



Hepatitis C Treatment: The Legality of Importing Medicines into the USA for Personal Use

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A detailed analysis of the FDA position on importing medication for personal use.

The Legality of Importing Medicines into the USA for personal use. Not because it is illegal, because it is not illegal, but because there is so much misinformation about this, particularly in Hepatitis C forums and other Hep C social media groups. This misinformation comes as complete myths, half truths and outright lies. One can only assume that most of this misinformation has its source in persons or entities with a vested interest in dissuading people from using Indian generics to cure their Hep C. By happy coincidence I am doing my PhD on the development of myths in the news media so it's an area in which I have some understanding and considerable interest. There are two areas to consider when asking the question "Is it legal to import medicine for personal use into the USA?"

What is the FDA's official attitude to this and how is this reflected in reality?

Firstly I will analyze the [FDA's published policy](#),

My comments are inserted in the FDA text are underlined.

The FDA official post reads as follows:

"In most circumstances, it is illegal for individuals to import drugs into the United States for personal use. This is because drugs from other countries that are available for purchase by individuals often have not been approved by FDA for use and sale in the United States. For example, if a drug is approved by Health Canada (FDA's counterpart in Canada) but has not been approved by FDA, it is an unapproved drug in the United States and, therefore, illegal to import. FDA cannot ensure the safety and effectiveness of drugs that it has not approved." (This can reasonably be described as a preamble)

"FDA, however, has a policy explaining that it typically does not object to personal imports of drugs that FDA has not approved under certain circumstances, including the following situation:"

1. "The drug is for use for a serious condition for which effective treatment is not available in the United States." (Obviously Hep C is a serious condition. The big question here are the two words "not available". Firstly low cost generic Sofosbuvir is not available in the USA. People then argue, "Ah yes but Sovaldi is available." This is only partially true because it is not available to everyone. It is available to some people but not most. It is available if a person has the correct health insurance or it is available if a person is wealthy enough to pay the \$90,000 to \$180,000 for a treatment or it is available if a person qualifies for some form of charity treatment. Otherwise Sovaldi is not available.

Here we have to get a little legalistic (I apologize for this getting complex but I will finish with a simple summary).

The word "available" is the critical word here:

The standard dictionary definition of "available" is: "Able to be used or obtained; at

someone's disposal."

synonyms: obtainable, accessible, easy to be had, ready for use, at hand, to hand, at one's disposal, at one's fingertips, within easy reach.

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So if something is too expensive for a person to purchase then it is not available to them. For example a penthouse in Manhattan is not available to me because I cannot afford one; nor is a Rolls Royce or a 50 carat diamond or a first class airfare. These are all not available to me because of their price.

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Therefore the Hep C treatment using Sovaldi in the USA "is not available" if a person genuinely cannot afford it. I believe that any reasonable person would agree with this.)

2. There is no commercialization or promotion of the drug to U.S. residents;

(This means that the person importing the drug does not plan or intend to promote or commercialize the drug to U.S. residents. In other words that the drug is solely for personal use.)

3. The drug is considered not to represent an unreasonable risk;

The FDA ruling on generic drugs is: "Generic drugs are chemical equivalents of approved brand name drugs. Since the safety and effectiveness of the brand name drugs have already been shown, generic drugs do not have to be tested for safety and effectiveness, as long as the generic drug is shown to be the same as an already approved drug. Generic drugs are approved under abbreviated new drug applications (ANDAs)." Gilead licensed India generics all conform to this requirement of being the same as already approved Sovaldi.

4. The individual importing the drug verifies in writing that it is for his or her own use, and provides contact information for the doctor providing treatment or shows the product is for the continuation of treatment begun in a foreign country; and

5. Generally, not more than a 3-month supply of the drug is imported

My summary:

1.Low cost generic Sofosbuvir is not available in the USA and Sovaldi is not available to most, or many, people.

2.If importing for personal use there is no intention for commercialization.

3.Generic Sofosbuvir is the chemically the same as the approved Sovaldi and does not represent an unreasonable risk.

4.You cannot bring in more than a three month supply

How is this reflected in reality?

In reality many people are bringing in many different forms of medicine for personal use. I know of a number who have brought in generic Sofosbuvir. I have not heard of even one single person who has been prevented from receiving a shipment of generic Hep C meds from India so long as they conform to the FDA requirements mentioned above.