also supported by the principle of reciprocity.
4. An analogous consideration applies to emergency service workers. Since healthy personnel are necessary for society to continue to function, the principle of efficiency requires that access to antiviral drugs be ensured for employees in these organizations.
5. Achieving maximal effectiveness (positive health outcomes) depends on the degree of compliance on the part of individual households and healthcare organizations and providers. That is, the impact of household antiviral post-

## Key Ethical Principles of Stockpiling Antiviral Drugs

exposure prophylaxis on illness attack rates in communities depends on the proportion of households that comply. The effectiveness of healthcare for a community also may rely on each hospital preparing adequately. Therefore, reliance on households and healthcare organizations to purchase and stockpile antiviral drugs in a system of shared responsibility is likely to have less overall effectiveness than a system in which the public sector retains initial and ultimate responsibility for purchase of the drugs.

6. Effectiveness also requires that antiviral drugs for household post-exposure prophylaxis can be dispensed within less than two days following the onset of illness in the case-patient. The infrastructure at the tribal, state and local level is a critical factor in complying with the principles of efficiency and effectiveness. The argument for stockpiling in households is that if tribal, state, and local governments cannot effectively distribute the drugs, having them in the home may result in greater individual and community protection.

7. Placing the burden on private insurance companies to purchase antiviral drugs would fail to comply with several ethical principles. Effectiveness would not be achieved if insurers did not uniformly comply or if co-pays dissuaded individuals and organizations from purchasing antiviral drugs. Efficiency would not be achieved because the commercial price of antiviral drugs exceeds the price paid by the Federal government and because any individual or organization could purchase antiviral drugs – even if such purchases were not required for an effective public health response to the pandemic. Equity would not be achieved because of the millions of uninsured or underinsured people.

8. If governments, public and private sector organizations, and individuals have to share responsibility for purchase of antiviral drugs, so too do the manufacturers of these products have an obligation to the entire society. Just as companies have reduced the price of antiretroviral drugs for low-resource countries with a heavy burden of HIV disease, the pharmaceutical industry has an analogous responsibility to the entire U.S. society to mitigate the impact of pandemic influenza. Multiple ethical principles would be served if manufacturers of drugs take responsibility for accepting a lower profit margin in preparing for a public health emergency.

9. Placing the burden for purchasing and stockpiling antiviral drugs on individuals and families, as part of the shared responsibility, is likely to fail to comply with effectiveness, efficiency, or equity. Results from a CDC survey indicate that pandemic influenza is not a major health concern of most Americans (only 1% identified it among their three leading health concerns); almost half believe that the risk of a pandemic has been exaggerated (48% versus 45% who believe that it has not been exaggerated); and fewer than 10% of respondents identified antiviral drugs (Tamiflu) as something they “personally could do to help prevent

## Key Ethical Principles of Stockpiling Antiviral Drugs

the spread of a flu pandemic.”<sup>3</sup> These attitudes and beliefs suggest that people are unlikely to stockpile voluntarily in their homes. This would fail to comply with effectiveness, as only a certain proportion (perhaps a minority) of households would be protected. It would fail to comply with efficiency, since the cost is highest for individual, non-governmental purchases of antiviral drugs. And it would fail to comply with equity, since those who could least afford to purchase the drugs would forgo them.

10. If shared responsibility is implemented in a way that calls for public and private sector organizations to purchase antiviral drugs for their employees, what should be done about institutions, organizations, or groups that fail to fulfill their responsibility in such a shared arrangement? Failure on the part of any groups to fulfill their responsibility, while consistent with a principle of autonomy, would go against the principles of effectiveness, efficiency, and reciprocity.

- a. When responsibility is decentralized, it is inevitable that some organizations will not purchase their share, decreasing the ability to achieve public health objectives and, if the non-compliant organizations are in the healthcare or emergency services sectors, violating the principle of reciprocity.
- b. If organizations or institutions refuse to buy antiviral drugs as part of shared responsibility, is there any way to force them to do so? Would doing so violate still another ethical principle, that of respect for the autonomy of institutions, organizations, and individuals in a free, democratic society? Alternatively, does the principle of effectiveness in a public health emergency permit coercive actions that would otherwise not be ethically acceptable? If so, what mechanisms for enforcement would be available?
- c. If a scheme for shared responsibility is put in place but is voluntary, and some institutions do not purchase the share of drugs for which they are responsible, should government at some level step in and provide the requisite supply? This solution would increase effectiveness but also would reduce the likelihood that organizations and individuals comply with the policy calling for their purchase and stockpiling of the drugs.

11. Procedural fairness requires that the process of decision making be *transparent, inclusive, impartial*, ensure *due process*, and be *accountable*. This requirement includes the need for community involvement, the inclusion of a wide range of individuals and groups in the decision making process, and a mechanism for challenge and revision of the chosen scheme, including the

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<sup>3</sup> American Institutes for Research. Pandemic Influenza Disease and Vaccine Cross-Sectional Survey final report. Submitted to the Centers for Disease Control and Prevention and the Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, April 2007

## Key Ethical Principles of Stockpiling Antiviral Drugs

opportunity for revising decisions about priorities in light of further evidence and changing circumstances.

### CONCLUSIONS:

- 1. It is important that national recommendations on antiviral drug strategies (treatment and prophylaxis) recognize the burden that will be posed and the ethical questions raised in purchasing and stockpiling the drugs.** Therefore, those recommendations should be based on the best scientific evidence, the process for developing the guidance should be transparent, and the recommendations should be vetted with those who may bear part of the responsibility for their implementation.
- 2. While there are several applicable ethical principles that must be considered in assessing policy options, the overriding principles are effectiveness and equity.** When the goal of a health policy is individual protection, it is reasonable for autonomy rights to take preference. However, when the goal is public health and individual choice interferes with public good, a strategy must be chosen that will achieve the community benefits in a way that ensures fairness.
- 3. Although autonomy is an important principle in a democratic society, greater autonomy in implementing a public health policy is likely to result in less effectiveness.** Autonomy, in some aspects, may be linked with effectiveness as personal responsibility for preparedness is likely to extend beyond antiviral drugs alone. On balance, however, because of the likelihood that many organizations and individuals will not choose to purchase and stockpile drugs, if effective implementation of the recommended policy is primary, the public sector will likely need to assume substantial responsibility either through direct purchase of the antiviral drugs or by facilitating purchase in a way that best assures broad compliance.
- 4. Devolving responsibility broadly for purchase and stockpiling of antiviral drugs to organizations and potentially to individuals will inevitably violate principles of equity and reciprocity,** unless the policy can be strictly enforced or a safety-net created that assures uniform access.
- 5. Efficiency becomes a prime principle in order to minimize opportunity costs.** While pursuing effective public health policy for pandemic preparedness, it is important to recognize that funds devoted to antiviral drug purchase and stockpiling are likely to be taken from other beneficial uses. Given the impossibility of balancing current needs against the risk of a pandemic which while certain to occur is uncertain in both timing and

## Key Ethical Principles of Stockpiling Antiviral Drugs

severity, a strictly utilitarian approach that relies on determining the best overall outcome would be impossible. An additional problem is weighing incommensurate values (e.g., keeping healthcare and emergency response workers on the job, on the one hand, and providing bullet-proof vests for policemen on the other).

6. **A policy that maximizes effectiveness, efficiency, and equity would, from an ethical perspective, be optimal.**