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VACCINE INFORMATION STATEMENT

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Influenza (Flu) Vaccine

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(Inactivated or Recombinant):

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What you need to know

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1 Why get vaccinated?

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Influenza ("flu") is a contagious disease that spreads around the United States every year, usually between October and May.

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Flu is caused by influenza viruses, and is spread mainly by coughing, sneezing, and close contact.

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Anyone can get flu. Flu strikes suddenly and can last several days. Symptoms vary by age, but can include:

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- fever/chills

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- sore throat

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- muscle aches

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- fatigue

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- cough

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- headache

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- runny or stuffy nose

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Flu can also lead to pneumonia and blood infections, and cause diarrhea and seizures in children. If you have a medical condition, such as heart or lung disease, flu can make it worse.

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Flu is more dangerous for some people. Infants and young children, people 65 years of age and older, pregnant women, and people with certain health conditions or a weakened immune system are at greater risk.

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Each year **thousands of people in the United States die from flu**, and many more are hospitalized.

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Flu vaccine can:

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- keep you from getting flu,

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- make flu less severe if you do get it, and

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- keep you from spreading flu to your family and other people.

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Inactivated and recombinant flu vaccines

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A dose of flu vaccine is recommended every flu season. Children 6 months through 8 years of age may need two doses during the same flu season. Everyone else needs only one dose each flu season.

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Some inactivated flu vaccines contain a very small amount of a mercury-based preservative called thimerosal. Studies have not shown thimerosal in vaccines to be harmful, but flu vaccines that do not contain thimerosal are available.

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There is no live flu virus in flu shots. **They cannot cause the flu.**

308 There are many flu viruses, and they are always changing. Each year a new flu vaccine is
 325 made to protect against three or four flu viruses that are likely to cause disease in the
 340 upcoming flu season. But even when the vaccine doesn't exactly match these viruses, it may
 344 still provide some protection.

348 Flu vaccine cannot prevent:

- 360 • flu that is caused by a virus not covered by the vaccine,
- 361 or
- 369 • illnesses that look like flu but are not.

383 It takes about 2 weeks for protection to develop after vaccination, and protection lasts
 387 through the flu season.

395 **3 Some people should not get this vaccine**

404 Tell the person who is giving you the vaccine:

- 419 • **If you have any severe, life-threatening allergies.** If you ever had a life-threatening
 435 allergic reaction after a dose of flu vaccine, or have a severe allergy to any part of this
 452 vaccine, you may be advised not to get vaccinated. Most, but not all, types of flu vaccine
 461 contain a small amount of egg protein.

- 471 • **If you ever had Guillain-Barré Syndrome (also called GBS).**

487 Some people with a history of GBS should not get this vaccine. This should be discussed
 490 with your doctor.

- 496 • **If you are not feeling well.**

516 It is usually okay to get flu vaccine when you have a mild illness, but you might be asked to
 522 come back when you feel better.

528 **4 Risks of a vaccine reaction**

543 With any medicine, including vaccines, there is a chance of reactions. These are usually
 555 mild and go away on their own, but serious reactions are also possible.

569 Most people who get a flu shot do not have any problems with it.

576 **Minor problems** following a flu shot include:

- 585 • soreness, redness, or swelling where the shot was given
- 586 • hoarseness
- 591 • sore, red or itchy eyes
- 592 • cough
- 593 • fever
- 594 • aches
- 595 • headache
- 596 • itching
- 597 • fatigue

614 If these problems occur, they usually begin soon after the shot and last 1 or 2 days.

625 **More serious problems** following a flu shot can include the following:

- 638 • There may be a small increased risk of Guillain-Barré Syndrome (GBS) after inactivated
- 654 flu vaccine. This risk has been estimated at 1 or 2 additional cases per million people
- 670 vaccinated. This is much lower than the risk of severe complications from flu, which can be
- 674 prevented by flu vaccine.
- 689 • Young children who get the flu shot along with pneumococcal vaccine (PCV13) and/or
- 707 DTaP vaccine at the same time might be slightly more likely to have a seizure caused by
- 724 fever. Ask your doctor for more information. Tell your doctor if a child who is getting flu
- 730 vaccine has ever had a seizure.

738 **Problems that could happen after any injected vaccine:**

- 750 • People sometimes faint after a medical procedure, including vaccination. Sitting or lying
- 767 down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your
- 781 doctor if you feel dizzy, or have vision changes or ringing in the ears.
- 7978 • Some people get severe pain in the shoulder and have difficulty moving the arm where a
- 04 shot was given. This happens very rarely.
- 818 • Any medication can cause a severe allergic reaction. Such reactions from a vaccine are
- 835 very rare, estimated at about 1 in a million doses, and would happen within a few minutes
- 842 to a few hours after the vaccination.
- 860 As with any medicine, there is a very remote chance of a vaccine causing a serious injury or
- 861 death.
- 873 The safety of vaccines is always being monitored. For more information, visit:
- 882 www.cdc.gov/vaccinesafety/

890 **5 What if there is a serious reaction?**

895 What should I look for?

- 911 • Look for anything that concerns you, such as signs of a severe allergic reaction, very high
- 915 fever, or unusual behavior.

930 Signs of a severe allergic reaction can include hives, swelling of the face and throat,

943 difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few

951 minutes to a few hours after the vaccination.

954 **What should I do?**

- 973 • If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1
- 985 and get the person to the nearest hospital. Otherwise, call your doctor.
- 997 • Reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS).
- 1010 Your doctor should file this report, or you can do it yourself through the
- 1034 VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

1040 *VAERS does not give medical advice.*

1047 **6 The National Vaccine Injury Compensation Program**

1062 The National Vaccine Injury Compensation Program (VICP) is a federal program that was

1074 created to compensate people who may have been injured by certain vaccines.

1090 Persons who believe they may have been injured by a vaccine can learn about the program
1114 and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at
1133 www.hrsa.gov/vaccinecompensation. There is a time limit to file a claim for compensation.

1139 **7 How can I learn more?**

- 1054 • Ask your healthcare provider. He or she can give you the vaccine package insert or
1059 suggest other sources of information.
- 1065 • Call your local or state health department.
- 1075 • Contact the Centers for Disease Control and Prevention (CDC):
- 1085 • Call 1-800-232-4636 (1-800-CDC-INFO) or
- 1092 • Visit CDC's website at mvw.cdc.gov/flu

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1098 Inactivated Influenza Vaccine