



The kava crisis began in late 2001, initiated by German health authorities. Since then, numerous actions and information from "opponents" and "proponents" of this popular and effective herbal remedy have been published. As a result, Phytopharm Consulting collected and reviewed all of these actions and publications, as well as all of the kava information currently available, and completed a comprehensive update

kava have been reviewed and re-evaluated by Phytopharm and compared to the evaluation of these cases by the health authorities, which led to the restrictive measures taken against kava. In addition, the resulting economic consequences for the main kava-producing countries in the South Pacific have also been assessed.

This extensive report and re-analysis builds the starting point for future strategic steps to actively rebut the (unjustified) kava restrictions.

Background

Kava has a 1000-year history of use in the South Pacific as a tranquilizing ritual beverage from the rootstock of the plant. In Europe, kava preparations have been used since at least 1886 to reduce stress and anxiety. Throughout its traditional and medicinal use, kava was never shown to have any severe side effects such as hepatotoxicity. Accordingly, due to its historical use and modern scientific data demonstrating safety and efficacy, the German BfArM (the German Federal Institute for Drugs and Medical Devices), which is analogous in authority to the U.S. Food and Drug Administration, has approved kava preparations as a nonprescription drug for the treatment of anxiety disorders, stress and restlessness. Until a short time ago, kava, with its centuries old reputation, was one of the top ten best selling herbs worldwide. However, in the last months of 2001 the situation changed dramatically and kava was subjected to actions of the international health authorities. A small number of adverse reactions reportedly associated with the use of kava products brought kava to the attention of health agencies in Europe and America.

In November 2001, European regulatory authorities placed restrictions on the sale of food supplements and herbal medicines containing kava. These restrictions were based on the actions taken by the German and Swiss health authorities. Finally,

Kava Update

Reviewing new activities in Europe to get this herb back on the market.

By Joerg Gruenwald & Cordula Mueller

of the kava situation in an article titled, "In-depth investigation into EU member states market restrictions on kava products", which was commissioned by the Centre for Development of Enterprise (CDE).

Due to the negatively affected kava-producing South Pacific islands, the Pacific Islands Forum Secretariat submitted a request to the CDE for assistance, resulting in the engagement of Phytopharm Consulting by CDE to provide sound scientific background information to evaluate justification of the kava restrictions initiated by European member states.

CDE is an ACP(Africa, Caribbean, Pacific)/EU organization created within the framework of the Cotonou Agreement. It focuses primarily on poverty reduction in the ACP states and is financed by the European Development Fund (EDF). Its objective is to provide rapid, effective support to assist the development of professional ACP enterprises and organizations operating in the private sector. CDE operates in cooperation with the European Commission, the European Investment Bank, EU Member States and ACP countries.

All available cases of hepatotoxic side effects connected to the consumption of kava-containing products, as well as all of the existing scientific information on

Dr. Joerg Gruenwald is president and Dr. Cordula Mueller is scientific consultant of Phytopharm Consulting, Berlin, Germany, a specialized business consulting company for herbal medicine, dietary supplements and functional foods. Dr. Gruenwald is also the author of the PDR for Herbal Medicines. Both authors can be reached at Phytopharm Consulting, Waldseeweg 6, 13467 Berlin, Germany; 49-30-40008100; Fax: 49-30-40008500; E-mail: jgruenwald@phytopharm.org; cmueller@phytopharm.org; Website: www.analyze-realize.com

the BfArM in Germany was the first authority to ban kava on June 14, 2002. Aside from Germany, France, Japan and Switzerland, the most recent kava bans and recalls have taken place in England, Australia, Canada, New Zealand and Singapore, including voluntary recalls in almost all European countries. To date, kava-containing products are still legal in the US. However, due to immense negative publicity, most companies marketing kava products have stopped selling their products because they fear possible lawsuits from consumers or organizations.

Economic Impact of Worldwide Kava Restrictions

The current kava restrictions are an economic disaster for producers and traders in the South Pacific Islands, particularly for the principal kava-producing countries including Fiji, Hawaii, Samoa, Tonga and Vanuatu.

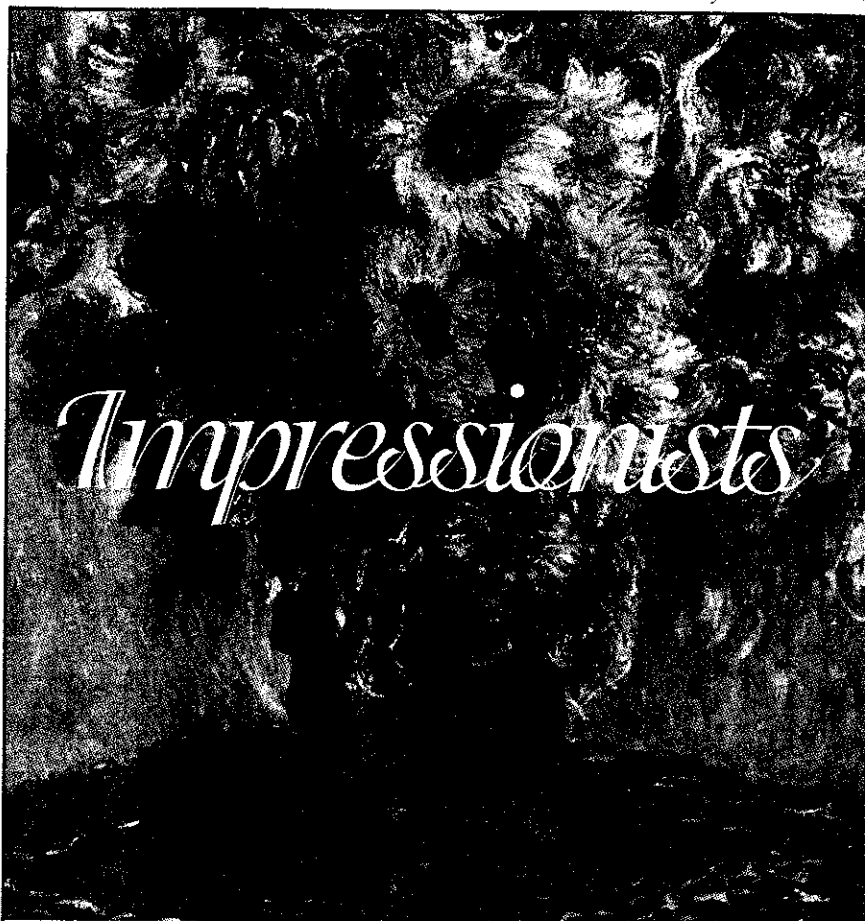
In recent years, a promising market developed for kava because of the increased worldwide demand for it. In 1998, when the export figures from the South Pacific islands reached its peak level, it was among the top-selling herbs in the U.S. and one of the fastest-growing herbs, posting 473% growth between 1997-1998. In the South Pacific region the annual production of kava was estimated to be about \$200 million. In the U.S., kava was widespread in the nutraceutical and food supplement market. Furthermore, the pharmaceutical market was centered in Germany with an estimated 1.3 million users.

Consequently, the land area planted with kava in the South Pacific has increased to almost 30,000 acres to fulfill the increased worldwide demand of kava. Therefore, the livelihood of many South Pacific people being engaged in the growing and production of kava is heavily dependent on a prospering kava business.

Negative publicity from these actions, together with the numerous kava bans, alerts and market recalls, as well as press reports, has greatly disadvantaged the kava growing indus-

try. Kava exports, especially from the South Pacific countries of Vanuatu, Fiji, Samoa and Tonga to the European and U.S. markets, came to a halt in late 2001 and caused an 80% decline in the market between 2001 and 2002. Con-

sequently, the domestic price of kava has severely declined and export earnings have been lost, severely threatening the livelihood of many South Pacific people. The world market for kava has been all but destroyed. As for the



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U.S. and Europe, companies using kava in pharmaceutical or food products were also confronted with severe profit setbacks.

Scientific Re-Evaluation of all Kava Cases

Well over 2000 years of traditional and ceremonial use of kava as a beverage has demonstrated that it is an effective and safe anxiolytic. For patients suffering from panic attacks or anxiety, taking kava preparations is often the first step toward a "normal," anxiety-free life. The efficacy and safety of kava in the treatment of conditions of nervous anxiety, stress and restlessness has been proven by 20 clinical trials, including more than 10,000 patients. The positive risk-benefit ratio of kava is supported by post-marketing experience in the U.S., Europe and other countries as well as by several expert commissions implemented by the German Health Ministry (e.g. Commission E).

The adverse event reports originated mainly in Germany, Switzerland and the U.S. From the 76 reported cases examined and evaluated, only four of them possibly relate to the intake of kava. Most experts have criticized the conclusions made by the German

health authority BfArM because the relevant case reports were predominantly insufficient due to inconclusive and missing information. Numerous experts and health authorities such as the U.S. FDA agree with Phytopharm's analysis and confirm kava as a safe and effective drug/supplement for treating anxiety and stress disorders. Furthermore, kava, in contrast to synthetic anxiolytics, does not lead to dependence. The withdrawal of the marketing authorization would only have been reasonable if it had been proven that kava had no benefit or that the side effects were so severe that the risk-benefit ratio was infinitely negative. This is not true for kava, as its risk-benefit ratio should be regarded as positive. Regarding the total risk, kava is safer than synthetic drugs and side effects or not, there are no synthetic drugs that reduce anxiety like it.

The incidence of hepatotoxicity with kava use is calculated to be 0.23 cases per 1 million daily doses. The causality in most cases remains questionable due to co-medication (other drugs including Paracetamol), a history of alcohol abuse or viral infections, which are all known to interfere with liver function. Other psychotropic agents like benzodiazepines, neuroleptics or

anti-depressants are known to have similar or higher incidents of hepatotoxic adverse effects.

So, if kava is banned today then synthetic drugs with a high and proven potential of severe side effects should be banned, e.g. the situation with Valium several years ago. Hence, the withdrawal of market authorization of kava preparations should be judged as unjustified.

Certainly the protection of the public against dangerous and toxic treatments, whether they are alternative or conventional, is of highest priority, and the reports of liver problems associated with kava consumption have to be thoroughly investigated and inconsistencies followed up. However, there are no convincing reasons to apply stricter assessment criteria for botanical remedies than for conventional, synthetic drugs. In addition, it is highly questionable as to why the authorities have not considered less strict but effective measures and applied them to "dangerous" drugs, such as improved product labeling and risk information in package leaflets. In this context, it has to be stated that German phytopharmaceutical companies already voluntarily provide such risk information with their kava products. NW

Recent Actions Undertaken To Rebut Kava Restrictions

Goals of an up-coming meeting

Based on the "In-depth investigation of EU member states market restrictions on kava products" the implementation of a precise lobbying strategy for undertaking future measures must be created for revising the restrictions. To that end, a kava stakeholder meeting to concentrate forces and develop a concrete and coordinated action plan has been organized.

This meeting is planned to take place in Brussels, Belgium in the coming months. A restricted number of delegates (approximately 30) from Europe and the Pacific will participate. This group will consist of growers, exporters, processors and distributors of kava products; national and international industry associations; scientific committees and selected donor agencies.

The main goals of this small "working" meeting will be to: Discuss the actual state of scientific knowledge of kava research as well as other relevant recent information; Define strategies that might be used to reintroduce kava into the European markets; Establish a detailed action plan and timetable, including a strong PR campaign; Implement an executive committee to coordinate the planned strategy and actions and estimate the costs of an appropriate strategy and discuss possible sources of funding.

These recent European activities give some hope that kava is not yet completely lost and that there may be a realistic chance to successfully restore the former good reputation of this herb. The number of voices backing kava and calling for a fight against the unjustified and unfair worldwide kava bans are constantly coming forth. These voices when unified in a strong lobbying and PR strategy will help to build a better future for kava and in general for the recently discredited herbals sector due to an increasing negative press.