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**Title: and Are Herbal Remedies Safe?**

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IN THE September 2002 issue of *The Platelet*, we described our presentation to the 2002 ITP Convention about complementary and alternative medicines. This included a survey of ITP patients and their families who attended the April 2002 Convention indicating that 63% of them described having used 1–9 different forms of complementary/alternative medicine. This practice among our patients is similar to reports from America and Europe that many, if not most, patients with persistent, troublesome illnesses use complementary/alternative medicines at some point.

The use of complementary/alternative medicines continues to receive intense study. In the December 19, 2002 issue of *The New England Journal of Medicine*, one of the world's most influential medical journals, three articles devoted to herbal remedies emphasized that they are a serious and growing public health problem. In particular, these articles emphasize the lack of quality assurance for herbal remedies, that these remedies are not subjected to the same controls required for licensing of traditional medicines. Amounts of active ingredients may vary enormously between products. For example, a study of six different Ginseng preparations demonstrated that some products contained only 10% as much of the active ingredient as was stated on the label while others contained three times the amount that was stated on the label.

Moreover, herbal remedies have been found to contain active drugs that were not listed on the label (such as digitalis compounds), some have been contaminated by bacteria such as salmonella, others have contained pesticides, and many have contained toxic metals such as lead and mercury. One study screening more than 500 Chinese patent medicines found that 10% contained undeclared drugs or toxic metals. In US poison control centers, there were 19,468 reports of reactions to herbal medicines in 2001, up from 6914 in 1998. However the US Food and Drug Administration (FDA) is often unable to investigate these reports because the ingredients in the herbal remedy and the manufacturer are often not identified.

Products containing ephedra are commonly used to curb appetite and increase energy. Ephedra is similar to the drug methamphetamine, known among drug abusers as "speed". An estimated 12 million people in the US use a product named "Metabolife 356" that contains ephedra, caffeine, and several herbs. A recent investigation revealed that the manufacturer has received 13,000 complaints, including reports of deaths. All of these observations demonstrate the rising concerns about the safety of herbal remedies, related to the remarkable increase in their use. As a result of these concerns, the European Commission and the US FDA are considering new rules to review the safety of herbal remedies, regulations for advertising claims about health benefits, and authority to remove unsafe products from the market.

We and many others believe that manufacturers of herbal remedies should provide evidence of safe manufacturing practices and be required to report all adverse effects to the appropriate regulatory agencies. Most importantly, the labels of these herbal remedies must contain a complete and accurate list of what they contain by both their botanical and common names. In the United States, the National Institute of Health has established a National Center for Complementary and Alternative Medicine to conduct scientific studies on the safety and effectiveness of herbal remedies. However, this research has been difficult because commercial sources of these herbs often lack careful production standards, and the content of the products is very different from batch to batch. These necessary studies should unequivocally document whether various herbal compounds are effective and safe.

No one, including the physicians, is happy with the side effects and inconsistent benefits of steroids, intravenous immunoglobulin, splenectomy, and other approaches used to treat ITP. But do remember this: each

of these treatments has a firm scientific rationale for its benefits, and there is clear evidence that each of them can be highly beneficial in many persons with ITP. The same cannot be said for alternative and complementary medications, where there is no scientific evidence that they are useful. Just because a person with ITP ‘feels better’ after taking an herbal preparation is not scientific evidence. This ‘better feeling’ could also have happened by chance or could have occurred after eating a lump of sugar. Or it may be the result of the supportive manner of practitioners of complementary and alternative medicine, who often are better at spending time and providing optimism than busy medical doctors.

The most important lesson for readers of *The Platelet* is that just because an herb is natural does not mean that it is safe, and claims of remarkable healing powers are not supported by firm evidence. So beware of herbal remedies!

(This information was presented in these 3 articles:

Straus SE. Herbal medicines – what’s in the bottle? *New Eng J Med* 2002;347:1997; De Smet PAGM.

Herbal remedies. *New Eng J Med* 2002; 347:2046; Marcus DM, Grollman AP.

Botanical medicines – the need for new regulations. *New Eng J Med* 2002;347; 2073.)