



Natural Plant Extracts

Export Market Opportunities in the USA

**A report for the Rural Industries Research
and Development Corporation**

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Foreword

Plant extracts are commonly the volatile aromatic oils contained in the leaves, stems and reproductive structures. Crop plants rich in these products are commonly called essential oil crops, although the term volatile oil crops is more accurate as most of the components of the oils have low boiling points and can be recovered from the plant tissues by steam or solvent distillation. The use of and trade in essential oils can be traced back as far as the history of civilisation and was a feature of ancient Mesopotamia, Egypt and India.

The primary markets for plant extracts are the flavour and fragrance industries which include soft drinks, food and perfumes. Over the last 50 years, the demand for essential oil products from plants has gradually increased because of a number of factors. Demand for flavouring and perfumery materials has risen because of the steep rise in the world population and a desire for greater variety in their food by the people of the industrialised countries. The increased concern for the environment and for the safety of food and the general difficulty in manufacturing synthetic alternatives has also contributed to the continued growth in demand for plant based essential oil products. Plant extract products also include medicinal and pharmaceutical materials such as medicinal herbs, morphine from poppies and insecticidal materials such as pyrethrum. The USA, Western Europe and Japan are the main consumers of these products and account for approximately 78% of total world consumption. The forecasted annual growth for these products is 3.5 to 4% for the next few years. Australia is well placed to capitalise upon these opportunities because of the existing farming skills, processing facilities such as extraction plants and the wide range of climatic conditions available for different crops.

In addition to these economic opportunities, the availability of additional high value crops will provide Australian growers with a greater opportunity for crop rotation, better soil management options and possibilities for integrated weed and pest management. Diversification also has social benefits such as greater employment opportunities for seasonal workers and more stability for the local regional community.

The objective of this targeted market analysis study was to identify specific opportunities in the USA for plant extract products capable of being economically produced and processed in Australia. This report identified a number of potential products for production evaluation in Australia based upon a number of specific selection criteria. This report will add to the comprehensive database available to Australian growers and industry and will assist with the continued growth of the rural based industries.

This project was funded from RIRDC Core Funds which are provided by the Federal Government.

This report, a new addition to RIRDC's diverse range of over 450 research publications, forms part of our Essential Oils and Plant Extracts R&D program, which aims to support the growth of a profitable and sustainable essential oils and natural plant extracts industry in Australia.

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Peter Core
Managing Director
Rural Industries Research and Development Corporation

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Executive Summary

Plant extracts are commonly the volatile aromatic oils contained in the leaves, stems and reproductive structures. The primary markets for plant extracts are the flavour and fragrance industries, and medicinal, pharmaceutical and insecticidal outlets. The USA, Western Europe and Japan are the main consumers of these products and account for approximately 78% of total world consumption. The forecasted annual growth for these products is 3.5 to 4% for the next few years.

Many growers in Australia, in particular Tasmania, are keen to investigate the availability of additional high value crops which have the opportunity for crop rotation, better soil management options and possibilities for integrated weed and pest management. Australia is fortunate in having in place extraction facilities for these opportunities. Diversification also has social benefits such as greater employment opportunities for seasonal workers and more stability for the local regional community.

Keane International Marketing Inc. of Chicago was employed by this project as a consultant to collate and analyse market information on plant extracts in the USA. From these results, the experience and knowledge of the consultant and the understanding of the local Australian capabilities provided by the author, the consultant was able to identify the most likely opportunities for Australian growers.

This report provided an overview of the industry in the USA and a detailed review of the USA market trends. Medicinal herbs was identified as the market segment with the greatest potential for Australian exports and details on the markets for medicinal herbs are provided. This report identified a number of potential products for production evaluation in Australia based upon a number of specific criterias. These include the market considerations, value adding opportunities, potential for growth, agronomic considerations, import substitution and favourable environmental climate.

Total retail sales of medicinal herb products in the USA were \$US3.866 billion in 1998. The major retail outlets are the natural food stores and the multilevel companies such as Amway and these outlets account for some \$US2.257 billion. The major products sold for all USA retail channels for 1998 were echinacea at 9%, Ginseng at 8%, ginkgo at 7%, garlic at 6%, St John's Wort at 6%, Goldenseal at 4%, Saw Palmetto at 4%, Aloe at 3%, multiherb products at 27% and all other products at 26%.

However, the mass market sales through food, drug and mass merchandise outlets such as supermarkets was identified as the segment with the fastest growth rate since 1995 with sales of \$US663 million in 1998. The top selling products for the mass market in 1998 were ginkgo, St John's Wort, ginseng, garlic, echinacea, Saw Palmetto and grape seed. The products with the fastest growth in sales for the 1996-1998 period were St John's Wort at 2801%, echinacea at 140%, ginkgo at 140% and Saw Palmetto at 138%. Kava and evening Primrose had growth rates of 473% and 104 % respectively, but their market shares were still very small.

In the last ten years, there have been major changes in the global environment for plant extract products. These include an increased consolidation in the market place with mergers and acquisitions of companies. There is also a trend for the increased involvement of large multinational companies such as Warner Lambert, American Home Products and SmithKline Beecham in the retail sales of herbal products. The entry of these major companies into the herbal market gives respectability to these products, but also drives the quality standards of the raw materials purchased from growers to a higher level.

In recent years, the consumer use of herbal products in the USA has increased quite substantially with less than 5 % of the population using these products in 1991 and almost 40% of the population using these products in 1998. This massive increase in consumer usage of medicinal products is a factor of increased advertising by the major companies, positive press publicity, and the spin-off from the "green", "natural" and "organic" sentiments within the community. Consumers are now driving the

increased demand and acceptance for herbal products and this trend is expected to continue in the foreseeable future. Positive media attention and consumer acceptance has turned several established products such as ginkgo and St John's Wort into superstar products almost overnight and this market volatility is likely to become a part of the industry and will have implications for producers supplying this market.

This report emphasised a number of important points to be borne in mind by prospective growers and producers of botanicals:

- the importance of establishing a market for the intended product before embarking on any large scale activities
- the importance of quality control and the establishment of quality standards for the product
- an awareness of the unpredictable nature of the market
- desirability of long term agreements between herb grower and buyer/processor
- the extremely high costs of introducing a new phytomedicinal extract on the market

The primary list of opportunities consists of eight herbs and five products suitable for specific extraction opportunities. These are echinacea, gingseng, St John's Wort, Kava, Saw palmetto, Valerian, goldenseal, feverfew, boronia, clarysage, chamomile, lemon balm and citrus oil. A secondary list of 10 opportunities was also prepared. Care is required when deciding on which crop to select as, for example, St John's Wort is a declared noxious weed in NSW and kava is a slow growing crop (3 years to harvest the roots) and is a prohibited drug in Australia.

Carbon dioxide extraction has been highlighted as a desirable new technology because it is environmentally friendly, there are no undesirable solvent residues in the final product and the end products are often different and of better quality. However, this technology is very expensive and may not be suitable for all growers. In addition, this process may produce a different end product and re-registration may be required.

These recommendations are real opportunities for Australia to export high quality products to the USA market. Although a number of these crops are already in the early stages of commercialisation and / or being actively investigated (several with RIRDC support) there is a role for RIRDC to continue to support the next stage of research in this field. The preliminary evaluation of the best crop production opportunities identified in this report warrants support as well as the down stream processing opportunities.

Industry Overview

The following market analysis reports on the opportunities for Australian, and particularly Tasmanian produced natural plant extracts and compounds to be exported to the USA.

Our opinion is that the greatest opportunities lie in the non food sectors of the flavour and fragrance industry and this report focuses on the natural extracts market which is considered to have the most potential.

As an organisational background, the Flavour and Fragrance (F&F) industry consists of three closely interrelated and often overlapping market segments. In order of importance these are:

- Flavour and Fragrance Compositions
- Essential Oils and Natural Extracts
- Aroma chemicals

There are approximately three hundred natural products used as raw materials in the F&F industry. The raw materials are offered in seven major groups: Essential Oils, Extracts, Oleoresins, Concretes, Absolutes, Resinoids, and Tinctures. Different market segments have different requirements.

Approximately half of these materials are produced from cultivated plants and materials and the remaining half are obtained either as by products of a primary industry or are harvested from natural wild plants.

The focus of this report is market driven. This is appropriate for the following reasons:

Low cost competitors threaten the profitability of many major segments of the existing market. In addition, there is a high degree of substitutability between products.

The Australian/Tasmanian plant extracts will have to compete with oils and extracts produced in a variety of temperate and tropical climates. Any natural extracts that can be produced in either the PRC, the former Soviet Union or Eastern Europe where the demand for international currency is a priority are likely to have a substantial impact on their supply and demand because they might be sold on the world market, stockpiled at below production costs to elevate prices, or bartered. There are many recent examples, including citronella oils, certain mint oils and several spice oils such as Coriander oil from Russia.

Many plant extracts are subject to adulteration. All extracts that possess components for which synthetic components are readily available are subject to adulteration even if the chirality of the synthetic additive does not match that of the natural product. This problem increases with the increasing value of the natural product.

In this report, the first priority has been to establish that the product has the potential to satisfy current or latent demand in the target market.

Producers considering distilling a known oil in a new location, or trying to expand into an existing market must ensure that the markets will accept additional supplies. Once this condition has been met, any new entrant must also ensure that they can supply the essential oil at the right time, place and price. It must also be in a form that is consistent with existing industry standards and specifications, and the ultimate goal should be to create a new standard that would differentiate the Australian production.

In the US commercial markets, plant extracts are used in the food and fragrance industries as a source of flavour or aroma and in the pharmaceutical industry to add flavouring and palatability. These markets require ultraclean, verifiable, high quality products, reliable supplies and competitive prices.

The quality requirements of the commercial markets are very specific. As a result, buyers for the food, fragrance and pharmaceutical industries tend to develop loyalties to suppliers of consistent product, and in many instances buyers only look to new suppliers in cases of political instability, crop failure or contamination.

Conversely, some of these extracts and oils are subject to climatic or political problems – where Australia offers greater security and this represents an opportunity.

To a large extent buyers have established their own quality standards. As a result, the accepted standard is the product that the market wants to buy. However, it is a vital marketing strategy to develop new standards that will differentiate Australian production from other sources.

The importance of the value added concept cannot be overstated, and this report will focus on value added opportunities and value added potential within Australia. Although production issues remain an integral part of the process, the market orientated approach increases the probability of commercial success. The focus, therefore, must be on ascertaining and efficiently fulfilling the needs and wants of the consumers.

Australia has a relatively short history of involvement in the essential oil industry, other than Tea Tree oils and Eucalyptus oils, and therefore is relatively unknown in the market place. This means that opportunities will have to be created and rigorous standards of quality and pricing established. This will require considerable coordination and cooperation at both the grower and primary producer level to ensure the production of unique high quality oils.

Australia has a unique opportunity in the greater utilisation of native species such as Boronia. Similarly there are opportunities for the improvement of existing plant extracts to establish new markets in related industries. ie. taking an identified opportunity and developing it into a new industry.

One example reviewed is the expansion of the market for Boronia oils from its primary and very specific use at 5-10 ppm as a flavour enhancer for berry crops and expanding its use as a fragrance in the perfume markets. This would involve the further processing of boronia concrete to boronia absolute.

The majority of temperate climate crops can be grown without difficulty in Tasmania and the infrastructure exists to implement crop development programs.

The value added potential within Tasmania includes an evaluation of the crops' suitability as a diversification opportunity from the existing production base and the existing extraction capabilities. The report emphasises the importance of improved extraction, the establishment of new standards for existing products and novel compounds, and the creation of new formulations and uses where appropriate. ie greater product differentiation and specific targets.

For the selected extracts there will have to be an emphasis on quality and the provision of detailed and meaningful specifications. Typically these are based on organoleptic properties and important quality components of the oil or extract. However, optimisation of the compounds specified or present in the oil does not automatically improve the quality or marketability of the product. It will be necessary to show that changing composition will establish a new standard or variation of an existing oil – potentially opening up possibilities for new uses or expansion of the existing market.

Market Driven Selection Criteria

Flavour compositions account for approximately 39% of the F&F industry, followed by fragrance compositions at 29%. Essential oils and natural extracts account for 17% and aroma chemicals for the remaining market.

The U.S. and Western Europe together account for 62% of total product consumption, and the three major industrial regions (including Japan), with only 15% of the world's population, account for over 78% of the F&F consumption.

Most major participants in the F&F industry operate internationally and maintain a presence in virtually all markets of the globe. The U.S. is both the largest producer and user of F&F products. France is the largest producer and exporter of upscale fragrance materials, and the major suppliers of the trade in raw materials for the F&F market are India, PRC, Brazil and Singapore.

There are over 800 major companies participating in the F&F worldwide. Of these, 14 companies, each having over \$130 million in annual sales shared an estimated 73% of the worldwide F&F market. IFF is the leader with annual sales of \$1,315 million followed by Bayer (combined sales of Haarmann & Reimer in Germany and Florasynth in the U.S. at \$1,150 million), Givaudan-Roure (Switzerland, with sales of \$1,117 million) and Quest International, division of Unilever with sales of \$996 million.

Beverage products are the predominant users of flavouring materials, and the continuing preference trends for segmentation and innovation is expected to benefit producers of specialty market products in particular.

The following observations are offered after reviewing the comparative potential market in the United States for the current essential oils and plant extracts in Australia.

Spices

The potential export market for raw products such as spices for further extraction either in Australia or overseas has declined significantly and is now subject to intensely competitive, low cost production from countries such as India and the PRC which are prepared to sell below their production costs in return for hard currencies. A recent example is the dumping of garlic and garlic oil from China.

Onion oil is now being evaluated in Tasmania, and the primary focus has been on utilising waste onions to produce a higher value product, but onion production is also already at a competitive disadvantage in the States to imports from Asia.

Similarly, anethole production from Fennel and Anise in both China and Turkey for the European and Turkish alcoholic beverage market (Raki, Pernod etc) has increased dramatically making the Australian production no longer competitive.

Global spice prices are usually quite volatile, and the huge price increases which frequently occur are primarily due to shortages in supply, not increased demand. Within the markets it has become clear that a commodity that is too cheap for too long will become short in supply and rise enough in price to make production once again worthwhile. It will then rise too far leading to overproduction and the whole cycle will start again. Recent examples are White Pepper with increases of over 80% and sharp increases in wholesale prices of Black Pepper.

Coriander has been in tight supply for the past three years and serves as a useful example of the swings in spice prices. Coriander is an easy crop to grow and it is widely used as a cheap but necessary ingredient in a variety of prepared foods, tobacco and liquor flavourings. It is grown worldwide in widely diverse locations with very different climates – in both the political and climatic sense. The U.S. imports Coriander from Canada, Morocco, Bulgaria, Romania, Russia, India and

Egypt – yet supplies have been short from all sources during 1995-98, and are now incredibly cheap during 1999.

The main factor in the shortage of Coriander has been the “too cheap for too long” syndrome where farmers almost universally decided that growing Coriander had become unprofitable and that other crops (such as Wheat in Canada) were better options. As the supply dwindled, anxious buyers bid up the prices for the diminishing supplies to secure their annual requirements and as prices rose to unrealistic levels, farmers planted too much of the crop again and the cycle began again.

Coriander is an example of many spices used in markets with relatively inelastic demand. Companies do not tend to use more Coriander when prices are cheap, or less when prices are high. The price fluctuations can be predicted by closely following the supply situation.

Unlike botanical extracts, spices are more or less commodity items. One 15 ton lot of Malabar Black Pepper is fairly interchangeable with another. This is certainly not true of the botanicals, where there are vastly differing quality considerations to throw into the equation.

After a comprehensive review of the market opportunities in the U.S. it is felt that there is greater potential for Australian expertise in other market segments and spice production should focus on satisfying domestic demand and import substitution.

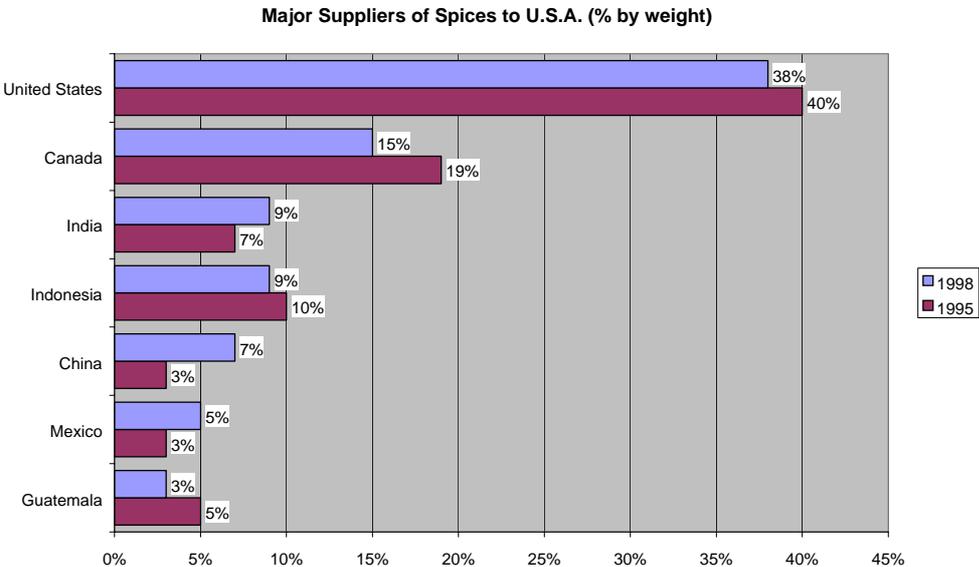
The following chart shows the major suppliers of spices for the United States. The US is the largest supplier to itself, primarily because of the volume of dehydrated onion and garlic, although its percentage share has dropped marginally in the past three years, the percentage, by weight, is over double that of other countries.

Although Canada provides a range of flavours and spices, the major part is also garlic and onion.

Outside of North America, the Far Eastern suppliers are primarily of exotic spices and fragrant woods, with cinnamon, pepper, nutmeg and cloves accounting for a major portion of the imports, and with nutmeg representing the major export from Indonesia.

The Central American producers are more opportunistic producing a large variety of cooking spices including black pepper, sage, mint etc., as well as more exotic products such as tumeric.

Table 1



Essential Oils

The U.S. is virtually uncharted territory for Australian exports of essential oils. The U.S. imports Oils of Lavender, Geranium, Eucalyptus, Citrus Oils and Tea Tree Oils from Australia.

Eucalyptus Oils

Eucalyptus Oils comprise the major volume but are now only a fraction of those exported to the U.S. by the PRC and Brazil.

Lower priced imports will continue to be a threat to Australian exports to the U.S. and the primary objective of the Australian producer must be to lower the cost of production – by increasing the level of extractable oils in the biomass; by implementing new efficient extraction methods and by continuing to add value to the existing production by the development of higher quality products. Improvement of the Eucalyptus oil crop is the subject of ongoing research in Australia and is not considered further in this report.

Mint Oils

In our opinion the U.S. does not represent a major market opportunity for Australian mint oils. There are better opportunities for Australia in Far Eastern markets and other, less competitive, more profitable niche markets for Australia to explore in the U.S.

Mint oil is the major essential oil crop for the U.S. market - in terms of production imports, and exports. It is produced in the Pacific Northwest under State marketing orders and in the Upper Midwest- particularly Indiana. Crude distillation begins in the field, but processing plants are located near to the production sites. Commercial production of all the mint oils requires very large quantities of biomass, stringent quality control and laboratory testing facilities.

Mint oils are widely used in chewing gum, toothpastes, mouthwashes and a wide variety of other confectionery and pharmaceutical products.

Mint oils are a major export for the U.S. – accounting for approximately \$90 million per year. The principal export markets are to Japan and the U.K., with France, Italy, Mexico and Far Eastern markets accounting for the balance.

Peppermint oil is the most important oil exported from the U.S. and consistent efforts have been made to increase both the quality and quantity of domestic production. U.S. production of peppermint oil has risen to over 3,500 tonnes and yields have increased to over 74 kilos/hectare – more than the Australian target for the same crop. This increase has, however, resulted in a decrease in the grower price by about 8% over the last three years and this price decrease continues as production expands.

In Australia, the production of peppermint oil is limited to Tasmania and Victoria where the cool temperatures favour the production of high quality oils, but the limiting factor for long term expansion is the lack of long term price stability and the increasing yields and production in the U.S. – which is the targeted market for the Australian production.

The Australian spearmint oil production is also centered in Tasmania and Victoria and targets the same market with the same results. The U.S. production of spearmint oil is also increasing with increased plantings in Washington, Idaho and Indiana resulting in an overall increase of over 17% in the U.S. crop in the last three years. However, prices to growers have fallen by over 10% and demand for tobacco products – which accounts for over half of the U.S. menthol market – continues to decline.

The U.S. is a net importer of menthol and imports from India, Germany, China, Japan, Brazil and Paraguay. Brazilian and Paraguayan oils are highly regarded for their quality and sell for a premium

price, and Indian menthol cannot be directly substituted by other sources, but overall there have been ample global supplies, weak demand and currency devaluations by India and China which have further weakened the market prices for these oils.

The world demand for peppermint and spearmint oils continues to increase at about 3% a year, but prices overall reflect a decrease. There is little evidence to suggest that the U.S. presents a major market opportunity for Australia for these oils and the focus for the Australian crop should probably be on Japan and other Far Eastern markets such as the Philippines and South Korea.

Citrus Oils

The U.S. is a major producer of citrus oils as well as an important importer and exporter of these commodities which are used primarily in the soft drinks industry, but also in food, confectionery and perfumery. Citrus oils are also now being used as an environmentally safe replacement for petrochemicals in such items as paints and household cleaners.

Even though the U.S. is a major producer, imports are significant because they are usually priced lower and they are often blended with domestic oils for both the domestic and export markets. There is also competition from synthetic oils for this market – and artificial oils currently account for between 25-30% of the total.

Orange is the most important citrus flavour accounting for half of the U.S. market, followed by lemon with a third of the total. Lemon-lime mixes have 10% of the total and lime alone accounts for 5%. Grapefruit, clementine and mandarin and mixtures of the three make up most of the balance.

Lime oil production has not fully recovered from hurricane damage in Florida and trade embargoes with Haiti have also adversely affected supplies – so the price of lime oil has been maintained, whereas the other citrus oils have declined in price. However, there is also a significant increase in the use of artificial lime oil for the same reason.

There is heavy competition from both Europe and South America. Brazil is a major exporter of orange oil and sells nearly 10,000 tonnes a year to the U.S. The U.S. in turn exports about 3,500 tonnes a year mainly to Canada and Japan, but also to Australia – an import which could be substituted by the domestic production.

Lemon oil prices have remained more stable because of strong demand from the soft drinks markets, and imports of lemon oil into the U.S. have increased by about 17%, whereas exports from the U.S. have declined by about 10%. Argentina supplies over half of the U.S. lemon oil imports, followed by Italy, Brazil, Spain and Uruguay accounting for most of the remainder. The principal markets for exports from the U.S. are to China, Japan, U.K. and Canada.

Overall, the citrus market is very price sensitive and opportunistic. The Far East is considered to provide more immediate potential for Australian citrus oils than the U.S., and there is unfulfilled domestic demand in Australia. It should also be noted that Australian production of citrus oils is actually declining.

Benefits of New Extraction Technologies

There is an opportunity in Australia to utilise new technologies with citrus oils. For example, subcritical CO₂ extraction can be used to develop new products such as flavour concentrates and waxes with enhanced flavour retention and fragrance. This is an ongoing research project in Australia and for this reason is not considered further in this report.

The Australian essential oil industry is dominated by a core group of only seven companies and all of them use either steam distillation, solvent extraction followed by steam distillation of the extract or solvent extraction followed by vacuum distillation of the extract.

Overall, the world market for essential oils using steam extraction, and that of oleoresins using solvent extraction processes has plateaued in recent years. New regulations in the major western markets limit the amount of detectable solvents in both oleoresins and essential oils. Extracts using subcritical processes have a better quality and command a premium in the marketplace since they eliminate solvents.

Therefore, it is anticipated that subcritical extraction methods using carbon dioxide will play an important role in the development of an Australian/Tasmanian plant extract industry with a definable character and standard. In general, in fragrance applications, these extracts are more concentrated with finer odour characteristics and are better fixed than traditional essential oils resulting in a longer lasting product.

Additional advantages are that, because of the low temperatures, the CO₂ process does not produce still notes which need additional time to mature in conventional extraction processes. Conversely, the process does produce more topnotes which are highly valued in the perfume industry.

With essential oils, the CO₂ process produces botanical extracts consisting of the essential oil and the lightest fraction of resins from the resinoid fraction. Lighter fractions of the resin are extracted which leaves behind proteins, waxes, sugars, chlorophylls and most pigments to yield a purer extract that is closer to the aroma of the original botanical material and which remains highly soluble.

A further feature, which is becoming increasingly important is that the process produces very low levels of monoterpene hydrocarbons – chemicals that do not contribute to the flavour and actually detract from the function of the extract in the food or beverage product. Similarly, there are no solvent residues. This is important not only in producing extracts which meet increasingly stringent solvent limitations, but also in removing any traces of solvent odour. It also creates an opportunity for the production of new oils from native ferns such as Fern Oil (*Dryopteris* spp) for the perfume industry – but the market for these products will have to be developed and commercial quantities be available.

Based on our evaluation, the major growth opportunities are in non food products, although some essential oils for the flavour industries have been selectively reviewed.

There are two broad categories of products which show the greatest growth potential. To some extent the requirements for each are overlapping, but specific products need to be developed for specific niche markets. However, the recommendations relating to the need for the development of high quality products with value added benefits; the trend towards the production of standardised extracts and the need for verifiable standards are common to both.

1. Non conventional specialty crops for manufacturing natural flavours and fragrances

We have selected the following crops for further commercial evaluation and development in Australia.

Clary Sage	(<i>Salvia sclarea</i>)
Lemon Balm	(<i>Melissa officianalis</i>)
Chamomile	(<i>Matricaria recutita</i>)
Boronia	(<i>Boronia megastigma</i>)

Lemon Balm and Chamomile offer opportunities as essential oils and in fragrance markets, provided that high quality extracts are the focus of production. Both crops also have extensive potential to

“cross-over” into mainstream cosmetic markets, but the main market in the States is likely to be in their further development as herbal extracts and they are included in that section of the report.

Boronia extract is uniquely Australian. Its indigenous nature offers Australian producers a remarkable opportunity to produce a unique high quality product and the ability to regulate the prices without fear of price competition. Boronia is considered sufficiently important to warrant specific further research.

Clary Sage Oil, (*Salvia sclarea*) is a potential export for Australia.

Until recently, its primary use in the U.S. has been as a flavouring for tobacco products, but demand appears to be declining for this use.

The other market for the use of Clary sage essential oil is as a fragrance and fixative in the perfume industry, and it is currently used more in low end products such as soaps, detergents, cream and lotions in combination with lavender, jasmine and other scents. Clary sage also has uses as a medicinal plant in herbal teas etc, and this could be a useful by product of the cultivation of the plant for extracts.

Currently it is cultivated as a short lived perennial in Russia, France and Hungary and the flowers are steam distilled immediately to minimise volatilization of the essential oils. The essential oils contain l-linalyl acetate, linalool and nerol and the concrete and absolute extracts include these compounds and sesquiterpenes.

The main opportunity is to expand its use into the high end of the fragrance industry, particularly in Eau de Colognes, and there would be a demand for its fixative and aroma characteristics for both concretes and absolutes. These would be concentrates containing at least 50% sclareol for the production of woody amber and balsamic aroma chemicals.

There has been some small scale production of Clary sage in Tasmania for a number of years, but the market will be for the refined sclareole and this cannot be produced economically with on site steam distillation.

The further development of this market will depend on the production of a high quality, standardised product, using either solvent or preferably CO₂ extraction techniques, which can be priced competitively with imports from Russia and Eastern Europe, and increasingly from Brazil.

Overall, the production of Clary sage oil is a product considered worth further study under actual growing and extraction conditions in Australia.

2. Phytomedicines and Herbal Extracts

There has been a huge surge of interest in recent years in the commercialisation of phytochemicals – drugs derived from botanical sources.

About 25% of the prescription drugs used in the U.S. originated from plant life and these are typically single molecule drugs such as Digitalis from foxglove, vincristine and vinblastine from the periwinkle, Etoposide from the Mayapple and most recently Taxol from yew.

These have been extracted on a commercial scale by companies such as Rhone-Poulenc Rorer, Hauser Chemical Research, NaPro BioTherapeutics, ChiRex, Polysciences and Xechem in the U.S. and Towers Phytochemical and Phytogen Life Sciences in Canada and Indena in Milan.

The emergence of companies committed to the exploitation of single molecular structure drugs was a later development. These were typically focused on a specific geographic region - e.g. Ayurcore on India, Panax on the former Soviet Union and Pharmagenesis on China. Other companies with this specialisation include Genelabs, Phytera, Paracelsian, Shaman Pharmaceuticals and BioFrontiers in the U.S. and Xenova in the U.K.

All of these companies use variations of the conventional techniques which are to extract, isolate, purify and identify the active agent and then prepare it in quantity by organic synthesis, genetic production using recombinant techniques or tissue culture.

However, this approach does not take into account what may be the greatest contribution made by herbal medicines which is the biological effect derived from a combination of agents, rather than a single molecular entity. It is the need to develop this technology that is a priority for the production of pharmaceuticals from plants that are not suitable for development into conventional single molecule drugs, but it is this very interaction of multiple molecules that has limited their recognition by the medical community.

The first serious attempt to produce plant derived drugs with multiple ingredients that deliver a therapeutic effect which cannot be derived from a single component has now been developed by Pharmaprint, Inc. This technology allows botanical medicines to be standardised, manufactured and patented for potential use as approved pharmaceuticals.

Essentially the Pharmaprint process uses analytical methods to screen natural medicines for their overall effectiveness. If they are found to have acceptable efficacy, specific molecular components are isolated and their concentration levels determined. Their bioactivity is also determined. The most active components are chemically identified and a precise standard by percent weight and bioactivity is established for each component. This is known as the “Fingerprint” for the medicine.

The technology can be applied to many natural medicines that have demonstrated clinical efficacy – such as those identified in this report – but which do not currently reach the criteria for pharmaceuticals.

The process is expensive – approximately \$500,000 for each botanical drug – but this includes validating the manufacturing process under GLP, and filing for the patent. Two phases of clinical trials cost a further \$1.5 million and the Phase 3 trials a further \$10-\$15 million. This is in contrast to the cost of drug development which would be more than \$230 million over 12 years.

The first Pharmaprinted products offered in the U.S. will be the seven standardised herbal remedies being introduced by American Home Products (Whitehall Robbins Healthcare) into the U.S. consumer market in 1998/99. It will have a supporting marketing budget of \$40 million over two years.

The Pharmaprint technology is used as an example of where the industry will be heading. The market will be for high quality, verifiable content raw materials.

The main focus of this report is on phytomedicines. ie. medicines prepared from one or more active constituents of plants and these are referred to in the text under the collective terms “botanicals” and “medicinal herbs” and “medicinals.”

Botanicals reviewed in this report include Echinacea, Ginseng, St. John’s Wort, Saw Palmetto, Valerian, Chamomile (medicinal), Feverfew, Golden Seal, Kava and Lemon Balm.

Botanicals offer strong export market potential as well as import replacement benefits. They offer the most significant opportunities for value added benefits and utilisation of the existing sophisticated refining processes. In addition, there is a growing domestic demand in Australia.

The production of medicinals requires that target markets be clearly identified as well as the processing procedures required to meet customer needs in the target markets. Until very recently, there has been a shortage of accurate information about production and demand levels and both demand and supply peaks fluctuate dramatically, but in general terms, the market for medicinal plant extractives has grown at over 20% a year for the past several years.

More extreme growth is common – the market for Echinacea in the States has grown by 72% between 1995-1997 to \$310 million annually. The sales of St. John's Wort has grown by 1,900% in the same period to \$200 million in annual sales in the U.S. alone.

Such extreme growth will ensure intense competition, but will also increase the demand for consistently high product quality and established standards. In the last two years the demand has been fuelled by the establishment of brand name products sold at premium prices in supermarkets, drugstores and mass retail chains throughout the country.

In the past, herbal products suffered from a poor image and the lack of standards for the biologically active constituents, as well as the lack of beneficial regulation. These issues are being addressed as companies like American Home Products and Warner Lambert enter the market with products capitalising on their own brand names. As a result the herbal market represents a large and growing market with increasing consumer acceptance and a growing need for high quality extracts. The ongoing segmentation and specificity of different markets will require the development of specific products and formulations which will be another incentive for a technically competent industry.

Standardised Extracts - Botanicals

The term standardisation is used frequently in this report. In principle it refers to the process of delivering a product with a specified minimum level of one or more plant constituents. In some cases this is by measuring the level of a crude herbal extract and establishing a standard amount of that chemical for future production. In this case the choice of chemicals to measure is of paramount importance e.g. Hypericin for St. John's Wort or kavapyrones for Kava.

In other instances, a fraction of the whole extract may be concentrated and standardised to whatever constituent is accepted by the industry as the most important. E.g. Saw palmetto.

In either case, the primary use of standardisation is to identify extracts that measure one or more particular compounds within a finished product and which provide a basis for verification. These compounds are referred to in the industry as "marker compounds" or "active constituents" – although the latter term is often inaccurate as most plants contain several constituents that act together or synergistically for the bioactivity.

Powdered extracts are not necessarily made by isolating such compounds and blending them into an inert base to achieve the defined level, although this is a common misconception. The vast majority are either extracts of the whole plant with all the soluble compounds extracted and adjusted until the marker or active compounds reach a specified level, or are extracts in which a specific fraction is obtained at the expense of other fractions considered to be non effective or even toxic. Most, however, are whole herb extracts containing all the components except insoluble compounds such as cellulose and fibre.

The benefits to the industry and the consumer in using an herbal extract in standardised form is that it ensures that sufficient amounts of the herbs constituents are present to deliver an efficacious product. This is, regrettably, currently not true for most herbal products – even the most important ones.

Most of the growth occurring in the use of herbal products is in the mass markets and the best way to communicate to the consumer is by quantifying (standardising) to the most broadly reported marker compounds. While it is possible, for example, to argue the finer points of the symbiosis between the hypericin and the flavenoids in St. John's Wort the consumer will be looking for the "0.3% Extract product" and taking this as a standard strength. Overall, the use of standardised products and their attendant qualifications on the finished product contributes to the broader use and acceptance of these products.

Standards for Essential Oils

The basic usefulness of standards for essential oils is as an aid for trade. They can be used to help determine the authenticity, geographical origin and quality of the oils. Standard Specifications have been established by many national standards organisations but the most comprehensive are those of the International Standards Organisation (ISO).

There are two types of standard which should be considered by the Australian essential oils industry. These are the actual specification and the method of analysis. The specification defines the limits for the measurement of the various parameters for the particular oil. Traditionally there have been physical determinations such as density, optical rotation, refractive index, solubility in alcohol and chemical determinations of major or other components of interest.

The analysis of essential oils is best carried out by Gas Liquid Chromatography, (GLC) and would be used to give detailed information on the composition of individual oils, as well as to confirm the absence or upper level of contaminants, solvents or undesirable components. This standard, in effect becomes the guarantee and is used to establish both price and comparability.

The standard needs to define the actual method of analysis since this is used to determine the actual parameters. This is particularly important in trying to establish GLC “fingerprints” of essential oils. The same method of analysis must be used for any comparative analysis involving different laboratories to get good inter laboratory reproducibility. Although most major essential oils companies have their own internal libraries of traces, it is beneficial to the Australian industry to conform to a higher standard than the norm and to actually develop its own standard for less common oils such as Boronia.

The specifications used by the Australian industry should include a chromatographic profile for the oil which sets out limits for the representative and characteristic components of the oil as determined by GLC. These should define the chromatographic conditions for obtaining the profile.

Although this type of specification is not legally enforceable, it is very likely that there will come a time – particularly with herbal extracts, that some legislative body such as the EU, or the FDA in the States, requires legislation. If this happens, it is very likely that an existing set of specifications would be adopted rather than incurring the time and expense of proposing yet another set. It is in the best interests of the Australian essential oil producers to be pro-active and to ensure that any proposed specifications are realistic and meet the needs of the producers, traders and end-users. The appropriate mechanism for doing this is through the Australian national standards organisations which are members of the ISO.

Organic certification

To be able to supply a manufacturer with medicinal herbs, it is imperative that the growers be certified as organic producers. In Australia, the National Association of Sustainable Agriculture (NASA) and Biological Farmers of Australia (BFA) are useful information sources for growers.

Strategic Alliances

There will be a need to establish market links for all products identified as opportunities. These include direct contact with the major industry players, pharmaceutical houses and major end users; the establishment of an effective distributor/dealer/agent network and most importantly, the formation of strategic alliances with major customers and the establishment of forward supply contracts.

Other Issues:

Additional issues investigated are niche marketing opportunities – including out of season supply, import substitution and the major legislative and regulatory concerns. These include items such as duties and tariffs, ISO Standards, FEMA/GRAS requirements and a consideration of the need for organic grower and producer certification.

Import substitution

The possibility for import substitution should be an integral part of the Australian herbal extract industry – not only because it is easier to develop the domestic market, but because it is evidentiary of a market which is not being adequately addressed.

The plant extracts industry in Tasmania has shown its ability to develop sophisticated cultivation and extraction technologies to produce world standard products with both poppy extracts and pyrethrum. With pyrethrum, the Tasmanian industry is now the second largest producer in the world – after years of dominance by East African producers. There is no reason that the same level of expertise could not be brought to bear on medicinal plant extracts and Boronia using existing CO₂ extraction technologies.

The medicinal herb market in Australia is estimated at \$30-40 million a year and is growing at 10-20% annually. Only one third of this market is supplied by domestically grown plants and two companies – Blackmores Pty Ltd and MediHerb Pty Ltd account for over 80% of the existing market. It is estimated that approximately half of the medicinal herbs used in Australia could be grown locally. (See Additional Crops Section).

The traditional reliance on European and Asian producers of medicinal herbs is changing. There is increasing competition from new producers in the South America who can match the temperate climate requirements for many of these crops, and who are investing heavily in the production of high quality products.

Chile, for example, is emerging as a major new source of St. John's Wort with a high hypericin content of 0.3% or more. Last year's production was reduced by two thirds because of El Niño, but Chile is expected to emerge as a major supplier of high quality botanicals in the future.

The chances of success for a new phytochemicals industry in Australia increase with the ability to take a fully integrated approach. Ideally, the major participant in Australia would be a production based company selecting and controlling the plant stocks, selecting and organising the planting, harvesting and processing and conducting all the quality control practices through to the production of the final, high quality extract, and then marketing the crop overseas directly to its strategic alliance partners.

U.S. Market for Botanicals

Size of Market

The market for botanicals in the United States is estimated at \$3.8 billion in annual retail sales. (See Table 2)

Table 2: U.S. MARKET FOR BOTANICALS: 1998

OUTLET	MARKET \$ Millions
Natural Food stores	\$1,207
Multilevel	\$1,050
Mass Market	
Food/Drug/Retail Mass merchandisers	\$663
Mail Order	\$320
Practitioners/Therapists	\$270
Tea (All Channels)	\$266
Specialty Shops	\$90
Total	\$3.866 billion

Sources: Keane & Associates/NFM, NBJ, IRI

Although botanical medicines are now available in almost any retail outlet including the corner grocery, the major channels are still natural food outlets and multilevel sales from such companies as Amway, Nature's Sunshine, Nu Skin International, Shaklee, and Shaperite. These account for 32% and 27% of the total respectively, with natural food outlets offering hundreds of products as whole herbs, tinctures, extracts and standardised products.

However, mass market sales through food, drug and mass merchandise outlets have seen the most dramatic documented growth in sales since 1995 and now account for 17% of the total representing sales of \$663 million. This has resulted from the entry of multinational consumer companies and the influence of major natural product chains such as Whole Foods and Wild Oats.

Other channels for the sales of botanicals are mail order catalogues, club store sales such as Sam's Warehouse and directly from health care practitioners (including acupuncturists, naturopaths and chiropractors) and sales over the Internet. Reader's Digest and Amazon have announced their intentions to sell herbal products over the Internet this year.

Best Selling Botanicals and Market Segments

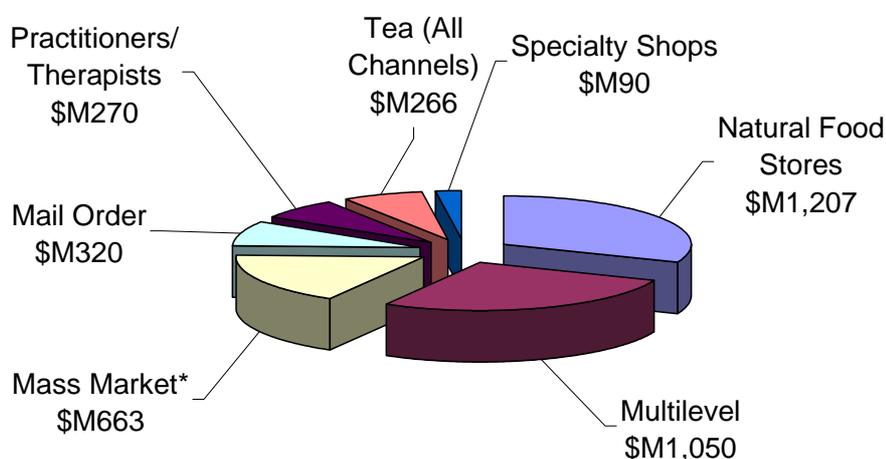
The most significant growth in the U.S. has occurred in the mass market channels of food, drug and mass merchandise outlets. Tables 3, 3a and 3b show the top selling botanicals in the \$600 million mass market in the U.S. in 1998.

Twelve botanicals account for 94% of the total mass market sales and all of these have exhibited greater than 25% growth in the last three years. Six products – Gingko, St. John's Wort, Ginseng, Garlic, Echinacea and Saw Palmetto account for 85% of the total sales. It is estimated that over 70% of the active ingredients for herbal medicines sold in the U.S. are imported.

Table 2a

US Market for Botanicals: 1998

Total \$3,866 billion



*Food/Drug/Retail Mass Merchandisers

Source: Keane & Associates/NFM,NBJ, IRI

Table 3: TOP SELLING BOTANICALS/HERBS: US MASS MARKET, 1998

BOTANICAL	US\$ Millions	Per cent Growth 1996/98
Ginkgo	\$138	140%
St. John's Wort	\$121	2,801%
Ginseng	\$98	26%
Garlic	\$84	27%
Echinacea	\$33	151%
Saw Palmetto	\$27	138%
Grapeseed	\$11	38%
Kava	\$8	473%
Evening Primrose	\$8	104%
Echinacea/Goldenseal	\$8	80%
Cranberry	\$8	75%
Valerian	\$8	35%
All Others	\$31	
TOTAL	\$583 million	

Sources: Keane & Associates/Food Drug & Mass Merchandise/IRI

Growth rates in the mass market sector have been phenomenal because of positive press and the entry of major multinationals.

In 1998, (see Table 4 and 4a) St. John's Wort exhibited an astonishing 2,801% growth and Black Cohosh, Green Tea, Elderberry and Kava all increased sales by factors of four to five times the previous year.

The more traditional products – Echinacea, Ginkgo and Saw Palmetto have all increased by over 100% since 1996.

Table 3a

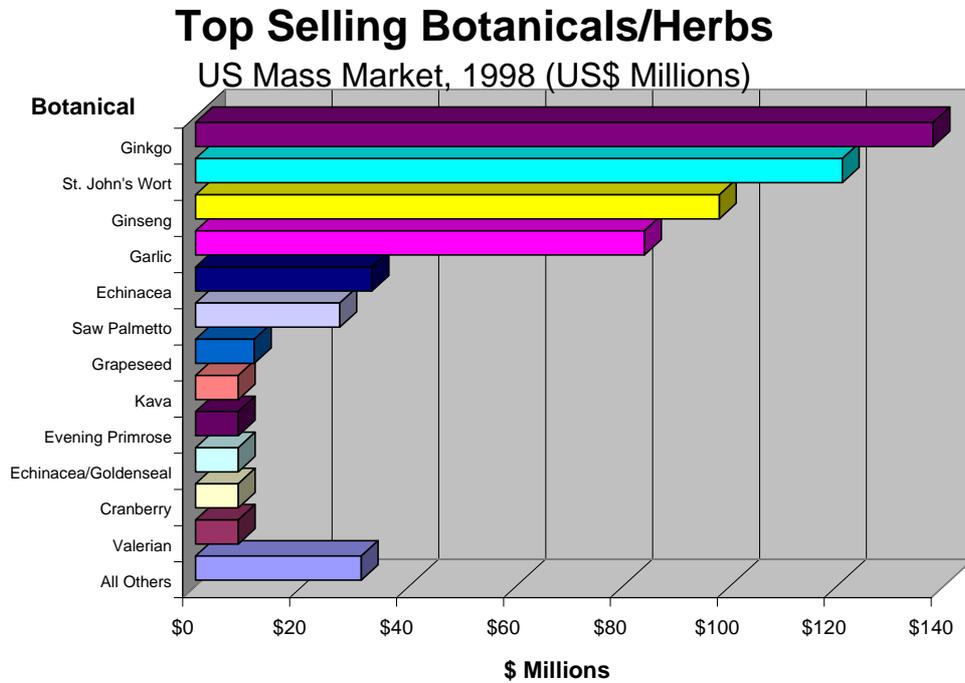


Table 3b

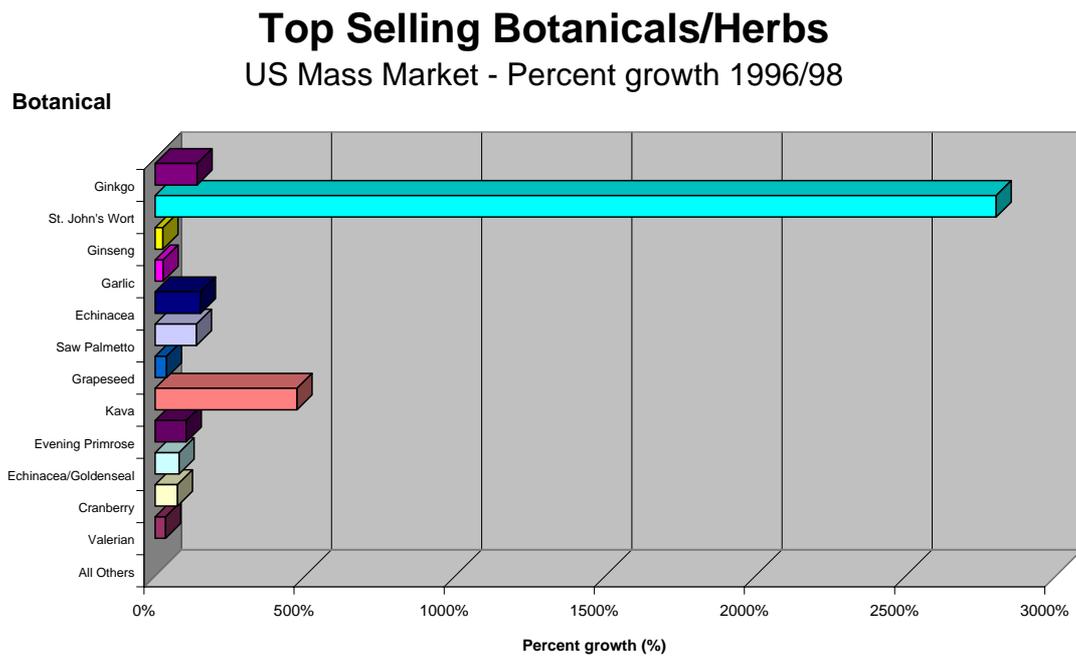


Table 4: FASTEST GROWTH IN US HERBAL PRODUCT SALES: (MASS MARKET 1998)

Herbal Product	Growth 1996/98 (Per Cent)
St. John's Wort	2,801%
Green Tea	1,007%
Black Cohosh	511%
Elderberry	497%
Kava	473%
Soy	163%
Echinacea	151%
Gingko	140%
Saw Palmetto	138%

Sources: Keane & Associates/IRI

In the natural food market channels, which largely pre-date the mass market channels, ten botanicals account for over 50% of the total sales – a figure largely unchanged since the previous year.

Echinacea, St. John's Wort, Gingko, Garlic, Saw Palmetto, Asian Ginseng, Goldenseal, Aloe, Siberian Ginseng and Valerian remain the top selling herbal supplements in these channels in 1997 and 1998, although the ranking of individual products has changed.

Table 4a

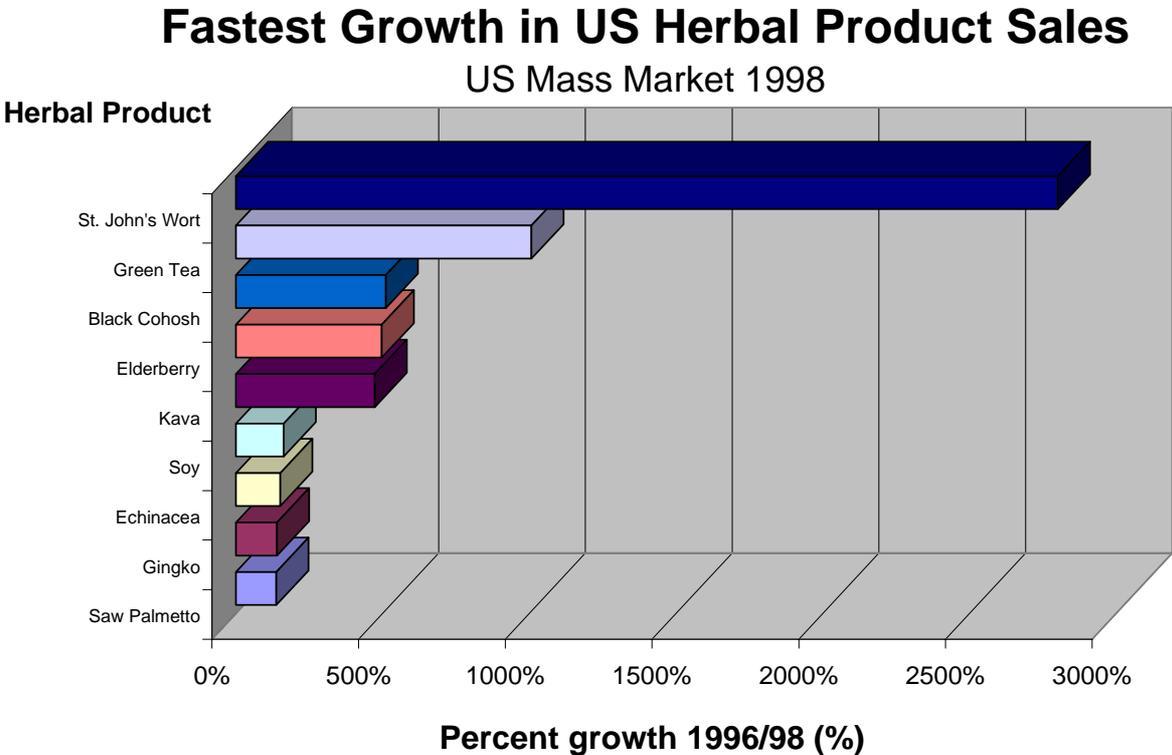


Table 5: RANKING OF US HERBAL SUPPLEMENT SALES 1997/1998 (NATURAL FOOD MARKETS)

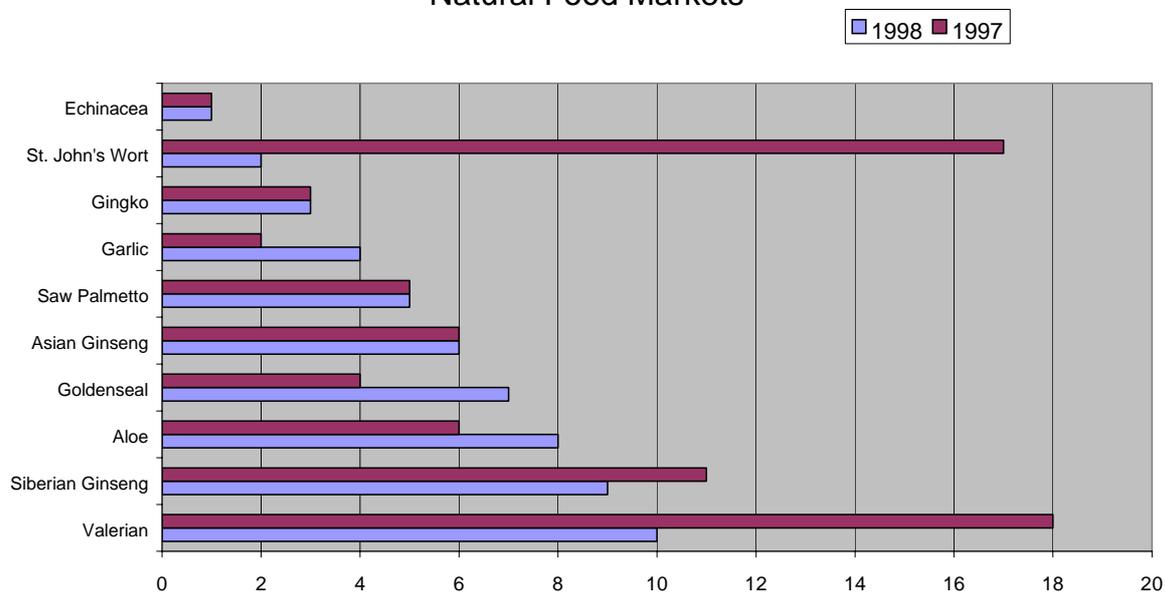
BOTANICAL	Rank		Percent of Sales	
	1998	1997	1997	1998
Echinacea	1	1	12%	10%
St. John's Wort	2	17	2%	9%
Gingko	3	3	7%	7%
Garlic	4	2	9%	7%
Saw Palmetto	5	5	5%	5%
Asian Ginseng	6	6	5%	4%
Goldenseal	7	4	6%	4%
Aloe	8	6	5%	4%
Siberian Ginseng	9	11	3%	3%
Valerian	10	18	2%	2%

Sources: Keane & Associates/WFM

Echinacea remains the leading product for the past two years, but St. John's Wort has risen from number seventeen in 1997 to number two in 1998. Valerian sales have also shown a significant increase - placing it in tenth place in 1997 compared to 18th place in 1997. (See Tables 5a and 5b).

Table 5a

Ranking of US Herbal Supplement Sales 1997/1998
Natural Food Markets



Taking all the U.S. consumer sales together in 1998, various multiherb combinations account for 27% of the total, but eight single actives contribute nearly half (47%) of total sales. (See Table 6). The single anomaly is Aloe and its prominence is due to the introduction of numerous cosmetic Aloe vera gels and creams for the treatment of skin conditions and sunburn in the mass market.

Table 5b

US Herbal Supplement Sales 1997/1998

Market Share

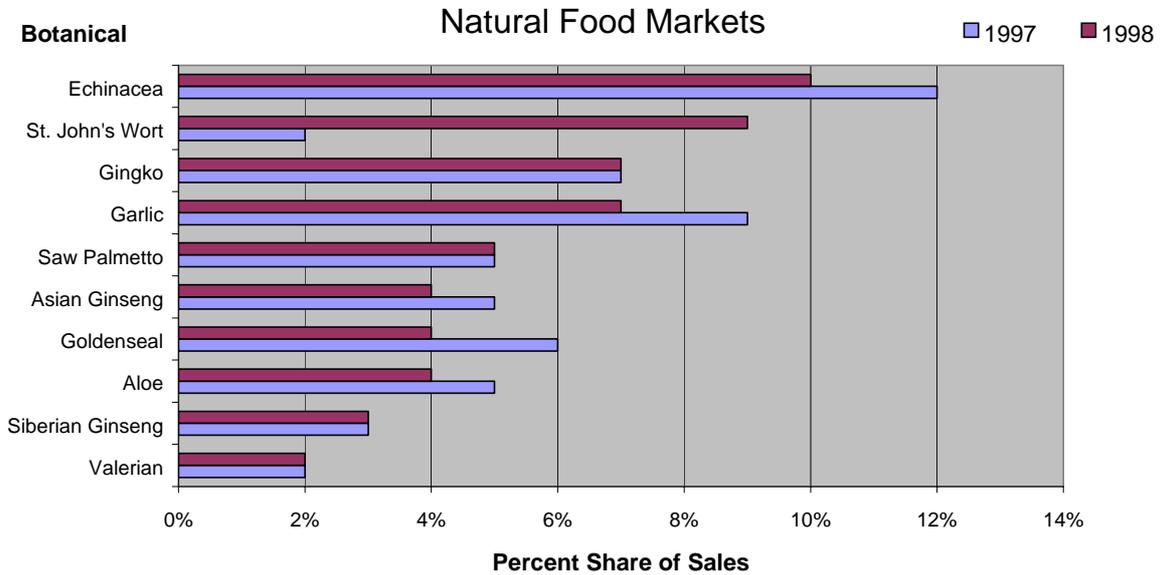
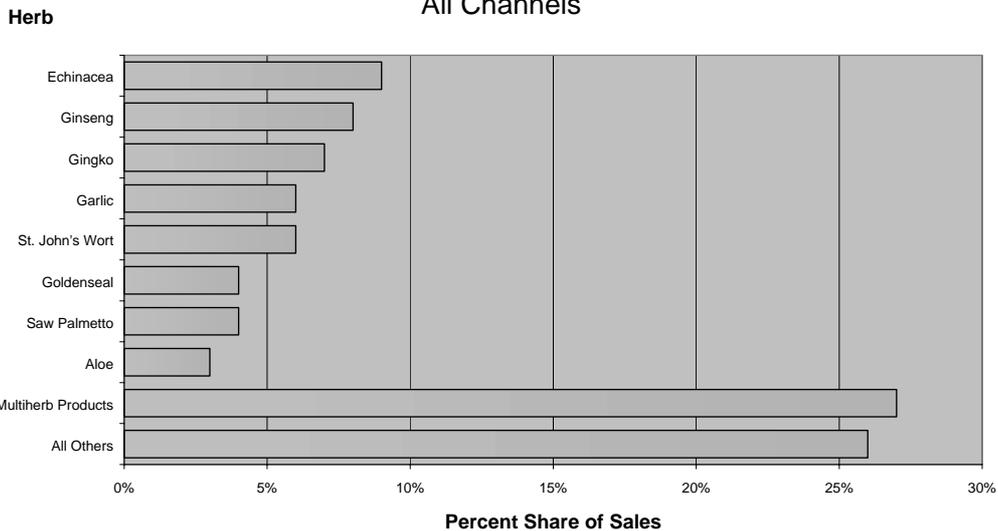


Table 6: U.S. CONSUMER SALES OF HERBAL PRODUCTS (ALL CHANNELS) 1998

Herb	Percent of Market
Echinacea	9%
Ginseng	8%
Gingko	7%
Garlic	6%
St. John's Wort	6%
Goldenseal	4%
Saw Palmetto	4%
Aloe	3%
Multiherb Products	27%
All Others	26%
Total	100%

US Consumer Sales of Herbal Products 1998

All Channels



Botanical Raw Materials: U.S. Market Trends

Over the last ten years there have been a significant number of changes in the global environment for botanical raw materials. These can be summarised as follows:

Increased Consolidation in an Increasingly Globalised Market

Botanicals are the fastest growing segment in the raw materials market in the U.S., valued at over \$600 million. Globally, the \$3 billion botanicals market is led by European companies, and these account for eight of the twenty three leading suppliers of botanicals.

The Martin Bauer Group, a German corporation with over \$250 million in sales and whose subsidiaries include Finzelberg, Plant Extract, (Plantextrakt), PhytoLab and Phytocon, is the market leader. Other major companies include the pharmaceutical giants Trostburg and Madaus of Germany and Schweizerhall of Switzerland, as well as specialty company, Indena of Italy – a \$200 million supplier of botanical derivatives for the pharmaceutical, cosmetic and food industries.

The leading U.S. supplier, Botanicals International, with over \$50 million in 1998 revenues is owned by the \$3 billion German based Zuellig Group, is also exclusive U.S. agent for Finzelberg. Euromed, a major supplier of standardised extracts of Saw Palmetto, Pygeum and Echinacea is a wholly owned subsidiary of Madaus of Germany. Madaus generates sales of \$400 million annually from botanical medicines alone. The majority of domestic U.S. suppliers fall into the \$20 million sales category. (See Chart)

There is an increasing consolidation in the botanicals industry at all levels of sales: wholesale, retail and suppliers. This demonstrates the increasing stability and maturity of the industry, particularly in the U.S. Beginning with the merger of Twin Labs and Nature's herbs in 1989, the following important mergers and acquisitions have taken place within the last four years.

Mergers & Acquisitions in the Botanicals Industry

Companies	Year of Merger/Acquisition
Celestial Seasonings/Botalia	1995
Chattem/Sunsource International	1997
Jones Pharma Inc./Crystal Star Herbs	1997
SmithKline/Abtei	1997
Celestial Seasonings/Mountain Chai	1998
Natrol/Pure Gar	1998
Natrol/Laci le Beau	1998
Quality Botanical Ingredients/ Botanical Products International	1998

Increase in Involvement of Multinational Companies in Natural Ingredients

Most of the large pharmaceutical companies have already entered the supplement business or are, at least, closely reviewing the market. Warner Lambert, American Home Products (AHP), Bayer and SmithKline Beecham are all introducing herbal products and this add respectability to this marginalised market. In addition, the entry of pharmaceutical companies producing supplements to meet drug standards is driving demand for high quality raw materials.

Involvement of Chemical Companies with Nutraceuticals

There has been an expansion of multinational chemical companies into the market sector now known as “Nutraceuticals” – a subsection of the nutrition and food supplement industry. Nutraceuticals comprise three principal areas – Plant derived products, food and feed additives and dietary supplements and all three are interwoven and complementary. DuPont, for example has started a separate nutraceuticals division within its life sciences division and has acquired Proteins Technologies International from Ralston Purina to develop its soy proteins technologies. Henkel Nutrition and Health Group (Germany) are offering anti-oxidants; Hoffman La Roche is introducing a range of omega-3-fatty acids and Lonza is targeting the market with a natural vitamin-like nutrient called L-carnitine.

The European market for nutraceuticals is projected to increase by 52% to \$1.6 billion within the next five years.

The multinational expansion trend is expected to continue from vitamins and minerals into newer and faster growing herbal categories, and this will put pressure on mid tier companies such as Sundown, Nature Made, NBTY, and Nature’s Resource which generate substantial revenues in the mass market. Ironically, it is the success of these companies, which have been thriving on herbal sales, that convinced Bayer, AHP and Warner that this was a market opportunity.

Increase in Advertising Investment in Botanicals by Major Companies

The rapid growth of the importance of botanical products has undoubtedly been tied to the significant increase in expenditure on advertising, particularly in the mass market channels. Prior to 1997/98, botanicals in the US were marketed primarily as a part of the natural foods industry. In 1998, Sunsorce spent \$250,000 on advertising its Ginsana products and this changed the traditional approach to the marketing of these products.

Table 7 shows the estimated advertising expenditures on botanicals in 1998.

Table 7

Estimated U.S. Advertising Expenditures on Botanical Products: 1998 (Mass Markets)	
Company	Est. Expenditure (\$ millions)
American Home Products	\$12
Bayer	\$35
Celestial Seasonings	\$25
Lichtwer Pharma	\$28
Pharmaton	\$26 (\$15 for St. John’s Wort)
Estimated U.S. Advertising Expenditures on Botanical Products: 1998 (Mass Markets)	
Pharmanex	\$15
Pharmavite	\$ 5 (Nature’s Resource)
Sunsorce (Chatterm)	\$43
Warner Lambert	\$15
Total	\$204

Sources: Keane & Associates/Advertising Age

These companies, with considerable resources and experience in launching consumer products into mass market channels have changed the American industry by bringing an increased awareness of botanicals to the average American.

Whitehall Robbins, Celestial Seasonings and Centrum all plan to introduce a line of herbal products in the U.S. during 1999 with major advertising budgets aimed at educating the consumer. In addition, several of the major perfume and cosmetics companies, including Estee Lauder and Revlon will be introducing cosmetics with natural plant extracts.

Pharmaceutical companies are banking on brand name recognition and the assurances and high standards that their names imply to expand this market.

However, success is not assured for the pharmaceutical companies entering this market. In contrast to the global market share of AHP's "One-a-Day" and "Centrum" in multivitamins, pharmaceutical companies have had only sporadic success in branding single vitamins like C and E, and the jury is still out on whether herbs are brandable. However, it is uncertain that consumers will more likely buy a product called "Feel Your Best: Tension" than single herbals like St. John's Wort or Kava Kava. What is clear is that the attention being given to herbal products by multinationals will significantly impact their potential market.

Increase in Product Awareness and Acceptance by Consumers

The consumer use of medicinal botanicals has increased ten fold in the last eight years. (See Table 6). Extensive consumer polling has been carried out in the U.S. annually since 1991, when consumer usage was approximately 3%.

The most dramatic increase occurred in 1997/98 when three independent surveys showed that consumer usage had jumped to almost one in three Americans on an occasional basis. New users accounted for most of the growth since 1997 but still only 7-8% of the U.S. population currently uses herbals regularly, compared to almost 45% in Germany. Most manufacturers expect the significant growth to come in mass markets when the remaining segment of the population start to use botanicals, and major multinational companies are preparing for this product launch now. (See Table 8 and 8a).

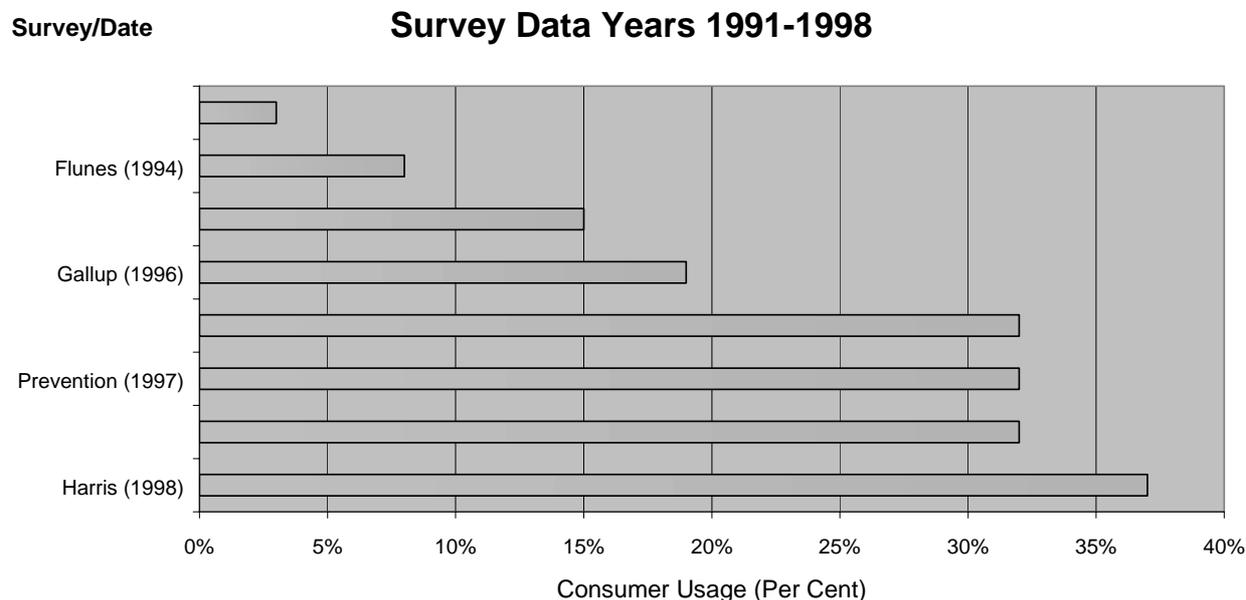
Table 8: INCREASE IN US CONSUMER USE OF MEDICINAL BOTANICALS: 1991-1998

Survey/Date	Consumer Usage
Eisenberg (1991)	3%
Flunes (1994)	8%
Gallup (1995)	15%
Gallup (1996)	19%
Gallup (1997)	32%
Prevention (1997)	32%
Hartmann/ New Hope (1998)	32%
Harris (1998)	37%

Sources: Keane & Associates, New England Journal of Medicine, Flunes 1994
Gallup Studies 1995, 96, 97, NFM, Harris.

Table 8a

Increase in US Consumer Use of Medicinal Botanicals



As botanical products became more visible, various special news reports heightened market awareness. Beginning in 1997 with the *Time* cover story, the American consumer has been inundated with special reports such as ABC Television and the Wall Street Journal's reports on Kava and St. John's Wort and subsequent features on Echinacea. These reports have resulted in dramatic increases in the sales of these products – often beyond the manufacturer's ability to supply products.

Positive publicity is a relatively recent event: previous publicity was either negative or reinforced the perception that botanicals and herbals were marginal markets originating in the 1960's when "Green," "Natural" and Organic" became buzzwords and synonymous with self care and controlling one's own destiny." The key to stabilising media coverage is good science and the growth of over 100% in botanical products in the mass market in the spring of 1998 indicates a new and widespread acceptance by the American consumer of these products.

Consumers are now driving the increasing demand for natural products and there is wider acceptance of herbal ingredients by all sections of the consumer market. This is also spurred by sports nutrition and media influence. In addition, herbal products are increasingly included as additions to common foods like potato crisps, soup, fruit drinks and even pet care products under a new category of products called "functional foods" which are not regulated since they are treated as dietary supplements.

Media attention has turned established products such as Ginkgo biloba, St. John's Wort and Melatonin into superstar products almost overnight. This market volatility with markets rising and falling in demand within very short periods causes increased pressure for the raw materials suppliers to respond in an efficient and profitable manner.

Rapidly rising demand usually means that some products are going to be in short supply – as is St. John's Wort now. St. John's Wort has taken the market by storm following extensive media coverage and possibly because so many people suffer from low levels of depression which they could try to self medicate.

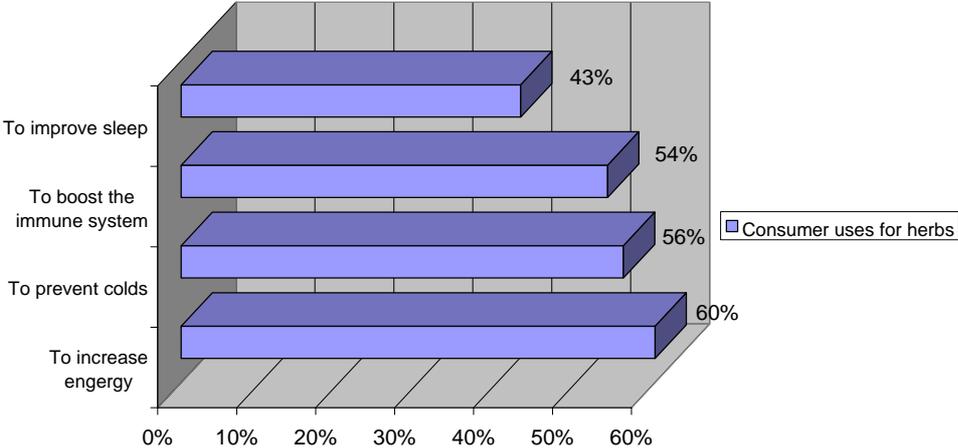
There is a growing trend for self medication, particularly for products designed as substitutes for OTC and prescription drugs, particularly those related to stress. For example, St. John’s Wort has found a ready acceptance as an alternative to Prozac, just as Kava kava has the potential to supplant some uses of valium. The success of Viagra will undoubtedly stimulate interest in natural ways to boost potency and this is already reflected in increased sales of Yohimbe extracts.

A recent nationwide consumer opinion poll conducted in the U.S. has confirmed that over 60% of American adults now are prepared to consider using herbal products as part of the answer to many common ailments, or as part of their daily regime within the next five years. The general perception now appears to be that herbals are helpful in a number of ways, or at least are benign and not harmful. Only four percent of those surveyed said they would never take herbal supplements.

The results, which are summarised in the following tables show, that consumers would consider taking an herbal remedy for a number of reasons including the following main responses.

Table 9

Consumer Perception of Benefits of Herbs

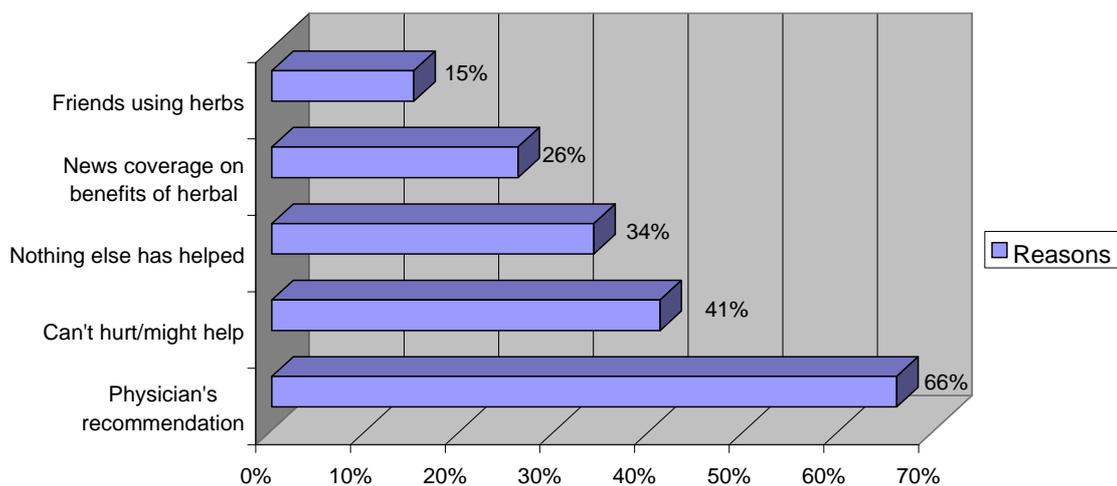


Perceived Benefit	Percent of Responses
To increase energy	60.0%
To prevent colds	56.0%
To boost the immune system	54.0%
To improve sleep	43.0%

However, when consumers were asked to focus on the use of herbals for the treatment of specific medical problems, the majority deferred to traditional medical practices. For example, when asked to focus on influences that would lead men to take an herbal supplement to help with prostate problems, the respondents cited:

Table 10

Consumer Reasons to Use Herbs



Reason for Consideration of Herbal	Percent of Responses
Physician's recommendation	66.0%
Can't hurt/might help	41.0%
Nothing else has helped	34.0%
News coverage on benefits of herbal	26.0%
Friends using herbs	15.0%

Differences between U.S. and European Raw Materials Markets

The U.S. market is considered to be in an evolutionary phase compared to Europe and the overall U.S. market for herbs and botanicals is relatively immature. Europe has a long history of research and processing of botanical extracts, and has much tighter regulations, established quality control procedures and decades of clinical data to support products. Overall, the European market is as well regulated as the drug industry and many of the compounds sold in the U.S. as dietary supplements are marketed as drugs in other countries (see Table 11).

Table 11

Leading European Phytomedicinals

Product	Botanical	Manufacturer	Sales \$Million
Tebononin	Gingko	Schwabe	\$195
Ginsana	Ginseng	Boehringer	\$50
Kwai	Garlic	Lichter	\$40
Effamol	Evening Primrose	Scotia	\$30
Echinaceae	Echinacea	Madaus	\$30

In Europe, the major therapeutic categories for botanical products are, in order of magnitude):- Cardiovascular (27%), respiratory (15%), digestive (14%), tonics (14%) and hypnotics and sedatives account for approximately 10%. In the U.S., the reverse is true – with sedatives, relaxants and other mood and memory enhancing compounds representing the largest category, and cardiovascular treatments at the lower end of the usage patterns.

Table 12

Fastest growing herbal categories in the U.S.

Category	Botanicals	12 Month Growth 97-98
Mild/Moderate Depression	St. John's Wort	490%
Calmative Herbs	Kava, Valerian, Chamomile Skullcap	47%
Brain/Circulation Herbs	Ginkgo, Gotu Kola	52%
Cold/Flu, Immune System	Echinacea, Goldenseal, Astralagus, Pau D'Arco	9%
Men's Herbs	Palmetto, Pygeum	23%

In both the U.S. and in Europe there has been a significant increase in the use of natural plant extracts as replacements for prescription pharmaceuticals. The major examples are the use of non pharmaceutical products for the treatments of menopause in women and there is a growing market for their use in the treatment and prevention of prostate cancer in men.

Germany is the leader in scientific herbal evaluation and its "Commission E" has evaluated 380 botanicals, approving 254 as safe and reasonably effective and disapproving 126 as ineffective, unsafe or both. The Germans use different criteria to assess a herb's benefits – a doctrine of "reasonable certainty" that the herb has the desired effect and is safe. Standard testing in the U.S. for approval by the FDA can cost up to \$500 million per product – a prohibitive amount to spend on botanicals that cannot be patented.

Under the German system, which is likely to become the model for the U.S., tests to establish "reasonable certainty" would cost \$1-2 million – well within the capabilities of most pharmaceutical companies.

Eventually, it is expected that the U.S. FDA will permit a long history of safe use as sufficient safety information for products that are intended for short term use. Nearly 50 botanicals and formulations, including Saw Palmetto and St. John's Wort, have already been submitted to the FDA as "Investigational New Drugs" (IND's). If, and when these meet the Agency's criteria for safety and effectiveness and are eventually approved as drugs, they will be allowed to make direct health claims instead of just structure and function claims.

Herbal medicines are sold as prescription drugs in pharmacies in Germany and France and they are covered by health insurance. This is the single most important factor affecting the use of herbal medicines in both countries. In Germany, about 80% of physicians regularly prescribe herbal medications compared to fewer than 10% of physicians in the U.S. Ginkgo, used as an herbal extract to improve vascular blood flow is Germany's most commonly prescribed drug, and other cardiac and urologic preparations such as Horsechestnut, Hawthorn and Stinging Nettle are much more important in Europe than in the U.S. In addition, the Europeans have a longer history of the use of botanicals for the treatment of dermatological conditions, with three of the top selling preparations – Soy extract, Chamomile and Comfrey committed to this usage. The following table shows the most frequently prescribed herbal "monopreparations" sold in Germany.

Table 13

Most Frequently Prescribed Herbals in Germany (1998): US\$millions

Botanical	Therapeutic Use	Retail Sales Value
Gingko biloba	Circulatory Preparations	284
Horsechestnut	Vein Preparations	70
Yeast Preparations	Acne, antidiarrhetic	36
St. John's Wort	Antidepressant	36
Myrtle	Cough Suppressant	22
Stinging Nettle	Urologic	20
Echinacea	Immune System	20
Saw Palmetto	Urologic/Prostate	19
Milk Thistle	Urologic	18
Ivy	Cough Suppressant	18
Mistletoe	Cancer Treatment	14
Soy Beans	Dermatological Uses	9
Chamomile	Dermatological Uses	9
Comfrey	Dermatological Uses	8
Kava Kava	Tranquilizer	8
Greater Celandine	Gastrointestinal Treatments	8
Bromelain (from Pineapples)	Anti-inflammatory	7
Cineole (Essential Oil)	Cold Remedy	7
Black Cohosh	Gynaecological Uses	6

Sources: Keane & Associates, German Prescribing Reports (95-97)

There are other notable differences. In the U.S., supplement companies tend to be smaller and more entrepreneurial. According to industry insiders, U.S. companies plan less, use more middlemen and have fewer purchasing contracts. On the one hand this supports a greater flexibility in the U.S., but in Europe customers know what they will be needing six months to one year ahead, and can generally forecast demand accurately enough not to have to inventory product and not to be so seriously affected by supply related price swings. Similarly, European companies tend to take a longer term view of the business and are more prepared to grow slowly. They also have more and longer long term contracts

Increase in the Role and Prominence of Suppliers of Raw Materials

Recently, there has been a dramatic shift in the role and prominence of suppliers of raw materials for botanical products. No longer are they faceless farmers selling commodity crops at a bargain price. Instead this section of the business is now populated by some of the largest most sophisticated companies in the business and there is a significant increase in the number of strategic alliances and mergers at the supply end of the natural products industry. All the manufacturers want to move closer to the supply channels to ensure continuity of supplies and verifiable quality and this is fuelling the commitment to long term supply agreements.

Leading domestic distributors are increasingly forming alliances with multinationals to enhance their market position. Botanicals International, for example, is owned by the Zuellig Group and serves as exclusive North American representative for Finzelberg. TSI, a subsidiary of Japanese based Inabata has formed research partnerships with the Chinese Academy of Sciences and signed distribution agreements with major ingredient manufacturers such as Pierre Fabre Sante of France.

The supply side of the herbal products industry has been rapidly changing from one characterised by a decentralised network of small scale growers and gatherers to a vertically integrated production system, dominated by multinational companies. Markets now depend heavily on access to appropriate processing facilities – including laboratory facilities for analysis. The establishment of several company owned Gingko biloba plantations in the U.S. is an example of vertically integrated production of raw materials by European manufacturers.

Trend towards Trademarked Raw Material Ingredients

The entry by major pharmaceutical companies into the botanicals arena signifies a significant change in focus.

Some recent examples are American Home Product's alliance with Pharmaprint for an entire line of botanicals under the Centrum® brand; Smith-Kline Beecham's introduction of their Abtei ® line of products from Germany; Bayer's 1998 introduction of botanical ingredients in its One-A-Day ® product line, and Warner Lambert's introduction of Quanterra ® single ingredient products.

Other companies who have introduced trademarked raw ingredients include Nutratech with its Advantra-Z weight loss products and Botanical International's CombiNature and NaturSpan lines.

One of the benefits of patents and trademarks is that they place responsibility on the supplier to provide a consistent product within a set specification.

Increase in Combination Formulas

In the United States there is a growing recognition of the concept of combination formulae compared to individual herbs. Formulae are already the models for both traditional European and Asian herbal products and this will eventually evolve in the United States leading to new products based on unique formulations.

Since botanical extracts and herbs cannot be patented, manufacturers are looking for additional methods of product protection, and combination formulas are harder to copy. Apart from trademarking, we can expect to see patents for novel methods of administration – such as controlled release products; processes of unique manufacturing techniques, formulae for specific conditions and unique dosage regimen. Botanicals International, for example, has developed a series of herbal extracts formulated to provide controlled release over a period of 8-12 hours.

Other unique delivery systems are also emerging – including a St. John's Wort transdermal patch and Yam Creams for oestrogen therapy. Botanicals are also appearing as healthy ingredients in conventional foods – including Gingko crisps and Kava corn chips.

American Ingredients Inc (AII) recently introduced its first trademarked combination product – Kavalorian – which combines Kava and Valerian extract.

In 1998 Bayer introduced its line of One-A-Day products combining herbs, vitamins and minerals which, with seven formulations, were targeted to specific health concerns including Tension & Mood Formula and Prostate Health. All the formulations in these products are combinations of extracts – not single extracts - and are targeted to mainstream consumers who perceive that herbal products made to pharmaceutical industry standards are of high quality and proven safety and efficacy.

Bayer is only marketing products with long track records and is avoiding controversial products. Similarly it has established rigorous standards for its raw materials – holding off on the introduction of an energy product until it has an assured supply of high quality ginseng.

Shortages and Limitations on Future Supplies of Raw Materials

The rapid, and often unprecedented, growth of the botanicals market inevitably leads to constraints on existing supply channels. This in turn stimulates a number of other changes – including increased cultivation of formerly wildcrafted plant populations, new sources of supply, erratic price swings and

an increased danger of adulteration. St. John's Wort and Kava are two recent examples of demand exceeding supply.

The renewed emphasis on commercial cultivation versus wildcrafting is shown in the following table which demonstrates the increase in the number of medicinal herbs actively cultivated and often exported from the United States within the last five years.

Of twenty five major herbal ingredients only Elderberry, Saw Palmetto and Slippery Elm now rely exclusively on wildcrafting for supplies and commercial plantings of Saw Palmetto are being introduced to offset the damage caused by recent natural crop failures in the U.S.

Table 14

Botanical	Wildcrafted	Commercial Cultivation Since 1994	Exported Since 1994
Aloe	–	YES	YES
American Ginseng	YES	YES	YES
Black Cohosh	YES	YES	YES
Burdock	YES	YES	YES
Cayenne	–	YES	YES
Chamomile	–	YES	YES
Cranberry	–	YES	YES
Echinacea	YES	YES	YES
Elderberry	YES	–	–
Evening Primrose	–	YES	YES
Feverfew	–	YES	YES
Garlic	–	YES	YES
Ginkgo	–	YES	YES
Goldenseal	YES	YES	YES
Grapeseed	–	YES	–
Hops	–	YES	YES
Kava	YES	YES	–
Milk Thistle	–	YES	–
Nettle	–	YES	–
Peppermint	–	YES	YES
Red Clover	–	YES	YES
Saw Palmetto	YES	–	YES
Slippery Elm	YES	–	YES
St. John's Wort	YES	YES	YES
Valerian	–	YES	YES

Shortages

Demand for key natural ingredients is very difficult to predict and significant shortages can arise from single crop failures – such as the Valerian Root crop in Poland this year which was damaged by floods. Anticipating a shortage the extract companies purchased much of the raw material for extraction. Similarly the normal three month harvesting of the U.S. Saw palmetto crop was completed last year after only two weeks with less than 20% of the normal production.

In practice, the major suppliers of the raw materials are dependent on the forecasting abilities of their customers, and base their global procurement on that basis, taking into consideration such factors as different harvesting times. For this reason there is a close cooperation between the major growers and the major buyers. Despite this cooperation, shortages occur for reasons that are often unforeseeable. These range from media attention to weather conditions. Once again, St. John's Wort is a good example.

Many botanicals such as St. John's Wort are once a year crops. After it has been harvested there is no further harvest until the following summer and prices jump considerably in the interim period – by over 30% this year for St. John's Wort. This may offer considerable opportunities for growers in the Southern hemisphere to take advantage of out of season production, although the trend towards the production of extracts and their year round availability will tend to negate this benefit in the long term.

Not all botanicals are in short supply at the same time. Some of the key natural products that are in stable supply this year are Echinacea purpurea herb (not root), Cat's claw, Goldenseal root, Ginkgo

leaves and Siberian and Eleuthero Ginseng. However, Valerian root, Saw palmetto and Cascara sagrada are in short supply this year.

Shortages, whether perceived, actual or created (by hoarding) affect all levels of the industry. It can result in adulteration when manufacturers care more about price and availability than quality or efficacy and several instances are known where prices can double or triple but with the retailer buying a lower potency product for twice the cost. Well known examples of adulteration in the U.S. industry include Chinese Goldenseal (*Coptis chinensis*) or Barberry for American Goldenseal and Missouri Snakeroot for *Echinacea purpurea* root.

The effects of botanical shortages can be lessened by better projections and growers working on the basis of annual contracts from manufacturers. This leads to stability in prices, availability and quality. The ideal goal for the developing Australian industry would be to establish exclusive alliances with high quality manufacturers and suppliers (such as Henkel, Indena and QBI on a global basis.)

Increase in Number of Companies Growing their Own Botanicals

Another trend is the increasing number of companies growing their own raw materials. Bio-Botanica in New Jersey, for example, has over 4,500 acres of its own organic land devoted to botanical raw materials.

Botanicals International is currently involved in three major cultivation projects – *Echinacea purpurea*, Goldenseal and Valerian to ensure continuity of supply for its customers.

To forestall future shortages, Indena has increased the percentage of cultivated botanicals from 10% to over 60% since 1989 and now has 6,000 acres of its own in sustainable cultivation

Acceptance of New Sources of Botanicals

There is a significant increase in the number of new sources of botanical raw materials, especially from within China, India and the former Soviet Union. In addition, many other countries including Australia, New Zealand and Canada are looking at botanicals as potential markets for new crops.

While Europe and the U.S. have traditionally set the standards for production and quality, these new sources are providing the competition which has helped to temper market prices. There is no evidence of any market resistance to new sources of these products, providing that the quality is acceptable, and the U.S. market has already accepted *Ginkgo biloba*, Milk thistle, Siberian Ginseng and Garlic from China. Eventually it is expected that these countries will also produce unique products which will be universally accepted. Recent examples are *Gymnema sylvestre* and *Ashwagandha* from India. In summary, the source of the material is less important than the consistency of the quality. However, even in times of shortage the emphasis on quality has increased.

Most manufacturers are reluctant to source their entire supply of a product from a single company or even country because of the possibility of crop failure or political instability.

Increase in Demand for Value Added Services

There is an increase in demand for quality raw material suppliers capable of supplying value added services such as extraction, processing and custom manufacturing and supply.

Raw material suppliers are now facing pressure from multinational competitors and also from large manufacturing clients as well. In the past many of the distributors or ingredient suppliers were merely re-sellers. Now, with the changes being forced upon them many of these distributors are producing either semi-finished goods, or private label brands. Rexall Sundown is one of the many companies

which have invested in mass market distribution and has expanded from 5,000 stores in 1995 to over 30,000 in 1999. As a result Rexall can now bypass raw material distribution and buy direct from the producer.

Brokers in particular, are being forced to diversify to remain viable and many are expanding to control supplies from planting through to processing, and even into manufacturing.

Major distributors are no longer just acting as commission sales agents for bulk products but are buying raw materials in different forms and providing them to the end user in a value added form. This may be as simple as using granulations for bulk products, or more likely with botanicals, to provide value added extracts or custom blends. The trend is likely to continue as profit margins increase from 5% for raw materials to 30-35% for value added products.

There is a movement towards vertical integration. Indena USA, for example, is investing in sustainable cultivation as well as providing custom formulations, scientific research and analytical validation. Triarco is another example of a company with an agricultural division as well as herbal processing facilities of its own.

The future for natural product ingredients lies in cultivation, plant engineering to allow the cultivation of products based on certain levels of market compounds and the provision of consistent and verifiable quality extracts.

Movement Away from Bulk Herbs

Bulk medicinal and culinary herbs have long been a staple for natural products retailers and remain popular because they offer customers myriad options for concocting their own teas, liquid extracts, capsules and oils in addition to culinary possibilities.

The emphasis for bulk herbs is for self service and requires both an educated consumer and a supportive retail sales force, together with a comprehensive reference section or a dedicated library of subject specific books.

The principal usage is in the form of hot or iced teas, and the market for teas has grown significantly. Herbal teas are most often used for digestion ailments and for detoxification, especially cleaning the liver.

Bulk herbs offer a high profit margin to retailers and this makes them attractive to small retail operations where profit margins are typically 50-100% and there is no recognized formula for pricing and very little comparative shopping

Disadvantages of bulk herbs are a limited shelf life, requirements for airtight closures and the need to store them away from heat and light. In addition, teas made from herbs are often refreshingly bitter, but not necessarily palatable. Therefore, customers typically make their own blends – adding stevia and licorice to the blend to take the edge of teas made with wormwood, ginkgo and valerian, and improving texture by adding such herbs as fenugreek, flax and marshmallow root which act as thickeners.

The market for bulk herbs is entirely different from botanical extracts, and is not considered in detail in this report because the objective is to identify value added opportunities for Australian botanical extracts in the U.S. However, the following list of the best selling bulk herbs in the U.S. (Table 15) will illustrate these differences

Table 15

Top Fifteen Best Selling Bulk Herbs in the U.S.

Rank	Bulk Herb/Plant Part	Therapeutic use
1	Psyllium Seed/Husk, (Powder & Whole)	Antispasmodic/laxative
2	Chamomile flowers	Anti-inflammatory/anti-spasmodic
3	Flaxseed	Fatty acids and fibre supplement
4	Lavender Flowers	Antiseptic. Mood enhancer
5	Peppermint Leaf	Digestive/Tonic
6	Licorice root	Endocrine tonic/Sweetener
7	Pau d'Arco Bark	Immunity/Liver function
8	Alfalfa Seed	Energy. Bowel cleanser
9	Slippery Elm Powder	Digestive
10	Red Raspberry Leaf	Menstruation: Antidiarrhetic
11	Burdock Root	Liver and blood functions
12	Rose hips (Seedless)	Immunity/Vitamin C source
13	Valerian Root	Nerve tonic. Anxiety relief
14	Kelp Powder	Thyroid tonic. Source of minerals
15	Nettle Leaf	Blood and Kidney tonic

Sources: Keane & Associates/Herb Market Review

Trend Towards Production of Extracts

The single most important trend in raw materials is the movement away from whole herbs and botanical powders to standardised extracts.

These are viewed by the consumer as more potent, and from the manufacturing point of view they offer a more consistent product by standardising to a specific marker or compound as well as the potential to reduce contaminants.

Indena has long been a leader in the supply of extracts and began in 1921 with the production of tinctures and fluid extracts for use in galenic preparations by chemists. Indena introduced the concept of standardised herbal extracts in the US in the mid 1980's. In 1998, to address concerns about solvents and alcohol based preparations, Bio-Botanica introduced a line of alcohol free liquid extracts.

The increasing concentration of the finished product that results from various types of processing demonstrates the importance of the value added concept to the supplier of botanicals. Value added opportunities exist in the botanical markets particularly in the development of high quality extracts.

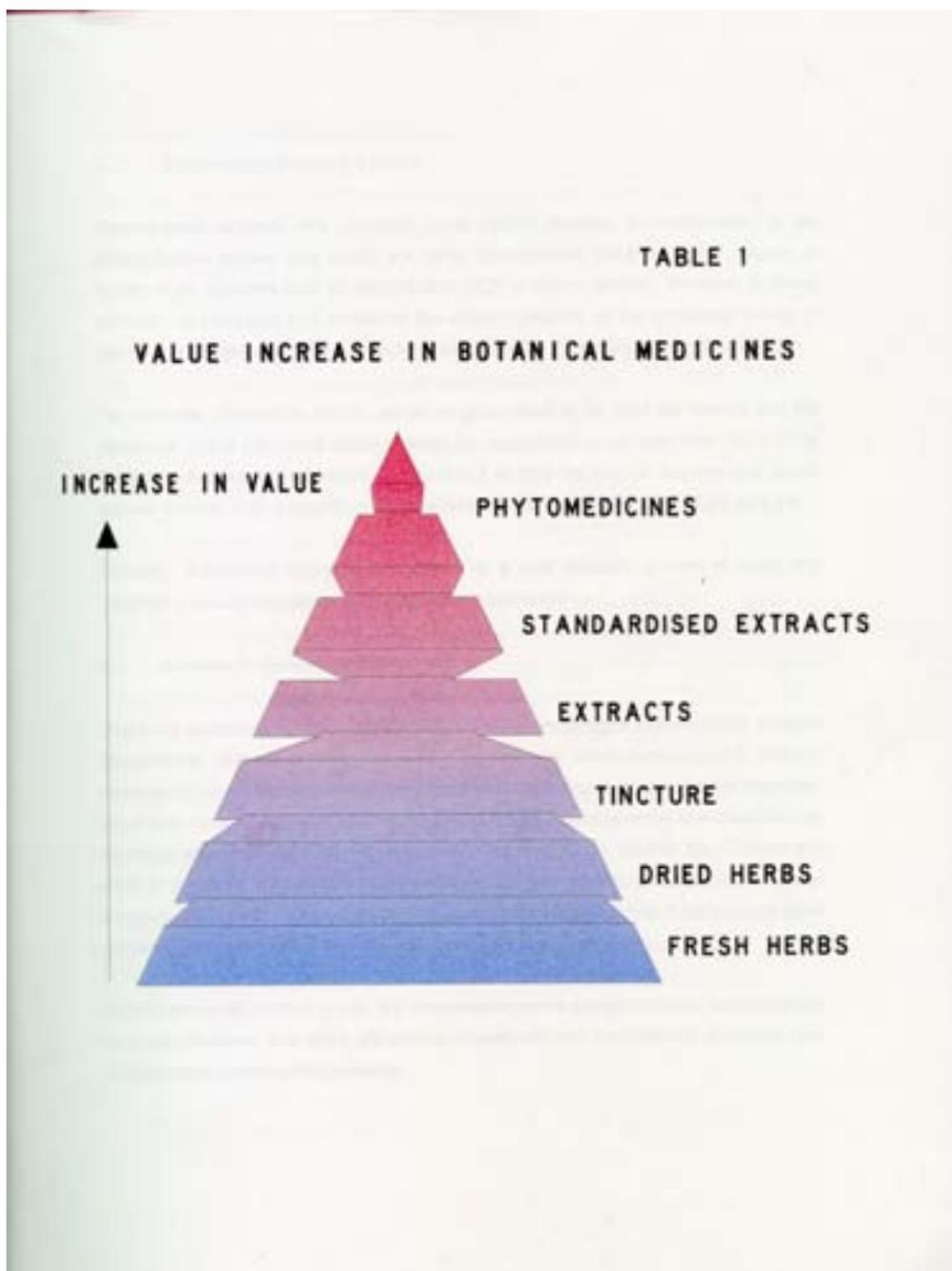
The following pyramid chart shows the progression in both value and concentration resulting from various processing techniques. The most concentrated and valuable product results from the most sophisticated manufacturing process. For example, the top of the pyramid represents a phytomedicine such as Gingko which has been standardised to one or two marker compounds, and eliminating other compounds in the process. Manufacturing a standardised extract – which is increasingly the article of choice – means that the material has been standardised to one or more chemical markers – which are not necessarily the active ingredient.) Tinctures are simple infusions of herbs in alcohol and are the precursors of extracts which result from further processing and concentration of the original material using a solvent extraction process. At the bottom of the value chain are bulk herbs such as teas and spices and also those which are bulk dried or sold in tea bags.

There are two primary types of extracts for medicinals. These are:

1. Botanical Extracts

These are extracts that do not have assayed active principals, and they are most often used for tablets, capsules and cosmetics. Typically these are hydroalcoholic extracts prepared from the simple maceration of the plant part in Ethanol/water combinations and then made into a powder by mixing the extract with an excipient such as maltodextrin or DCP (Dicalcium phosphate).

The higher quality products specify (but do not guarantee) the plant part and the constituent/excipient ratio – usually 4:1 for powdered extracts of such medicinals as St. John’s Wort and Valerian. The active ingredient is not defined – but a broader term is generally used such as “Essential Oils” for Valerian and “Volatile Oil;s” for st. John’s Wort.



2. Standardised Botanical Extracts

Standardised extracts are prepared in a similar manner by maceration in an ethanol/water solution and which are either standardised using additional solvent or added to an excipient such as Maltodextrin, DCP or silicon dioxide. However, in these extracts the plant part and content of the active ingredient, or the presumed active, or the marker compound which is generally recognised by the trade is also guaranteed.

For example, chamomile extract would be guaranteed to be from the flowers and the Apigenine active ingredient would typically be guaranteed to not less than (NLT) 1.0%. Similarly, Valerian extract would specify that it is from the root or rhizome and would contain not less than a specific amount of valerianic acid – usually either 0.8% or 2.5%

Similarly, Goldenseal would be guaranteed to a total alkaloids content of about 5% alkaloids – usually representing hydrastine and berberine.

Increase in Concerns over Quality

There are increasing concerns over quality as suppliers struggle to meet rising demand for products. Botanicals from the Far East, in particular, have been subject to scrutiny because of contaminants ranging from heavy metals to illegal drugs. Recent examples are Panax Ginseng Extracts contaminated with PCNB fungicide which is allowed for use on Asian crops but prohibited for use on Ginseng in the U.S. Neither the FDA nor the EPA in the U.S. has established procedures for the detection or removal of these products from herbal products and there is a growing likelihood that if the industry does not adequately police itself it will be faced with regulatory intervention.

Manufacturers of finished goods are incorporating more stringent quality parameters in their specifications, and more are dealing directly with the raw material producers and processors to obtain quality products.

Increases in Regulatory Controls

Apart from food uses such as flavourings, spices and items such as candied ginger etc., there are four primary regulatory avenues for botanicals in the U.S. These are:

- Dietary supplements
- Dietary supplements with structure/function claims
- As an approved Over The Counter (OTC) medication
- Investigational New Drug/New Drug Application (IND/NDA)

In the U.S., the main concern for companies in the U.S. supplements market is the increasing scrutiny from the Federal Trade Commission (FTC) over specific advertising claims based on the manufacturer's interpretation of the Dietary Supplement and Health & Education Act (DSHEA) of 1994.

DSHEA currently regulates botanical medicines as dietary supplements. These are defined as “a vitamin, a mineral, an herb, or other botanical (or) an amino acid.” Under the 1994 law the FDA cannot restrict a dietary supplement unless the Agency receives complaints of harm, and the supplement law does not cover foods. As a result many companies are marketing products with some highlighted health benefit affecting disease or mood with little or no regulatory supervision, and the development of these “functional foods” is currently the fastest growing trend in the food industry in the U.S.

There is little doubt that in due course the FDA will regulate these products and particularly health related claims. Currently, “structure function claims” which purport to influence certain functions such as those of the heart are permissible but any health claims would require extensive data to support it.

For example, Saw Palmetto cannot be sold with the promise that it will cure an enlarged prostate, but the label may say it will “improve urinary flow “ in older men or even state simply that it is “for the prostate.”

Meanwhile product labels and advertising are required to carry the statement: “This statement has not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.”

At the moment, herbal products in the U.S. are not required to meet any established standards of effectiveness or safety for medicinal products – which require extensive laboratory and clinical trials before approval. Under the existing law, consumers have no assurance that an herbal product contains what the label says or even that it is free from harmful contaminants. There is, however, a misperception that if a product is sold over the counter that it is FDA approved and this is a cause for regulatory concerns.

Under the present system, only the name of the herb must appear on the label. There are no indications of use and no required standards of purity and quality. This lack of information and quality assurance will undoubtedly change since it is not in the best interests of the consumer.

There are other regulatory channels for botanicals apart from dietary supplements and supplements with structure/function claims. The third regulatory category is as an approved OTC medication. There are several botanicals already in this category in the U.S.- although most of them are natural laxatives. (See Table 16).

Table 16

Botanicals Approved in the U.S. as OTC Drug Ingredients

Botanical	Approved Use
Aloe (<i>Aloe ferox</i>)	Laxative
Cascara sagrada	Laxative
Peppermint Oil (<i>Mentha piperita</i>)	Antitussive
Psyllium (<i>plantago afra</i>)	Laxative
Red Pepper (<i>Capsicum spp.</i>)	Counterirritant
Senna (<i>Cassia senna</i>)	Laxative
Slippery elm (<i>Ulmus fulva</i>)	Demulcent
Witch Hazel (<i>Hamamaelis virginiana</i>)	Astringent

This classification does not mean that they cannot be also sold as dietary supplements, but that they can carry additional specific therapeutic claims. The U.S. botanicals industry has petitioned the FDA for the last 10 years to have European phytomedicines reviewed as old drugs based on their extensive use in Europe but the FDA has not yet made a decision on these requests.

The fourth regulatory category available for botanicals is via the IND/NDA (Investigational New Drug) process – formerly restricted to the pharmaceutical industry. To date there are over 50 botanicals or botanical formulas containing IND ingredients including Saw Palmetto, Valerian extract, Ginkgo biloba and St. John’s Wort waiting for review.

The likelihood is that the FDA, under pressure from industry and consumer interest groups will eventually adopt procedures which will address clinical trials for traditional herbal products differently from drug trials. This would allow, for example, a long period of safe use, to be taken into consideration and even used as the basis for the risk assessment.

Development of Analytical Methods & Quality Assurance (QA)

The difficulty facing the industry in the U.S. is that despite their widespread use, FDA approval is not required prior to marketing herbal “supplements.” Their safety and efficacy have not been proven and their content of bioactive ingredients are not assured. They are merely classified as dietary supplements along with vitamins and minerals and sold without prescription under DSHEA, despite being used to treat a wide variety of medical conditions.

However, the FDA does reserve the right to institute manufacturing guidelines for herbal extracts and dietary supplements in the future and this will eventually happen, together with the introduction of more stringent controls on these products, analogous to those in a regulated drug development.

There is currently no official methodology for measuring marker compounds or active ingredients in botanical materials, and this is only now being developed to allow different laboratories to make direct comparisons using accepted standards when assaying raw materials.

All standardised extracts are sold with documentation verifying their level of potency. However, there is no consensus in the industry as to which constituents should be standardised in individual extracts. In addition, every independent lab has its own method of validation – and often these are proprietary and not published for the industry.

In the absence of regulatory action, the industry itself will have to bear the responsibility for the standardisation of botanical extracts. Some of this is already underway, but needs to be improved. Many botanicals are standardised on marker rather than active chemical components and there is a need to analyze and identify these components in order to ensure a fully standardised product. i.e. a batch to batch replicable and verifiable final product.

For example, St. John’s Wort is standardised for the marker hypericin, although this compound is not directly related to its anti-depressant activity, and the benefits of the herb appear to be related to other substances all working together to counter depression. Similarly, Valerian is typically standardised to 0.8% valerenic acids, and Echinacea to 4% Echinacosides.

The market leaders, such as Indena and Botanicals International already produce concentrated extracts standardised to contain consistent quantities of the active compound, and offer products identified by comparison to previously established reference standards for the particular botanical – usually by TLC and HPLC.

Validated methods for Ginkgo, Echinacea and Panax Ginseng are near completion and others are under development for Kava and St. John’s Wort. The first three botanicals to be validated in the U.S. will be Ginkgo biloba for anacardic acid, ginkgoflavone glycosides and ginkgoterpenoids; Ginseng for ginsenosides; and Echinacea for total polyphenols.

One way to resolve this issue of variability is to develop different levels of purity and quality. For example three different levels of extract could be offered, depending on the known constituents: e.g.

- Level 1:** This would be used where the main active constituents are known and standardised in the finished product e.g. Ginkgo
- Level 2:** Active constituents are not clearly known but “Typical constituents” are known and act as markers for quality control e.g. Valerian.
- Level 3:** There is insufficient information on the active ingredients to create a fully standardised product. This would apply to such botanicals as Echinacea and Saw Palmetto and would be determined by industry acceptance. In the case of Echinacea

the industry acceptance is of a product containing a known quantity (usually 4%) of Echinacosides.

Eventually the entire industry will either regulate itself, or be regulated to establishing conditions of quality and levels of active ingredient which can meet verifiable standards.

Analytical Methods

Major suppliers use a variety of analytical tools for the verification of their products. Some, such as Botanicals International (BI), with their Identilok processes have incorporated these into trademarked technology. This is currently the state of the art programme for both herbs and spices, and includes the use of thin layer chromatography (TLC) to verify the presence of actives and constituents in herbs and botanicals. The chromatogram is then compared to a standard and a previously published reference for that particular botanical.

BI then uses a sophisticated analytical spectroscopic technique (FTIR) that utilizes infrared radiation to provide functional information about its botanicals. For each botanical, the spectra record displays the absorption characteristics of functional groups and for a singular marker. For identification purposes, the spectrum of the botanical is overlaid with an established IR spectrum for that particular species.

Microscopic and macroscopic examinations are also performed and these, when used with a digital image reference data base, enable adulterations to be uncovered instantly.

The final arbiter is the use of high performance liquid chromatography (HPLC) which selectively measures chemical constituents, whether active or marker compounds, such as flavonoids, polyphenols and alkaloids. This can be compared to a fingerprint or botanical profile to ensure that all the constituents are present in the correct ratio.

The Use of Marker Compounds in Analysis

The use of marker compounds in the analytical phase of development will increase with the issuance of pharmacopoeia monographs and as overall quality of the raw materials improves. The monographs will cover analytical and quality control methods as well as the therapeutic aspects of the herb. The importance of establishing these marker compounds can be illustrated using St. John's Wort as an example:

In St. John's Wort, the primary compounds of interest as marker constituents include the two naturally occurring pigments, hypericin and pseudohypericin (naphthodianthrones). These compounds are characteristic markers for this genus and are extracted in methanol. They both absorb visible light with a maximum absorption at 588 nm and are highly fluorescent in methanol when exposed to UV light. Both pigments are similar in their absorption and emission spectra, including their absorptivity. Separation of these two pigments is necessary to determine the concentration of each pigment, and methods are provided in the pharmacopoeia for the determination of both pigments and the flavonoid classes of compounds.

Hypericum perforatum can be differentiated from adulterants by the presence of hyperforin and rutin, which are absent or negligible in other species. Adulteration can also be detected through TLC analysis to identify other species. For example, *H. barbatum* can be distinguished by the presence of the compound orientin; *H. montanum* contains a turquoise fluorescing vegetable acid in addition to chlorogenic acid and only *H. tetrapterum* and *H. maculatum* contain emodin.

An accurately measured dose of a marker constituent is especially relevant when studies show a therapeutic value of a constituent different or more specific than the whole plant. Milk thistle seeds (*Silybum marianum*) historically has been used for mild digestive complaints, especially those centered on liver function. Silymarin, a flavonolignan complex found in the seeds at 1.5-3.0% has

been shown in its purified form to partially inhibit liver damage from death cap mushrooms. Depending on the intended use of a milk thistle product, one consumer may choose to use a well manufactured, but not standardised, tincture as a digestive aid, whereas anyone with a diagnosed liver disease would prefer a standardised product concentrated to 80% silymarin.

For certain herbs, industry standards have established maximum daily limits of specific compounds to guard against potential side effects or abuse. For example, Ephedra products are labelled to provide a dosage no greater than 120 mg of the contained alkaloids per day in four equal doses. Similarly, it is recommended that kavalactone consumption from Kava be limited to 300 mg per day.

Raw material buyers now routinely insist on certificates of analyses and MSDS sheets and other documents to verify authenticity (species verified), method of identification, botanical part used, country of origin, micro-organism levels and pesticide residue levels.

Pesticides and Contaminants

The main market for herbal products (herbal processors/manufacturers and pharmaceutical companies) primarily demands an organic product, and growers cannot use synthetic chemicals to control pests, weeds and diseases.

Many herbal crops are relatively free of pests and diseases, but weed control is a major production cost both financially and in labour.

There is also a recognised need for testing for contaminants such as pesticides, heavy metals and solvents. As fewer botanicals are wildcrafted and more are commercially cultivated the risk of pesticide contamination increases.

With the trend towards extracts the potential for concentrating contaminants also increases. Bulk herbs entering the U.S. are still routinely fumigated with methyl bromide and pesticide contamination will remain a problem because so few pesticides are registered for use on these minor crops – virtually ensuring that any pesticide residue will be of an unauthorized product. Curiously, this has led to the issuance by some companies of spurious analytical certificates which confirm the absence of compounds which in all likelihood would never be used on these field crops anyway, but which ignore possible contamination by commonly used herbicides and insecticides.

In Australia, the National Registration Authority (NRA) has now granted off label permits for the use of 11 agricultural chemicals on herb crops until mid August, 2000. These require research to be undertaken to support the establishment of permanent MRL's (maximum residue levels) on minor crops and undoubtedly will help the botanicals industry. However, the elimination of pesticide residues in the final product remains a priority.

Cleanliness of raw materials is vital at all stages of production and the processing plant should be monitoring bacterial and fungal infections, rodent and insect infestations for all deliveries of bulk herbs.

Criteria for Selection of Botanicals

The botanicals selected in this report have met the criteria established in the following guidelines.

1. Market Considerations

There must be an existing, viable market in Europe, the U.S. or the Far East which has shown quantifiable growth for several years. It must have an established market and a long history of safe use.

The largest market for botanicals, both in manufacture and consumption, is in Europe, followed by Asia and Japan which each represent approximately one third of European annual sales, followed by the U.S. The U.S. market lags primarily because the current regulatory environment prohibiting health claims.

However, there is remarkable agreement between the most popular herbal medicines used worldwide, even allowing for regional and cultural differences and the historical western bias against scientific and clinical evidence from developing nations.

2. Value Added Opportunities

All of the crops selected offer significant opportunities for value added production in Australia. The opportunities cover a spectrum from the selection of cultivars with enhanced desirable characteristics to the use of critical CO₂ extract as a solvent and the establishment of new markets in related industries.

3. Potential for Growth

The market is fickle and opportunistic for all herbal products grown for medicinal purposes. For this reason it is important to concentrate on crops which have proven staying power in terms of market demand, and to concentrate on providing a higher quality product and a continuing source of supply.

The majority of phytomedicines are 2-3 year crops in terms of time to first commercial harvest. Therefore, exceptionally heavy demand and “this year’s wonder drug” scenarios should be viewed with caution – prices cannot be expected to remain stable for more than one year before there will be a trend to overproduction and a resulting decline in prices.

The opportunity to capitalize on high priced markets is very limited – less than two years from planting to drug production from most botanicals - and for this reason the emphasis must be on a longer term focus and an improved product.

Future growth is expected to be primarily fueled by a greater penetration of the universe of consumers. As products move into the mainstream channels this will be supported by greater advertising and expanded shelf space.

The percentage of U.S. households that purchase supplements – 30% for herbs and 65% for multivitamins – is expected to rise to 50-75% - depending on which consumer survey is believed to be most accurate. The number of shoppers who have used supplements, alternative medicines or natural products or who have a high awareness of them are also rising, paving the way for an even greater number of consumers.

Long term forecasts, however, should be more conservative. As distribution is approaching saturation to the point where pricing pressures and brand consolidation are significant trends, at some point in time consumer penetration will also plateau.

Education, marketing, prices and safety issues will affect the pace of consumer uptake, and the general economy, health care trends and regulation will also have an impact, but the most important factor affecting growth will be the frequency and dosage of supplements taken by existing consumers – in addition to the recruiting of new customers.

There is also the question of the presence or absence of a “boom product.” In the last few years growth has benefited from explosive sales of St. John’s Wort, Glucosamine and Ginkgo biloba. These products not only drove a spike in the curve but also focused media attention on the industry.

To a large extent, the media has driven the industry – not the other way around. However, there is a limit to the number of supplements that have the emotional appeal and tangible results of St. John’s Wort or Kava kava – so these explosive growth rates should not be regarded as the business norm.

The hard work still lies ahead in building markets and creating scientific data to support sales, but it should be noted that several of the selected botanicals fall into the fastest growing category of botanicals in the U.S. – the herbal anxiolytics (anti-stress products) – which includes Chamomile, Valerian, Kava and Ginseng.

The final key to the widespread use and acceptance of botanicals in the U.S. will be the endorsement of the medical community and, equally important, the reimbursement by managed health care organisations and insurance companies for their use as part of the health care system.

4. Agronomic Considerations

All the crops selected are considered likely to grow well in Australia/Tasmania – in fact three of the recommended medicinals – St. John’s Wort, St Mary’s (Milk) Thistle and Valerian are likely to grow so well that they are capable of becoming noxious weeds outside the cultivation area.

Other desirable agronomic characteristics for most of these plants includes the ability to produce a harvestable crop within two years of planting and the ability to transplant seedlings mechanically, or at least precision drill seeds directly.

Other peripheral characteristics considered are the overall vigour of the plant, its resistance to pests and diseases and its potential for value added benefits – particularly, for example, in the transition from low cost, low technology products such as dried roots to botanical extracts. e.g. Valerian, and Goldenseal.

Australia offers some specific advantages for medicinal plants because of its climatic diversity and geographic position. Endemic species, such as Boronia, are exploitable and there are also opportunities for new commercial production of other plants such as Kava (*Piper methysticum*) which require tropical and sub tropical climates.

Australia offers possibilities for out of season production for overseas markets for many plants which are usually grown in the Northern Hemisphere. Examples include Echinacea, Valerian and Chamomile. This geographic advantage will diminish in time due to newly emerging competition from South America, particularly Argentina, Chile and Paraguay and the transition in market demand from dried plant parts to extracts will also erode this advantage.

Commercial cultivation of medicinal botanicals is also an attractive alternative to traditional crops whose value has declined either because of supply and demand pressures or loss of popularity due to other factors such as health concerns for tobacco.

The overall perception of Australia is very favourable for the production of herbal extracts. Outside Australia there is no perceived history of industrial misuse, and little of pollution or contamination. There is also likely to be a reasonable availability of certifiably organic land. Other less quantifiable but important benefits to a new industry are the political and climatic stability and the relative stability of the currency compared to other producers.

5. Import Substitution

Approximately 100 herbs are commonly used in Australia. Of these, thirty eight are not grown in Australia, and thirty three of them are considered to be high demand herbs with an existing domestic market which is typically greater than the ability to supply it from domestic sources. The Australian market for Echinacea root alone is estimated to be three times the domestic supply, or about 150 tonnes per annum.⁶⁵

Twelve of these high demand crops are not currently commercially sourced in Australia and supplies are either imported or rely on wildcrofing. The most important of these herbs (in alphabetical order) are:

Angelica (Don Quai) (*Angelica sinensis*), Astralagus (*A. membranaceus*), Black Cohosh (*Cimifuga racemosa*), Celery (*Apium graveolum*), Damiana (*Turnera diffusa*), Eyebright (*Euphrasia officianalis*), False Unicorn Root (*Chamaelirium luteum*), Golden Seal (*Hydrastis canadensis*), Gotu Kola (*Centella asiatica*), Mullein (*Verbascum thapsus*), Schisandra (*S. chinensis*) and Withania (*Withania somnifera*).

Of these botanicals, Celery seed is very cheap and available from many sources, and Schisandra will not fit well into any anticipated commercial production of herbs. Black Cohosh is the same family and has similar agronomic requirements to Goldenseal – a recommended botanical. Licorice, Angelica and Astralagus share common agronomic requirements and are usually planted in batches to allow harvesting of the roots/rhizomes on an annual basis after the third year.

It is imperative that medicinal herbs be grown under organic production systems, preferably by certified organic farmers. In Australia the BFA (Biological Farmers of Australia), NASA (National Association of Sustainable Agriculture) and other biodynamic farming groups can provide information about organically certified conditions.

6. Favourable Environmental Climate

The principal determinant in this category is that the products chosen have a long history of safe usage.

Other important issues are that validated analytical standards are developed or are under way. The lack of general chemical tests for quality for many of these botanicals, even for pharmaceutical grade materials, offers an opportunity for the Australian industry to develop products which have verifiable levels of selected components. These would follow international guidelines such as the German E Commission etc.

This report identifies other issues that may affect quality. These include proper identification of the drug; suitable cultivation procedures; processing techniques including stabilisation and extraction – particularly the choice of solvent and the eventual separation of the fractions.

In terms of a regulatory environment, it is important that the selected herbal medicines have IND or NDA potential in the US and major markets.

All of the selected crops are on the American Herbal Pharmacopoeia (AHP) prioritization list. The AHP's goal is to provide authoritative herbal monographs containing accurate, critically reviewed information on selected botanicals to provide guidance in the appropriate use of herbal therapeutics. The inclusion of a plant on the list of prepared or prioritized monographs is, in itself, a recognition of the importance of plant and its potential use as a phytochemical.

The U.S. Pharmacopeia has selected six botanicals for development of full monographs in a newly established program to generate standards and analytical methodology for medicinal plant products.

In addition to Gingko and Garlic, these are: Ginger (not included in this survey since it is also in ample supply), Valerian, Feverfew, and Ginseng.

In addition, all of the selected crops have been awarded Drug Identification Numbers (DIN's) in Canada for preparations containing the botanicals included here. Almost all of the DIN-bearing products are in the OTC category for Traditional Herbal Medicines (THE's) and are considered appropriate for treatment of self diagnosable, self treatable, self limiting conditions for short periods of time. Feverfew is included because it is the only modern herbal recognised in Canada by a DIN for a specific therapeutic application – to help prevent recurring migraine headaches – and there is a growing demand for a verifiable standardised products as well as drug grade extracts.

Crops Considered but Not Included

Of the top twelve “dietary supplements” in the United States, six are plant derived preparations: Ginkgo, St. Johns Wort, Echinacea, Garlic, Goldenseal and Saw Palmetto. Of these, the following plants have been considered for further evaluation in Australia but are not recommended for the following reasons.

Ginkgo Biloba

The concentrated extract of the leaves of Ginkgo biloba is the most important medicinal extract to be marketed in Europe and the U.S. in the last decade. In 1998 over 5.5 million prescriptions were written for it in Germany.

The conventional production of extract involves macerating the leaves in an acetone water mixture and extracting under a partial vacuum. After removal of the solvent the extract is adjusted to a potency of 24% flavenoids. The extract also contains a complex of 6% terpenes including the unique ginkgolides A, B, and C and the sesquiterpene, bilobalide.

Ginkgo is not included in this review because its current and projected demand is amply satisfied by cultivation in Germany alone. Since the plant grows almost universally, Australia offers no particular advantage over other producers and research efforts could be better focused on other plants.

An opportunity may exist for producing an extract with reduced levels of ginkgolic acids to below 5 ppm – the level now required by the German Government. The removal of the ginkgolic acids is a function of the extraction process, and may be facilitated by the use of CO₂ as a solvent. Tests would be required to verify this.

Garlic

Garlic is not included in this survey because it is also in plentiful supply and likely to remain so in the foreseeable future.

In addition to domestic sources in the U.S., and significant imports from Europe, the export of Chinese fresh garlic has increased from 3 million pounds in 1991 to more than 54 million pounds in 1994. At the same time, China sold garlic in the U.S. at \$0.06 cents/pound compared with their actual production cost of \$0.27 per pound – a price which eventually resulted in action by the U.S. Customs to require Chinese importers of fresh garlic to post bonds or cash deposits equivalent to 376% of the invoice value.

However, even now the cost of production of garlic in the U.S. is over double that in China and the current price and availability of garlic makes it an unattractive investment for new suppliers, even of the oil or extracts.

Hawthorn Extract

This plant is not included in the list of target crops despite its short supply and its importance in Europe for the following reason:

The leaves, flowers and fruits of the hawthorn (*Crataegus laevigata*) constitute one of the most widely used heart remedies in Germany and the herb was selected in 1990 as the “Drug of the Year” by German Druggists. It is already available in the U.S. as a food supplement, but the consensus is that it is a product that should be used by the consumer with considerable caution.

Although toxic effects are uncommon even at large doses the self treatment of cardiac problems based on the self diagnosis of such problems should not be encouraged. The availability of a standardised hawthorn extract for clinical trials would be a major step forward in the U.S. use of this potentially useful extract, but this is a long term project with little short term prospects for profitability.

The cultivation of hawthorn in Australia and the development of such an extract would best be undertaken in conjunction with one of the German pharmaceutical companies.

Bulk Herbs

Most bulk herbs are produced in countries with low labour costs. In addition, Europe is the centre and major consumer for medicinal herbs and the production of alternative crops in the EC is being promoted to help alleviate the massive surpluses of traditional crops. Therefore, the challenge for Australian growers is to produce crops of superior quality at a competitive price, or to utilise added value opportunities.

Since it is unlikely that Australian growers could compete effectively in the production of bulk, dried herbs, because of high transport costs, the focus has to be on value added products. Import substitution is a separate consideration.

Selection of Botanicals for Further Consideration In Australia

Based on the criteria established earlier, the following botanicals are recommended:

Primary List

Echinacea	<i>(E.purpurea & E. angustifolia)</i>
Ginseng	<i>(Panax quinquefolius & P. ginseng)</i>
St. Johns Wort	<i>(Hypericum perforatum)</i>
Kava	<i>(Piper methysticum)</i>
Saw palmetto	<i>(Serenoa repens)</i>
Valerian	<i>(Valeriana officinalis)</i>
Goldenseal	<i>(Hydrastis canadensis)</i>
Feverfew	<i>(Tanacetum parthenium)</i>

Use of New Extraction Technologies in Australia

The benefits of new extraction technologies have been described earlier in this report, and a number of crops offer specific opportunities for CO₂ extraction. These include:

For CO₂ Extraction

Boronia	<i>(Boronia megastigma)</i>
Clary Sage	<i>(Salvia sclarea)</i>
Chamomile	<i>(Matricaria recutita)</i>
Lemon Balm	<i>(Melissa officianalis)</i>
Citrus Oils	

Several of the plant selections may be controversial in Australia – but are included because they represent a viable market opportunity for exports to the U.S. and European markets as well as significant opportunities from value added processing to extracts.

St. John's Wort is a noxious weed in Australia and St. Mary's Thistle (Milk Thistle) and Valerian possess the potential to become noxious weeds, but they can all be selectively cultivated or harvested for medicinal purposes.

St. John's Wort and St. Mary's Thistle are already established in Australia and do not pose a new threat of danger as an introduced weed species. Echinacea is an introduced species but is unlikely to pose any danger as a weed since it suffers from competition with other plants and seed germination is poor. It is also easily controlled by grazing stock. There are established biological controls for both St. John's Wort and St. Mary's Thistle.

Kava is controversial because of its psychotropic potential but Australia offers a good environment for the commercial production of this crop under controlled conditions and the opportunity to produce extracts standardised to known kavalactone content.

Secondary List

Other candidates for small scale cultivation should include:

Angelica	<i>(Angelica archangelica, A. sinensis – Don Quai)</i>
Astragalus	<i>(Astragalus membranaceus)</i>
Bilberry	<i>(Vaccinium myrtillus)</i>
Evening Primrose	<i>(Oenothera biennis)</i>
Horsechestnut	<i>(Aeculus hippocastanum)</i>
Licorice	<i>(Glycyrrhiza glabra or G. uralensis)</i>
Milk Thistle	<i>(Sylibum marianum)</i>
Nettle	<i>(Urtica dioica)</i>
Stevia	<i>(Stevia rebaudiana)</i>

[Hawthorn Extract *(Crataegus laevigata)* See previous notes.]

General Recommendations

Plant Breeding Programmes

There is a need to establish a breeding program for the selection of superior cultivars of most of the selected botanicals. This is particularly true of the selection of *E. angustifolia* for drug content. Other research topics should include canopy development, resistance to disease and lodging, speed of root growth, and seed and seedling germination related issues. Micropropagation techniques, especially tissue culture, will greatly assist in the development of crops such as Ginseng in Australia.

Similarly, there is considerable room for improvement in the development of cultivars of other botanicals selectively grown for their phytochemical content. Not surprisingly, considering their weed status, these have not been developed for St. John's Wort and St. Mary's Thistle (Milk Thistle) for example. Australian biotypes may well have a headstart in the content of desirable constituents for many of these crops.

In addition, it is suggested that an in depth review be conducted to determine whether or not *Stevia rebaudiana* can be commercially grown and processed in Australia. Stevia is a plant that produces a variety of high potency, low calorie sweeteners in its leaf tissues which are used in a number of countries including Japan, Brazil and China, and virtually every industrialized country uses part of the worldwide production of Stevia as a replacement for artificial sweeteners.

The economic production of Saw Palmetto is dependent on a large labour pool or the use of mechanical harvesting techniques.

Plant Metabolism Studies and Exemptions for Herbicide Use

Weeds are difficult to control without recourse to chemicals, and weeds are likely to emerge as the number one problem facing growers, particularly if the crop is grown for two or more seasons. The use of mulches can reduce overall labour requirement for weeding by over 70%, but it would be helpful if the organic certification guidelines prohibiting the use of black plastic mulches could be waived for medicinal crops.

At some point for the Australian herbal industry to be successful it will be necessary to perform required plant metabolism studies on a special use basis to justify the use of herbicides in early growth stages before plant establishment, and later in the growing season prior to harvesting. Echinacea could well be the pilot crop for such a programme.

In the interim there is a need for the National Registration Authority to continue to grant off label permits for use of herbicides on herb crops. Many pesticide residues can be removed during processing and in the final extraction process. Therefore, residue concerns should focus on the chemical fate and residue in the plant rather than on the prohibition of uses during cultivation.

The overall goal should be for zero tolerances for pesticide residues in the final product.

Need For Standards

There is an urgent need for uniform standards. These are in the process of being developed in Europe, but in the interim Australian growers should be using these as a guideline for the establishment of their own quality assurance program.

The industry will need to establish analytical tests for quality to enable comparative crop and processing tests to be undertaken and to support existing quality standards used by major traders in the crop.

There is a need to assess the effect of drying, storing and processing on the chemical composition of all of the selected crops. The use of more sophisticated extraction processes offers benefits in greater yields, purity and stability and fewer losses due to chemical, biological or heat degradation.

Commercialisation

Finally, with all these crops there is a need to get a commercial volume onto the world markets to assess fully the crop's potential, and to establish Australian identity and standards of quality.

Growers need to work with major buyers and determine their requirements in conjunction with commercial cultivation plans and production should be on a supply contract basis between the grower and the buyer. The importance of strategic alliances with potential purchasers in defining the market and delivering a product specifically for that market cannot be overstated.

There is an opportunity for a small certified seed industry for some botanicals such as Echinacea.

Suggested Standardised Products

The production of standardised extracts for the selected botanicals should focus on the following: (Listed in alphabetical order).

Botanical	Objective/Developmental Goal/Market Need
Angelica (<i>Angelica sinensis</i>)	High quality extract standardised on the ligustilides content.
Astragalus (<i>A. membranaceus</i>)	Cultivars with high phytochemical content. Standardised extract.
Bilberry (<i>Vaccinium myrtillus</i>)	High grade fruit extract standardised to at least 25% and preferably 36% anthocyanosides.
Boronia (<i>B. megastigma</i>)	Selection of improved genotypes with high contents of desirable oils and negligible content of undesirable monoterpenes. Increased production of boronia absolute and expansion into the fragrance market. Establishment of standards.
Chamomile (<i>Matricaria recucita</i>)	Identification of optimum growing conditions. Production of chamomile extracts with a verifiable azulene content. Consideration of CO ₂ extraction.
Echinacea (<i>E. angustifolia</i>)	Selection and production of superior cultivars from a broad genetic base with <i>E. angustifolia</i> as the target species. Production of a high quality product of verifiable components using accepted industry standards or marker compounds.

Evening Primrose (<i>Oenothera biennis</i>)	Contract production of high Gamma-linoleic acid (GLA) content hybrids in conjunction with a pharmaceutical or phytochemical company.
Feverfew (<i>Tanacetum parthenium</i>)	Selection of cultivars with higher parthenolide content (at least 0.2% and preferably up to 1.0%) and development of a verifiable standardised product as well as drug grade extracts.
Ginseng (<i>Panax quinquefolium</i>)	Production of a standardised extract with a guaranteed content of Ginsenoides.
Goldenseal (<i>Hydrastis canadensis</i>)	Develop improved cultivars and consider as crop rotation with ginseng. Develop standards and extract with verifiable content of both hydrastine and berberine.
Kava (<i>Piper mysticum</i>)	Development of a pharmaceutical grade extract or a standardised extract which has a consistent and verifiable content for therapeutic use, with a kavalactone content of 30% plus.
Lemon Balm (<i>Melissa officianalis</i>)	Candidate for CO ₂ extraction to enhance yields. Subsequent development of essential oil in fragrance industry.
Licorice (<i>Glycyrrhiza glabra</i>)	Development of cultivars with 20-25% Glycyrrhizin content Development of a standardised extract.
Saw Palmetto (<i>Serenoa repens</i>)	Review economics and feasibility of Saw Palmetto production in Australia with particular reference to harvesting of the ripe berries. Develop a standardised extract with specific total sterole and fatty acid contents.
St. John's Wort (<i>Hypericum perforatum</i>)	Selection of cultivars with improved, possibly Australian, biotypes with higher hypericin content and better seed germination. Improved extraction and drying processes are also critical. Establishment of standards.
St. Mary's Thistle (<i>Silybum marianum</i>)	Extract standardised to contain 70-80% silymarin
Stevia (<i>Stevia rebaudiana</i>)	Review prospects for commercial production in Australia. Goals for attainable yields of 2-3,000 kg/ha of dry leaf with stevioside content ranging from 15-20%
Valerian (<i>Valeriana officianalis</i>)	Develop new standards for verifiable quality and the production of medicinal grade valerian containing at least 2.5% valeric acid. Valerian is a good candidate for the use of CO ₂ as the extraction solvent to avoid the enzymic degradations common to other higher temperature extraction processes.