Declaration of Dr. Albert C. Weihl, M.D.

I, Albert C. Weihl, M.D., hereby submit this declaration in order to provide information about the use of Adenocard® (adenosine injection) in the emergency room and ambulance settings. I have extensive experience in the use and administration of Adenocard® as well as with emergency room and ambulance practices. I am Board certified by, among others, the American Board of Emergency Medicine and the American Board of Internal Medicine. I am an Oral Board Examiner for the American Board of Emergency Medicine. My C.V. is attached hereto as Appendix A.

I hereby declare as follows:

1. I am familiar with the drug Adenocard®, which is indicated for conversion to sinus rhythm of paroxysmal supraventricular tachycardia (PSVT), including that associated with accessory bypass tracts (Wolff-Parkinson-White Syndrome). Adenocard® is primarily used in an emergency room or ambulance setting. In most cases, need for the product is sudden, and speed of administration is critical.

2. The Adenocard® label describes administering up to three doses of Adenocard® to patients for the treatment of PSVT. The label recommends a third dose -- of 12 mg -- only for patients who do not respond to the first two injections. However, in clinical practice, paramedics and emergency department personnel often switch to alternate treatment modalities if patients do not respond to one or two adenosine injections.

3. It is important in emergency situations to have the proper dose of adenosine prepared and ready to use. Adenocard®'s current strength and packaging is ideal for rapidly and reliably administering the correct dose of adenosine to patients. When emergency medical personnel need to administer Adenocard®, they simply unwrap a single prefilled syringe and administer its full contents to the patient. If a second dose is needed, a second full syringe is administered. The individual packaging virtually eliminates the possibility of dosing error.

4. Similarly, with the existing generic formulations of adenosine, the entire vial is drawn into the syringe and administered.
5. I have been informed that there is a proposal to package adenosine in 18 mg and 30 mg strength vials, labeled for treatment of PSVT. I have been asked whether vials of these strengths would be beneficial or useful. It is my opinion that such vials would not be useful in an emergency setting and would lead to waste and the potential for dosing errors.

6. With 18 mg and 30 mg strength vials, emergency room personnel and paramedics will be forced to measure out the proper dose (either 6 mg or 12 mg) from the vials before administering adenosine. In a critical situation, such as in a bumpy ambulance or in low light, this can easily result in dosing errors.

7. The proposed multidose vials would not be more efficient than current packaging because each single dose of adenosine would have to be drawn individually. I would warn against drawing up multiple doses of adenosine into a single syringe because adenosine is only effective in treatment of PSVT if administered as a rapid bolus. Although some drugs, such as lidocaine, can be slowly titrated into a patient by administering multiple doses from a single syringe, adenosine, because of its extremely short half life, is likely to be ineffective unless administered as a forceful rapid bolus. Indeed, in my experience, adenosine is practically unique in having to be administered extremely rapidly in order to be effective.

8. Therefore emergency room personnel and paramedics are trained to administer the drug with a pressure injection. Since these personnel are accustomed to administering the entire 6 mg or 12 mg vials or prefilled syringes, if a larger vial is used, there is a real possibility that they may mistakenly inject an entire 30 mg vial into a patient.

9. Such dosing errors may put patients at unnecessary risk of complications and adverse events such as hypotension, bronchospasm, or high-grade atrioventricular (AV) node block. For example, a period of prolonged asystole could be created by such a dosing error. A prolonged period of asystole could lead to other unneeded treatment such as atropine injection.

10. In my opinion, if these larger vials were available and used in the hospital emergency room, every nurse and paramedical unit would have to be extensively retrained in the use of the drug. Since generic manufacturers do not provide in-service training, the need for retraining should be placed as a box warning on these larger vials to avoid over dosage.

11. Even in a large emergency room practice such as mine, the need for adenosine is sporadic and limited, perhaps one or two times a month. Adenocard®, or currently available generic adenosine, is not sufficiently expensive to make the cost savings (if any) on the use of larger vials offset the costs of the necessary retraining.
I declare under penalty of perjury that the foregoing is true and correct, to the best of my knowledge, information, and belief. Executed on October 20, 2004, in Madison, Connecticut.

[Signature]

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(203) 421-7069 (office fax)
e-mail: albert.weihl@yale.edu

Date of Birth: August 22, 1946, Cincinnati, Ohio

Positions:

2004 - Present:
Assistant Clinical Professor
Section of Emergency Medicine
Departments of Surgery and Internal Medicine
Yale University School of Medicine
New Haven, Connecticut

2002 - June 2004:
Co-Director, Chest Pain Center
Yale-New Haven Hospital
New Haven, Connecticut

December 2000 - July 2001:
Acting Section Chief/Department Chair
Section of Emergency Medicine/Department of Emergency Services
Yale University School of Medicine/Yale-New Haven Hospital
New Haven, Connecticut

February 2000 - September 2000:
Acting Residency Program Director
Emergency Medicine Residency Program
Yale-New Haven Medical Center
New Haven, Connecticut

1997 - Present:
Oral Board Examiner
American Board of Emergency Medicine

1993 - 1998:
Residency Program Director
Emergency Medicine Residency Program
Yale-New Haven Medical Center
New Haven, Connecticut

1991 - 2004:
Assistant Professor
Section of Emergency Medicine
Departments of Surgery and Internal Medicine
Yale University School of Medicine
New Haven, Connecticut
1991–June 2004: Educator, Director
Department of Emergency Services
Yale-New Haven Hospital

1990–1998: Assistant Medical Director
Department of Emergency Services
Yale New Haven Hospital

1989–1990: Medical Director
New Haven Sponsor Hospital Program
Yale-New Haven Hospital/Hospital of Saint Raphael

1988–1990: Acting Medical Director
Department of Emergency Services
Yale-New Haven Hospital

1987–1991: Attending in Internal Medicine
Department of Emergency Services
Yale-New Haven Hospital
New Haven, Connecticut

1982–2000 Emergency Department Physician
Middlesex Hospital/Shoreline Clinic
Middletown/Essex, Connecticut

1980–1991: Assistant Clinical Professor
Department of Internal Medicine
Yale University School of Medicine
New Haven, Connecticut

1982–1987: Attending in Internal Medicine
Hospital of Saint Raphael
New Haven, Connecticut

1978–present: Attending Physician in Internal Medicine
Yale-New Haven Hospital
New Haven, Connecticut

1978–1987: Physician, Department of Internal Medicine
Community Health Care Plan
150 Sargent Drive
New Haven, Connecticut

1977–1978: Associate Staff
Department of Emergency Services
Fairfax Hospital
Falls Church, Virginia
1976 - 1978: Lieutenan t Commander, Medical Corps
United States Naval Reserve
Hyperbaric Medicine and Physiology Department
Naval Medical Research Institute
Bethesda, Maryland

1975 - 1976: Emergency Department Physician
Winchester Hospital
Winchester, Massachusetts

1974 - 1976: Clinical and Research Fellow
Endocrine and Thyroid Units
Massachusetts General Hospital

1973 - 1974: Senior Assistant Resident in Medicine
Yale-New Haven Hospital

1972 - 1973: Junior Assistant Resident in Medicine
Yale-New Haven Hospital

1971 - 1972: Intern in Medicine
Yale-New Haven Hospital

Degrees:
1971 M.D. Yale University School of Medicine

1967 B.S. Molecular Biophysics - Yale College
Degree earned in three years

Professional Organizations:
1988 - present Society for Academic Emergency Medicine
1987 – 2004 American College of Emergency Physicians
1975 – 2004 American College of Physicians
1994 – 2001 American Medical Informatics Association
Board Certification:

1998  Re-certification, Diplomate, American Board of Emergency Medicine
1989  Diplomate, American Board of Emergency Medicine
1977  Diplomate, Subspecialty Board in Endocrinology and Metabolism
1974  Diplomate, American Board of Internal Medicine
1972  Diplomate, National Board of Medical Examiners

Licenses:

1992  Hawaii
1973  Connecticut

Committees and Boards:

September 2002  Co-Chairman, 5th Fifth National Congress of Chest Pain Centers
Society of Chest Pain Centers and Providers
New Haven, Connecticut

2001-2004  Claims Committee (Risk Management)
Yale-New Haven Medical Center

2000-2004  Ethics Committee
Yale-New Haven Medical Center

February 2000-September 2000  Graduate Medical Education Committee
Yale-New Haven Medical Center

1998-present  Editorial Board
Emergency Medicine Reports

1996-1998  Chairman, Subcommittee on Medical-Legal Education
Graduate Medical Education Committee
Yale-New Haven Medical Center

1995-2004  Chairman, Clinical Computer Workstation Committee
Yale-New Haven Medical Center

1995-1998  Graduate Medical Education Committee
Yale-New Haven Medical Center
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<td>B.S., Magna Cum Laude, Yale College</td>
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<td>Phi Beta Kappa, Yale College</td>
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July 1, 2004


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