

FDA Alert for Tamiflu®

by Philip A. Belcastro, Ph.D.

With the advent of H1N1 people and parents of school age children are faced with the decision to vaccinate or take their chances in surviving the flu season unscathed. A considerable proportion of New York City parents have decided not to vaccinate themselves or their children. Predictably a significant number of these adults and children have chosen to be medicated with a 'flu prevention drug'. Many of those that have contracted H1N1 or another flu virus have been treated with the antiviral drug Tamiflu®. Tamiflu® (Oseltamivir) is indicated for flu prevention and treatment in adults and children aged 1 year and older. **The FDA has just released an alert to health care providers of potential dosing errors with Tamiflu in liquid form.**

Health care providers usually write prescriptions for liquid medicines in milliliters (mL) or teaspoons—a milliliter is a measure of volume such as a liquid. Tamiflu® is dosed in milligrams (mg)—a milligram is a measure of weight (mass). The conversion is complicated and in fact not exact. Confounding the dosing problem further is the dosing dispenser packaged with Tamiflu®—it has hash-marks only in 30, 45 and 60 mg. **The FDA has received reports of errors with Tamiflu® where dosing instructions for the patient do not match the dosing dispenser.**

The nexus of the FDA alert is the dosing dispenser provided with Tamiflu®. With the dispenser calibrated in 30, 45 and 60 mg; the

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health care provider is required to convert fixed milligram doses of the drug into doses measured in milliliters. Secondly, sometimes the dispenser supplied by the pharmaceutical manufacturer with Tamiflu® is lost, or the health care provider chooses to use another dispenser. This introduces the potential of miscalculating the correct dose of Tamiflu® to dispense. A third concern: the FDA recommends that prescribers **avoid prescribing Tamiflu® (liquid form) in teaspoons**. This can lead to inaccurate dosing when Tamiflu is administered via a teaspoon. *“If a prescription is written in teaspoons, the pharmacist should convert the volume to mL and ensure that an appropriate measuring device, such as an oral syringe calibrated in mL, is provided. **The dosing dispenser packaged with the product should be discarded.** (FDA, 2009-A)”*

Tamiflu® for Oral Suspension (liquid form) was approved for use in treatment and prevention of influenza in pediatric patients 1 year of age and older. On October 30, 2009 the FDA approved **Emergency Use Authorization** for Tamiflu® for infants less than 1 year of age. However the FDA (2009-A) **warns**, *“Health care providers should be*

aware that there are limited data on safety and dosing when considering Tamiflu use in seriously ill, young infants with confirmed 2009 H1N1 influenza, or in one that has been exposed to a confirmed 2009 H1N1 influenza case. Infants should be carefully monitored for adverse events when Tamiflu is used.” It is extremely important that children and infants receive the precise dose of Tamiflu®.

Understandably the side effects and adverse effects of Tamiflu®, as any such drug, can range from minor to life threatening and fatal. Further, the potential for adverse effects increases if Tamiflu, or any medication, is administered in incorrect doses—especially in an overdose regiment. The side effects reported most often in Tamiflu® users are nausea and vomiting. Rare cases of: anaphylaxis (severe reaction that can result in death); serious skin reactions, delirium and abnormal behavior leading to injury or death have also been reported. **The FDA (2009-B) recommends that pediatric (children and infants) patients with influenza taking Tamiflu® should be closely monitored for signs of abnormal behavior.**

One additional note—the **FDA has authorized the use of certain lots of expired Tamiflu® during this public health emergency (FDA,**

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Suicide's Far-Reaching Repercussions for Others

by Danna Ethan, Ed.D.

In most cases, suicide is a solitary event and yet it has often far-reaching repercussions for many others. It is rather like throwing a stone into a pond; the ripples spread and spread (Alison Wertheimer, *A Special Scar*).

College can be a very stressful time for many students--juggling schoolwork and job, fitting in with peers, developing intimate relationships, facing higher academic stakes and living up to your expectations and those of others. Being at a large community college where it may be hard to develop close friendships or connect meaningfully with a professor, it can be easy for students' emotional problems to go unaddressed. In addition, depression (or other severe mental health problems like bipolar disorder and schizophrenia) often becomes apparent between the ages of 18 and 24, and can severely limit students' ability to cope with the transition to college. For someone who has lost hope and is unable to reach out to family, friends or others--suicide may feel like the only viable escape from despair.

Suicide is the second leading cause of death among college students. Results from a 2006 survey

of over 26,000 undergraduate and graduate students from 70 colleges and universities revealed that "relief from emotional or physical pain" was the leading reason cited for suicidal thinking followed by "problems with romantic relationships." A generalized desire to end life and problems with academics or school ranked third and fourth. More than 5 percent of the students surveyed reported having attempted suicide at least once and more than half reported having at least one episode of suicidal thinking at some point in their lives.

The topic of suicide is veiled in fear and stigma resulting in an abundance of misinformation. Here are some common myths:

MYTH #1: Most people who commit suicide have warned someone of their intention.

TRUE. 80% of people who commit suicide revealed their intention to at least one other person. Always take a suicide threat seriously.

MYTH #2: Most people who attempt suicide do not try it again.

FALSE. A person's risk of completing suicide increases with each attempt. In fact, a previous suicide attempt is a leading risk factor.

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MYTH #3: You can not stop someone who wants to commit suicide.

FALSE. Many suicidal people experience “suicidal ambivalence”, where they are not sure if they want to live or die. They may “gamble” with death in the hope that someone will save them.

MYTH #4: Among young adults, more females kill themselves than males.

FALSE. Females attempt suicide more, using methods that increase the chance of someone saving them (cutting, pills). Males complete the act four times more than females with methods that limit their chance of survival (suffocation or using a firearm).

MYTH #5: If a suicidal person’s spirits suddenly lift, then there is no need to worry about that person harming him/herself.

FALSE. An unexplainable lifting of spirits of a severely depressed person is a warning sign of suicide. This person may have made the decision to commit suicide and therefore feels unburdened and relieved.

MYTH #6: Talking to a troubled person about suicide will introduce

or reinforce suicidal ideas.

FALSE. If you approach someone you are concerned about with the topic of suicide, it is highly unlikely that this will trigger a suicide attempt. Speaking in a caring and direct manner to the person will often provide great relief and may be a crucial starting point for their thinking about healthier alternatives to dealing with insurmountable problems.

How do you know if someone is suicidal? Warning signs include:

- Dramatic mood changes
- Talking about suicide or death
- Expressing no purpose in life
- Withdrawing from family, friends, society
- Engaging in risky activities or acting recklessly
- Showing agitation or anxiety
- Increased alcohol or drug use
- Changes in sleeping or eating patterns
- Seeking out means like firearms or pills to hurt him/herself

If someone is displaying these signs, what can you do to help?

- Primarily, most suicide attempts are signs of extreme distress rather than a need for attention or harmless cry for help. Someone who seems suicidal needs immediate mental health assistance and should not be left alone.

- Do not handle or ‘treat’ this by yourself – even if you are sworn to secrecy. Seek help as soon as possible from someone specializing in suicide prevention like a mental health professional or social worker. Call BMCC’s Counseling Center (212-220-8140) or 800-273-8255(TALK), the 24-hour National Suicide Prevention Hotline.
- Remove methods that could be used for a suicide attempt such as stockpiled pills, firearms, alcohol or sharp objects.
- Be willing to listen and allow the person to express feelings without labeling the feelings as “good” or “bad.”
- Offer hope and practical alternatives (without sounding like you have all the answers).
- Talk about suicide in a matter-of-fact way. If you act shocked or uncomfortable, the person may not share their intentions.
- Above all, show concern, support and take all suicidal gestures, threats and attempts seriously—and immediately seek out professional help for this person.

Armed with knowledge, resources and a caring attitude, we can make a difference and help those in emotional pain return to living a fully functioning life. For more information on suicide, visit

www.save.org (Suicide Awareness Voices of Education – “SAVE”) or www.afsp.org (American Foundation for Suicide Prevention).

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Editor’s Note

If you need some sense on how to talk to someone that is contemplating suicide you would benefit from visiting the following website: <http://www.metanoia.org/suicide/index.html>. The site contains a wealth of valuable resources for both the helping/concerned person and the person contemplating suicide.

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2009-B). Under the *Shelf Life Extension Program*, if analysis of the available data indicates a drug is still acceptable for use, the FDA can authorize its use beyond its expiration date.

To be certain medications like Tamiflu® can provide the desired effect and be life saving. However any medication incorrectly dosed, especially when administered to children and infants, has the potential for a tragic effect. Whenever a medication is started, even an over-the-counter (non-prescription) medication, **the patient should be observed for any reactions. Such reactions should be reported to the physician and pharmacist immediately; for advice and consultation.** Severe reactions such as anaphylaxis can result in death in just hours. Severe reactions may necessitate immediate emergency care by dialing 911. Dosing compliance, that is the correct dose at the correct time intervals, is so important in terms of the drug's effectiveness as well as safety. Never hesitate to call upon your physician and pharmacist for consultation regarding the medications you or loved ones are taking. Such consultation is part of their obligation to you as their patient

and is part of the safety net that protects patients from the adverse risks of medication.

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Babybel Withdrawal

by Alexandria Ynoa

I am a lover of cheese; a dairy dreamer, if you will. I have an obsessive fetish, almost, for all things curd. From the milder havarti and gruyere to the sharpest cheddars, cheeses dominate my food pyramid, outstandingly prominent amongst the “lesser” meats and vegetables. For me, cheese is no snack or sandwich topper. A fresh, milky twist of mozzarella and a knife -- and there is dinner. There is only one thing that holds me back from my mousey dream diet: cholesterol.

My troubles with cholesterol are inherited. I never met my maternal grandfather who died at 45 of heart disease. My mother and her four sisters have high cholesterol. I am now one of high cholesterol's victims. It is the only thing that keeps that waxy red wrapper on the Babybel.

I learned of my cholesterol issue the first time I had blood drawn the summer before I went away to college. I was told that my bad cholesterol readings were “off the charts” and I would have to make some major changes to my diet. I was instructed to stay away from fried foods, not to eat eggs and to stay away entirely from my beloved cheese.

At first it was really tough to

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eliminate cheese. There are aids for people who are hooked on things (patches and gum for smokers, rehab for drug abusers). The fact that I had to do this “cold turkey” made it far more difficult to deal with. After all, what is a turkey sandwich without cheese? I knew there was absolutely no way I could remove my darling dairy from my life entirely. Over time though, I have found a few creative ways to eat healthier and incorporate my one true love into my diet.

For starters, I no longer eat fried foods which taste just as good steamed or grilled. I have stopped using grated and shredded cheeses on my soups, salads and pasta dishes, as they taste much the same without the cheese. I have limited my cheese-snack consumption to a small Babybel with my lunch daily. The thought of survival on cheeseless sandwiches was also a tough road to get around. But the removal of mayonnaise has allowed me a slice or two per sandwich.

Really, what is apparent here is that the foods we eat depend on the choices we make. What any person likes can be incorporated into his or her life with a little tweaking and a lot of moderation. But if you have a

taste for a fried wing, have one. If you really need that slice of pizza, but have just one. And if it is a piece of cheese you crave--just cut it a little smaller than usual.

Contributing Editor's Note

Even in your teens and twenties, you can have high cholesterol. And if your total cholesterol level is 240 mg/dL or higher, you have more than twice the risk of coronary heart disease as someone with levels below 200 mg/dL. Cholesterol is a waxy, fat-like substance produced by our liver. Cholesterol can also be found in certain foods such as red meat, whole milk and eggs. We need a certain amount for our body to function properly, but too much cholesterol can increase a person's risk of developing heart disease. Did you know that many of us can avoid taking medication by taking control of our cholesterol levels? First, have your cholesterol screened with a simple blood test by your doctor. Keep your cholesterol in check by maintaining a healthy weight, eating a diet low in saturated fat and getting regular exercise. For more information, visit: www.american-heart.org.

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