

IN THE CIRCUIT COURT OF THE SEVENTEENTH JUDICIAL  
CIRCUIT, IN AND FOR BROWARD COUNTY, FLORIDA

OFFICE OF THE ATTORNEY GENERAL, )  
DEPARTMENT OF LEGAL AFFAIRS, )  
STATE OF FLORIDA, )  
 )  
Plaintiff, )  
vs. )  
 )  
ASAP MEDS, INC., a Florida Corporation )  
d/b/a Meds-Stat, )  
 )  
Defendant. )  
\_\_\_\_\_ )

Case No. 04-16032 Div.09

STATEMENT OF INTEREST OF THE UNITED STATES

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October 22, 2004

Comes now the United States and files this Statement of Interest, pursuant to 28 U.S.C. § 517, to advise the Court of its interest in this matter.<sup>1</sup>

### SUMMARY

This action is about price gouging. HHS supports the State of Florida's efforts to prevent price gougers from charging unconscionable prices not reasonably related to the fair market value of pharmaceuticals sold. Price gouging complicates CDC efforts to ensure that vaccine is distributed to the high priority populations. This is a particular public health problem due to a loss of much of the influenza vaccine for the 2004-2005 flu season.

Influenza, commonly known as the "flu," is a contagious respiratory illness caused by influenza viruses. Every year in the United States, on average: 5% to 20% of the population develop influenza; more than 200,000 people are hospitalized because of influenza complications; and approximately 36,000 people die from complications of influenza virus infection. Each influenza season is unpredictable, with cases of influenza typically peaking between December and March. Therefore, the severity of this year's 2004-2005 influenza season is not known, and cannot be forecast with any certainty. The best way to prevent influenza is to receive an influenza vaccination each fall.

On October 5, 2004, Chiron Corporation notified the U.S. Department of Health and Human Services (HHS), through the Centers for Disease Control and Prevention (CDC), that none of its influenza vaccine would be available for distribution in the United States because of contamination problems with its production facility in the United Kingdom. As a result, the expected supply of inactivated influenza vaccine (containing killed virus) has effectively been cut in half.

As a result of this shortage, CDC has announced priority groups for vaccination with inactivated influenza vaccine for the 2004-2005 influenza season. These priority groups include those who benefit from and need the vaccine the most: the elderly, the infirm, children between ages 6 and 23 months, pregnant women, health-care workers, and people with serious underlying medical conditions, such as heart or respiratory problems. Several state health departments have issued orders limiting vaccine distribution to those in greatest need, and state attorneys general have taken action against distributors

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<sup>1</sup> 28 U.S.C. § 517 provides:

The Solicitor General, or any officer of the Department of Justice, may be sent by the Attorney General to any State or district in the United States to attend to the interests of the United States in a suit pending in a court of the United States, or in a court of a State, or to attend any other interest of the United States.

who are reportedly charging up to ten times the usual price for vaccine. A small number of thefts of vaccine stocks have been reported across the country, and clinics are running out of vaccine, having to turn away large numbers of people who have stood in line for hours.

Price gouging exacerbates these problems, by contributing to hoarding and removal of vaccine from established distribution channels. Providers who would typically purchase vaccine for Medicare beneficiaries will be disinclined to do so because the reimbursement rate for influenza vaccine is established at about \$10.10 per dose. Price gouging may also have a similar negative impact on Florida's Medicaid program by removing vaccine from established distribution channels. Furthermore, price gouging may contribute to other evils such as tampering, counterfeiting, and product contamination, because providers who obtain vaccine from price speculators do so without any assurance that the vaccine has been handled, stored, and shipped according to accepted practices. Accordingly, this Court should grant the relief requested in Florida's Complaint and Application for Preliminary Relief.

### **BACKGROUND**

#### **A. The Influenza Vaccine Shortage.**

On October 5, 2004, Chiron Corporation notified the CDC that none of its influenza vaccine (Fluvirin) would be available for distribution in the United States for the 2004-2005 influenza season. The Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom had suspended the company's license to manufacture Fluvirin vaccine in its Liverpool facility for 3 months due to contamination problems, thus preventing any distribution of the vaccine in the United States. As a result, the expected supply of inactivated influenza vaccine has been reduced by approximately one-half for the 2004-2005 influenza season.

The remaining supply of inactivated influenza vaccine is approximately 58 million doses of Fluzone manufactured by Aventis Pasteur, 33 million doses of which have already been distributed within the United States. Purchasers of the vaccine include health care providers, the United States government, and wholesale distributors. A limited amount (approximately 3 million doses) of live attenuated influenza vaccine (LAIV/FluMist) manufactured by MedImmune, Inc. is available to healthy children and adults between the ages of 5 and 49 years.

In light of the current shortage of vaccine, CDC, in coordination with its Advisory Committee for Immunization Practices (ACIP), has prioritized the populations originally targeted for vaccination and issued interim recommendations for influenza vaccination for the 2004-2005 season. These

recommendations became effective on October 5, 2004, and supersede earlier recommendations. The priority groups include the following:

- All children aged 6 - 23 months.
- All adults aged 65 years and older.
- Persons aged 2-64 years with underlying chronic medical conditions.
- Residents of nursing homes and long-term care facilities.
- Children aged 6 months -18 years on chronic aspirin therapy.
- All women who will be pregnant during the influenza season.
- Healthcare workers involved in direct patient care.
- Household contacts of infants less than 6 months of age.

Projecting the numbers of the people in these categories who sought and received vaccination in 2002-2003 to the current influenza season (and also factoring in a 5% increase in growth of both the population and vaccination demand), it is estimated that approximately 48.2 million doses will be needed to vaccinate individuals in these priority groups. The CDC recommends that persons who are not included in one of the priority groups described above should not receive influenza vaccine in order to increase its availability to those in the priority groups.

**B. This Action.**

Two companies manufacture most of the influenza vaccine for use in the United States, Aventis Pasteur and Chiron. These companies either contract directly with end users such as doctors, health departments, hospitals, nursing homes and pharmacies, or sell their products to distributors. Vaccine sold to distributors is then resold to end users. In addition, some vaccine is distributed through the speculator market. Speculators typically purchase vaccine from end users for redistribution at a higher price. During a shortage, speculators can purchase vaccine at prices generally higher than the standard market will bear, then resell them at even higher prices.

On October 13, 2004, the Office of the Attorney General, Department of Legal Affairs, State of Florida, brought suit against defendant ASAP Meds, Inc., a Florida corporation, for violations of state law relating to the "unconscionable acts and practices" of defendant in selling to a Kansas City pharmacy five vials of influenza vaccine at a rate of over \$900.00 per vial. The catalogue price for this vaccine is \$85.00 per vial. The State of Florida is seeking to enjoin the Defendant from, among other things, charging unconscionable prices not reasonably related to the fair market value of pharmaceuticals sold. As part of

its complaint, the State asserts that the pricing of influenza vaccine at such an extreme level reduces the availability of the vaccine to those persons who need it most. The U.S. Department of Health and Human Services agrees with this assertion.

### **C. The U.S. Department of Health of Human Services.**

One of the largest federal agencies, the U.S. Department of Health and Human Services (HHS), is the principal agency for protecting the health of all Americans. Comprising 12 operating divisions, HHS's responsibilities include public health; biomedical research; food, drugs, and medical devices; Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP); social services; and more. Component agencies within HHS include the Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid Services (CMS), and the Food and Drug Administration (FDA). CDC is recognized as a leader in protecting the health and safety of people, at home and abroad, by providing credible information to enhance health decisions and promoting health through strong partnerships. In addition, under the authority of section 1928 of the Social Security Act (42 U.S.C. § 1396s) and section 317 of the Public Health Service Act (42 U.S.C. 247b), CDC purchases quantities of vaccine through State immunization programs for administration to particular groups of individuals, primarily children. CDC and the States purchase approximately 55% of the total pediatric vaccine used in the US each year. CMS administers the Medicare program, and works in partnership with States to administer Medicaid, SCHIP, and health insurance portability standards. FDA is statutorily charged under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § § 321 *et. seq.*, with ensuring that vaccines are safe and effective; it also certifies the manufacturing facilities of vaccine manufacturers. While the federal government is a central player in the effort to address the influenza vaccine shortage, distribution of influenza vaccine normally is a private sector endeavor over which the federal government has limited control.

The disappointing loss of much of the Nation's influenza vaccine due to contamination during manufacturing poses a serious challenge to the Nation's vaccine supply for the upcoming flu season and to the health and well-being of those who most need the influenza vaccine. Tommy Thompson, the HHS Secretary, has called upon all Americans to work together to ensure the vaccine gets to those individuals. While the vast majority of Americans have been working to meet this challenge, unethical parties have been looking to profit unjustly at the expense of the public's health. On October 14, 2004, the Secretary sent a letter to the attorney general of each State encouraging them to thoroughly investigate reports of

price gouging and prosecute those engaging in this unethical and illegal activity to the full extent of the law.

### **STATEMENT OF INTEREST**

#### **Price Gouging Of Influenza Vaccine Risks The Public's Health, Particularly The Most Vulnerable Of The U.S. Population: The Elderly, Infants, And Those With Chronic Medical Conditions.**

##### **A. Price Gouging Leads to Allocation of Scarce Influenza Vaccine Not Based on Who Has the Most Need.**

Parties engaging in price gouging such as that described in the Florida complaint have interests that are discordant or diametrically opposed to vaccinating the maximum number of at-risk persons in CDC's recommended priority groups. While the federal government is interested in allocating scarce vaccine resources among those vulnerable populations at greatest risk for complications from influenza, vaccine profiteers are only interested in allocating vaccine so as to achieve the greatest windfall profits for themselves. Therefore, it is possible that speculators may hoard vaccine in the hopes of driving market prices even higher, thereby compounding the shortage of vaccine for at-risk populations. Moreover, vaccine doses in speculators' possession are not available to CDC, the State of Florida, and other public health authorities responsible for directing allocation in a manner consistent with CDC/ACIP recommendations. The Federal contract, which provides for purchase of vaccine to be distributed through the States, accounts for 12% of the total number of doses available this year.

##### **B. Price Gouging Risks the Health of Medicare and Medicaid Eligible Patients, Vulnerable Populations Most in Need of Receiving the Influenza Vaccine.**

Medicare, the Nation's largest health insurance program, covers nearly 40 million Americans. Enacted in 1965, the program provides health insurance to people age 65 years and over, those who have permanent kidney failure, and certain individuals under age 65 with disabilities. Medicare is administered by CMS. Medicaid, also enacted in 1965, is a program jointly funded by the federal government and the States, in which the federal government matches state spending to provide medical and health-related services to its beneficiaries. Medicaid beneficiaries include low-income families with children, aged, blind or other disabled people on Supplemental Security Income; certain low-income pregnant women and children; and certain people who have very high medical bills. States have the authority to establish eligibility standards, set the rate of payment for services, and determine the type, amount, duration, and scope of services. In Florida, the Agency for Health Care Administration (AHCA) develops and carries

out policies related to the Medicaid program. Price gouging for medical supplies and services, such as that alleged in the complaint, may have a negative impact on both the Medicare and Medicaid programs.

Providers who would typically purchase vaccine for administration to Medicare beneficiaries will be disinclined to do so this year, because the reimbursement rate for influenza vaccine established by CMS is approximately \$10.10 per dose, plus an amount for providers' services in administering the vaccine, for a total reimbursement of \$18 per dose. These rates are determined in accordance with a methodology established by statute which does not provide for adjustments. As a result, because of the mismatch between the fixed reimbursement rate from Medicare and the exorbitant rates charged by price gougers, substantially fewer Medicare beneficiaries in at-risk populations are likely to be vaccinated. According to the CDC, the typical influenza season in the United States causes an estimated 36,000 influenza-related deaths per year and accounts for over 200,000 hospitalizations. These numbers could increase if at-risk populations are not vaccinated because of the lack of vaccine availability through established sources and distribution channels.

Price gouging may have a similar negative impact on Florida's Medicaid program by removing vaccine from established distribution channels. By contributing to a mentality of scarcity and hoarding, vaccine profiteers may interfere with the State's ability to provide vaccine to these vulnerable populations. According to the Consumer Assessment of Health Plans Survey, 2003, which represents Medicare fee-for-service and Medicare managed-care, approximately 22.5 million individuals received flu vaccine under these plans.

**C. Price Gouging May also Result in Violations of the Federal Food, Drug, and Cosmetic Act due to Tampering with, and Counterfeiting of, Influenza Vaccine.**

The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § § 321 *et seq.*, and its implementing regulations, 21 C.F.R. Parts 1-1299, set forth certain requirements concerning the distribution of drugs, such as the influenza vaccine, as well as requirements that govern, among other things, the storage and handling of such drugs.<sup>2</sup> The FDCA and Title 18 of the U.S. Code (the Criminal Code) prohibit the counterfeiting of, or tampering with, drugs such as the influenza vaccine.<sup>3</sup>

Price gouging can lead to the counterfeiting of, or tampering with, the influenza vaccine.

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<sup>2</sup> Although FDA licenses influenza vaccine under the Public Health Service Act (PHSA), 42 U.S.C. § 262, vaccines also meet the definition of "drug" under the FDCA, 21 U.S.C. § 321(g). Vaccines are thus subject to many of the FDCA requirements that apply to human drugs. The influenza vaccine is a prescription drug under the FDCA. 21 U.S.C. § 353(b)(1). The biologics licensing section of the PHSA also is a source of authority for vaccine storage requirements. 42 U.S.C. § 262.

<sup>3</sup> 21 U.S.C. § 331(i); 18 U.S.C. § 2320; 18 U.S.C. § 1365.

Counterfeiting a drug; selling, dispensing, or holding for sale a counterfeit drug; and tampering with a drug are federal crimes.<sup>4</sup> Price gougers create a public health risk by increasing the likelihood that the flu vaccine will be tampered with or counterfeited. Unchecked price gouging may lead to an exorbitant increase in the market price for flu vaccine. This exorbitant market price, in turn, may increase the incentive for counterfeiters to manufacture fake, ineffective and potentially unsafe vaccines, and for distributors to dilute the vaccine to increase supply.<sup>5</sup>

### CONCLUSION

While most Americans have been acting responsibly in light of the challenge posed by the current vaccine shortage, some unethical individuals have been looking to profit unjustly at the expense of the public's health. The U.S. Department of Health and Human Services strongly supports the State of Florida's efforts to enjoin any price-gougers from charging unconscionable prices not reasonably related to the fair market value of pharmaceuticals sold.

Respectfully submitted,

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<sup>4</sup> 21 U.S.C. § 331(i); 18 U.S.C. § 2320; 18 U.S.C. § 1365.

<sup>5</sup> Federal felony criminal convictions can be obtained for such acts. For example, on November 15, 2001, information was received by the Western New York Health Care Fraud Task Force alleging that Dr. Marvin Galler was diluting flu vaccine which was later administered to his patients. The FDA Forensic Chemistry Center reported that the vaccine seized at Galler's medical practice was diluted to the point that there was very little vaccine left in the bottles. On July 7, 2003, Galler appeared in the Western District of New York and was convicted of one felony count of violating 21 U.S.C. § 331(k) and 333(a)(2) - Adulteration of a Drug.





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October 22, 2004

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that a true and correct copy of the foregoing Statement of Interest of the United States has been sent via U.S. mail and via fax this 22 day of October, 2004 to:

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