Hepatitis C Action & Advocacy Coalition

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RE: Immediately Approve ANDAs For Generic Ribavirin 200mg Capsules
Deny Delay Tactic "Citizen Petition" of Brand Manufacturers – Docket# 2003P-0321

Dear Director Buehler and Dockets Management staff,

As a patient advocate and a person living with Hepatitis C, I am writing to strongly urge FDA to immediately approve the ANDAs for generic ribavirin capsules and deny the misnamed "Citizen Petition" (docket # 2003P-0321) actually submitted by the brand manufactures of this drug. The Petition has no merit, should be denied, and should not delay the immediate approval of these ANDAs

Hepatitis C community members and healthcare professionals are well aware that the pertinent patents and/or market exclusivities for brand ribavirin manufacturers expired in December, 2001, which should have made way for legal entry of generic competition of the drug. Generic makers filed ANDAs 6 months prior to that date in preparation for that legal competition. As expected, the brand manufactures filed the usual frivolous patent infringement lawsuits in order to delay the ANDA approvals and competition, for up to 30 months. The usual catch –22 ensued, with the courts waiting to see the FDA application and labeling approvals before ruling; and the generics division of FDA, sitting on the fence, slowing even the processing of those applications, hoping the courts would make a decision without them.

The brand manufacturer's lawsuit being baseless, Summary Judgment was ruled in federal court against the brand drug makers on July 14, 2003. The day after that ruling, this "citizen petition" was submitted to FDA. The petition contradicts actual law, and has nothing to do with the safety, efficacy or even valid labeling of the drug. It is simply a last ditch delay tactic, to continue to misuse the FDA regulatory function to make the 30-month decision period a *de facto* 30-month extension of market exclusivity.

The intent of pharmaceutical patents and market exclusivities is to give, for a limited time, brand manufacturers a rightful reward, for their research and development of safe and effective innovative pharmaceuticals. The intent of FDA generic regulation is to allow safe and effective generic versions of those drugs to enter the market when that time has expired; this in turn allows lower cost competition and greater access to people in need of those medications; in this case greater access to people living with hepatitis C.

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The actions of the brand manufacturer in the current situation regarding ribavirin are a shameful perversion of the intent of these laws and the FDA's regulatory function and process. The FDA has the regulatory authority to stop it now, if it chooses to do so. Deny the so-called "citizen petition" and immediately approve the ANDAs for generic ribavirin.

You may contact me at any time regarding this matter.

Thank you,

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Cc: Rep Nancy Pelosi, D-CA
Richard Klein, Office of Special health Issues, FDA
CBS News
New York Times
Newark Star-Ledger
Publicly circulated to community advocates, healthcare providers and persons living with Hepatitis C

Statement of Purpose
The Hepatitis C Action & Advocacy Coalition (HAAC) is a grassroots, all-volunteer group of individuals committed to non-violent direct action to end the Hepatitis C crisis. We work to provide access to life-extending treatments to people with Hepatitis C, foster effective prevention efforts, encourage sound public health policies, and to ensure adequate funding and resources for the care, treatment, and prevention of Hepatitis C. We work cooperatively with government and industry when progress is being made, and take to focused, non-violent direct action when progress is stalled. We accept no money from pharmaceutical companies.
Ending the Hepatitis C crisis is our highest priority.