Appendix 7.8

The patient was a 70 year old man with a history of hypertension, atrial fibrillation, CVA, diabetes and carcinoma of the colon with lymph node metastasis who was referred for MRI to determine the presence or absence of liver metastasis. Prior to coming for an MRI this patient had a CT of the abdomen and pelvis and developed itchiness in the throat and a single hive on the forehead following intravenous iodinated contrast administration. The patient was taking several medications, including lisinopril and nifedipine for hypertension, and methyldopa and digoxin for his heart. He was also receiving chemotherapy. Approximately one to two minutes after administration of Combidex the patient complained of facial flushing. He then became unresponsive, diaphoretic, with labored breathing and a weak and irregular pulse. The patient also [illegible] in his right [illegible] and experienced urinary incontinence. Oxygen was administered immediately but no other treatment was given at the time.

Instead of immediately treating the patient, paramedics were called to the outpatient MRI. After arrival the paramedics performed CPR and delivered oxygen via ambu-bag. Epinephrine and atropine were not administered until the patient was being transferred by ambulance to the emergency room approximately 9 minutes and 14 minutes from the initial event. Upon arrival in the emergency room, the patient was determined to be in cardiac arrest and attempts to resuscitate him were unsuccessful.

An autopsy was conducted; the medical examiner concluded that the cause of death was cardiopulmonary arrest due to anaphylactic shock from intravenous administration of Combidex. The patient also had hypertensive coronary sclerotic heart disease with multifocal and diffuse interstitial myocardial fibrosis, multifocal remote micro and macro myocardial infarcts, intramyocardial arteriosclerosis, cardiomegaly and nephrosclerosis.

2. Death

There was one patient who died following administration of Com
was in a study for the liver indication and received a direct bolus
of 1.1 mg of iron on January 22, 1996. Copies of supporting do
complete CRFs, autopsy report, report of toxicology laboratory
report, and all laboratory reports were included in the original N
pages 119 to 159.

The patient was a 70 year old man with a history of hypertension
CVA, diabetes and carcinoma of the colon with lymph node
referred for MRI to determine the presence or absence of liver m
coming for an MRI this patient had a CT of the abdomen and pel
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iodinated contrast administration. The patient was taking several
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his heart. He was also receiving chemotherapy. Approximately
after administration of Combidex the patient complained of facial
became unresponsive, diaphoretic, with labored breathing and a
pulse. The patient also demonstrated weakness in his right arm a
urinary incontinence. Oxygen was administered immediately bu
was given at the site and paramedics were called.

After arrival the paramedics performed CPR and delivered oxyge
Epinephrine and atropine were not administered until the patient
transferred by ambulance to the emergency room approximately
minutes from the initial event. Upon arrival in the emergency roo
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heart disease with multifocal and diffuse interstitial myocardial fi
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cardiomegaly and nephrosclerosis.

It is noteworthy that no reactions even approaching this degree
with the dilute administration used for lymph node evaluation as
the labeling and that it is likely that prodromal signs and symptom
that may occur with the dilution will allow for discontinuation of
necessary.