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Emergency Medicine

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The undersigned submits this petition under _____ (relevant statutory sections, if known) of the _____ Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs (under 21 CFR, Part 5.10) to request the Commissioner of Food and Drugs to issue a "Black Box" warning on the class of medications identified as Angiotensin Converting Enzyme Inhibitors (ACEI). This class of medications has been well documented to cause life-threatening angioedema (severe allergic reaction with swelling of the airways) resulting in preventable death and disability.

B. STATEMENT OF GROUNDS

I am petitioning to add a "Black Box" warning to a class of medications. Because of the well-recognized risk of life threatening angioedema and upper airway obstruction, I believe that the ACE inhibitors (ACEI) should receive such a classification. I have recently treated at Boston Medical Center 4 patients with life threatening angioedema associated with ACEI within the past 6 months alone, and am aware of several deaths (and the literature reports several deaths) due to this complication. Patients who develop life threatening upper airway obstruction from ACEI are among the most challenging patients encountered in the practice of emergency medicine. Such patients often present with massively distorted anatomy, protruding and enlarged tongues, and may have anatomic features (short, large neck) that may make it quite difficult to establish a surgical airway rapidly should intubation be impossible. Life threatening and fatal cases of ACEI induced angioedema have been well described in the medical literature (English and other languages).¹⁻³⁸ Further, Ishoo et al have published a 10 year review of angioedema at our institution, including 36 cases that were induced by ACEI.³⁹ I believe that this complication is so dangerous that the FDA should issue a "Black Box warning" for this class of medications.

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02P-0374

CPI

EVIDENCE UNFAVORABLE TO THE PETITION:

The ACEI have clearly been demonstrated to be effective anti-hypertensive medications and to reduce morbidity and mortality associated with hypertension, heart failure, myocardial infarction and other cardiovascular conditions. These agents may also prevent the development of progressive renal failure in certain populations.⁴⁰⁻⁴³ However, I believe that the risk of angioedema, an unpredictable and life-threatening condition, should require the addition of a Black Box Warning” for this class of medications.

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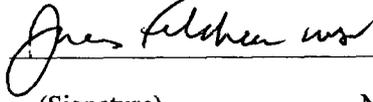
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C. ENVIRONMENTAL IMPACT STATEMENT

None

The undersigned certifies that, to the best of his/her knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



(Signature)

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