

**Dr. Robinson Questions for the Record**  
**"Flu Preparedness and Response Efforts in the Midst of a Trying Flu Season"**  
**House Energy and Commerce Subcommittee on Oversight and Investigations**  
**February 3, 2015**

NOTE: CONTENT AS OF MARCH 2, 2015

**The Honorable Marsha Blackburn**

**1. Children have been hit particularly hard with the flu -- over 50 tragic deaths so far this season. I understand that the market for Tamiflu in suspension form is relatively small in the U.S. The suspension form would be needed for children. Does the CDC currently have this liquid form of Tamiflu in its stockpile?**

**Answer:** While allowing the commercial market to accommodate general demand during the 2014-15 influenza season, the Centers for Disease Control and Prevention (CDC) Strategic National Stockpile (SNS) has 100,000 treatment courses of liquid Tamiflu™ on order for pediatric populations (**Table 1**). This product is expected to be delivered to the SNS in 2015 in order to allow the commercial market to accommodate for market demands for suspension in the 2014-2015 flu season.

For this year's influenza season, Genentech prepared 2.8 million treatment courses of liquid Tamiflu™ for U.S. distribution with over 900,000 treatment courses still available at the manufacturer and in U.S. wholesale and retail markets (**Table 2**). Thus far, supply of the oral suspension (liquid) formulation has met U.S demand during this influenza season.

**Table 1. CDC/SNS inventory of Influenza Antiviral Drugs (02/23/15)**

Product	Formulation	Course
Tamiflu	30mg	11.8 M
Tamiflu	45mg	3.3 M
Tamiflu	75mg	36.6 M
Tamiflu Suspension*	6mg/ml	0
Relenza	5mg	10.7 M

\*100,000 courses on order, due in Aug 2015

**Table 2. Current Inventory of Tamiflu in U.S. Commercial Market (02/25/15)**

Formulation	Genentech Inventory (U.S.) (in millions)	Estimated U.S. Wholesale + Retail Inventory (in millions)	Total U.S. Inventory (in millions)
75 mg (adult, capsules)	2.814	0.614	3.428
Oral Suspension (6 mg/ml bottles)	0.442	0.464	0.906
45 mg (pediatric, caps)	0.082	0.083	0.165
30 mg (pediatric, caps)	0.258	0.146	0.404
<b>TOTALS</b>	<b>3.596</b>	<b>1.307</b>	<b>4.903</b>

**2. Is there an adequate amount to address a pandemic or even a severe flu season like this year if there were to be a shortage? If no, what contingency plans are in place for children who need a suspension of this medication?**

**Answer:** Yes. As documented in Table 1 above, in addition to the pediatric suspension that is on order, there are more than 15 million treatment courses of Tamiflu™ (30mg and 45mg capsules) in the CDC/SNS that could be used for children. For children who cannot swallow, these capsules may be opened, mixed with a thick sweetened liquid (like chocolate syrup), and given that way. In addition, Tamiflu 75mg capsules may be compounded by a pharmacist to make a suspension formulation as stated in the Food and Drug Administration (FDA)-approved Tamiflu package insert (commonly done in pharmacy practice). There are also 10 million treatment courses of Relenza™ presently available in the CDC/SNS that could be used for children over 5 years of age. We believe there will be a sufficient supply of influenza antiviral products for pediatric populations, including the liquid formulation, in support of pandemic preparedness within the CDC/SNS. If a shortfall is experienced, the FDA will reach out to pharmacies, as it does routinely, and directs them to make liquid formulations from encapsulated products. CDC and the Biomedical Advanced Research Development Authority (BARDA) in the Office of the Assistant Secretary for Preparedness and Response will reach out to the manufacturers and wholesalers to make more product available from U.S. and non-U.S. sources.

**3. Have you had any discussions with generic manufacturers regarding a generic suspension formulation once Tamiflu loses its exclusivity in 2017?**

**Answer:** BARDA and CDC are evaluating replenishment needs for all stockpiled antiviral drugs including Tamiflu suspension. As those evaluations continue, CDC will engage

manufacturers accordingly. We are aware that the following manufacturers are considering manufacturing generic versions of oseltamivir when the patent expires on Tamiflu™:

- Teva Pharmaceuticals, Barr Laboratories, Mylan Laboratories, and Ranbaxy Laboratories previously have stated interest in making oseltamivir;
- Cipla (INDIA) started manufacturing a generic product for the Indian market in 2008 and in 2009, which has been recognized by the World Health Organization for being as effective as oseltamivir (drug trade name Antiflu).

**4. As you know, the Public Readiness and Emergency Preparedness Act, or "PREP Act", authorizes the HHS Secretary to issue a declaration that provides liability immunity to organizations that manufacture countermeasures to diseases such as influenza. In fact, there currently is a PREP Act declaration in effect for pandemic influenza vaccines, which has been extended multiple times. The current declaration is set to expire at the end of the year. In light of the ongoing public health challenges associated with pandemic influenza do you expect this PREP Act declaration to be extended before the end of the year?**

**Answer:** The Public Readiness and Emergency Preparedness Act ("PREP Act") coverage in support of medical countermeasures for several diseases and threats, including anthrax, smallpox, botulism, nuclear, and pandemic influenza threats such as H5N1, H7N9, and other potential pandemic influenza viruses expires on December 31, 2015. HHS is reviewing options regarding the extension of PREP Act coverage past 2015.