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June 3, 2010

VIA FACSIMILE 301-847-3531

Margaret A. Hamburg, Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Re: Fentanyl Duragesic prescription mediation pain patch warnings

Dear Dr. Hamburg

I am writing you as an attorney who handles personal injury litigation and also writes health and safety articles, asking that the FDA form a special task force to address the virtual epidemic numbers of accidental prescription drug overdoses caused by Fentanyl/Duragesic pain patches within the United States (see attachments). I also suggest that part of your task force look into the growing epidemic recreational illegal use of these pain patches by theft or improper acquisition of the pain patches and deaths arising from such recreational use. I have been blogging on this topic for two years and have reviewed news reports of accidental deaths, and our firm also has accepted two cases connected with deaths caused, at least in substantial part, by an accidental Fentanyl overdose due to use of prescription pain patches.

On the topic of prescription use of Fentanyl/Duragesic pain patches, my suggestions are as follows:

1. The FDA should issue a very strongly worded letter to all physicians outlining that Fentanyl is 80 to 100 times more powerful than morphine drop for drop;

2. Outline the number of known accidental deaths due to prescription use of these drugs, including the fact that patients may be disoriented while on the drug and may fail to properly follow the patch removal and application instructions;
3. I suggest that the FDA consider one or more of the following actions:
 - a. Prescription of any Fentanyl pain patch must only be administered for terminal illness or terminal cancer patients, or
 - b. Prescription of any Fentanyl pain patch must only be supervised and handled by either hospital staff, or home health care nurse, e.g. patients not authorized to remove or handle patches, and
 - c. Strongly suggest the use of any other less powerful pain medication in the case of non terminal/cancer patient pain control.

On the topic of illegal use of Fentanyl/Duragesic, I suggest that the FDA work with the DEA to control the conversion or theft of these pain patches and increase the warnings about sudden accidental overdoses amongst the public in general.

I would appreciate it if someone from your office would acknowledge this letter and respond with an outline of what the FDA is actively doing with regard to this growing epidemic affecting health and safety.

I look forward to hearing from you.

Very truly yours,

Richard N. Shapiro

RNS/mgc
Enclosures